

Subject Case Report Forms

0085 (Prod: Bio Virtus Research Site Sp. zo. o.)

Generated On: 15 Dec 2014 17:19:50

All time stamps listed in this document are displayed in GMT

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: Subject

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

Screening number	0085
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Site number	BIO
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Subject Status

Form: Subject Status

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

26 JUL 2013
DD/MMM/YYYY

Randomization Time

15:55
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Date of Visit

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

Date of Visit

06 JUL 2013
DD/MMM/YYYY

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Additional Informed Consent

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

Has the subject given written informed consent for
Bio-banking for Biomarkers of Exposure and Risk
Markers?

Yes ☒

Consent Date

06 JUL 2013
DD/MMM/YYYY

Has the subject given written informed consent for
Bio-banking for Transcriptomics (Pharmacogenomics)?

Yes ☒

Consent Date

06 JUL 2013
DD/MMM/YYYY

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Inclusion Criteria

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

Inclusion Criterion Number	1
Inclusion Criterion	Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF.
Result	Yes
*If any has been answered No, subject must not be included in the study.	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

Inclusion Criterion Number	2
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Inclusion Criterion	Subject is aged from 21 to 65 years (inclusive).
---------------------	--

Result	Yes
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*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

Inclusion Criterion Number	3
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Inclusion Criterion	Subject is of Caucasian origin.	<input checked="" type="radio"/>
---------------------	---------------------------------	----------------------------------

Result	Yes	<input checked="" type="radio"/>
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*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

Inclusion Criterion Number	4
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Inclusion Criterion	Smoking, healthy subject as judged by the Investigator based on all available assessments in the Screening period/day of Admission	<input checked="" type="radio"/>
---------------------	---	----------------------------------

Result	Yes	<input checked="" type="radio"/>
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*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (k.jarus) 30 May 2014 12:25:56

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Inclusion Criterion Number

5

Inclusion Criterion

Subject is a current smoker
(based on
self-reporting), who for the
last 4
weeks has smoked at least
10
commercially available
non-menthol
CCs per day (no brand
restrictions)
with a maximum yield of 1
mg
nicotine ISO per cigarette,
as labeled
on the cigarette package.
Furthermore, the subject
has smoked
for at least the last 3
consecutive
years. The smoking status
will be
verified with a urinary
cotinine test
(cotinine 200 ng/ml).

Result

Yes

*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

Inclusion Criterion Number	6
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Inclusion Criterion	The subject is a current smoker who does not plan to quit smoking in the next 3 months.
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Result	Yes
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*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Inclusion Criteria (7)

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

Inclusion Criterion Number	7
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Inclusion Criterion	The subject is ready to accept 5 days of SA.	<input checked="" type="radio"/>
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Result	Yes	<input checked="" type="radio"/>
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*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	1
Exclusion Criterion	As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason).
Result	No
*If any has been answered Yes, subject must not be included in the study.	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (k.jarus) 30 May 2014 12:25:57

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Exclusion Criterion Number	2
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Exclusion Criterion	A subject who is legally incompetent, physically or mentally incapable of giving consent.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	3
Exclusion Criterion	The subject has medical condition requiring smoking cessation, or clinically relevant diseases in the judgment of the Investigator.
Result	No
*If any has been answered Yes, subject must not be included in the study.	

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Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	4
Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥32 kg/m2. <input checked="" type="radio"/>
Result	No <input checked="" type="radio"/>

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	5
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Exclusion Criterion	As per Investigator or designee judgment, the subject has medical conditions which require or will require in the course of the study, a medical intervention (e.g., start of treatment, surgery, hospitalization) which may interfere with the study participation and/or study results.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	6
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Exclusion Criterion	The subject has used nicotine containing products other than commercially available CC as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	8
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Exclusion Criterion	<p>If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator or designee if these can potentially interfere with the study objectives or subject's safety.</p>
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	9
Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid. <input checked="" type="radio"/>
Result	No <input checked="" type="radio"/>
*If any has been answered Yes, subject must not be included in the study.	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	10
Exclusion Criterion	The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in the study.
Result	No
*If any has been answered Yes, subject must not be included in the study.	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (k.jarus) 30 May 2014 12:25:57

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Exclusion Criterion Number	11
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Exclusion Criterion	The subject has a positive urine drug test.	<input checked="" type="radio"/>
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Result	No	<input type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	12
Exclusion Criterion	Positive serology test for human immunodeficiency virus (HIV) 1/2, Hepatitis B or Hepatitis C. <input checked="" type="radio"/>
Result	No <input checked="" type="radio"/>

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	13
Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission. <input checked="" type="radio"/>
Result	No <input checked="" type="radio"/>

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	14
Exclusion Criterion	The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child).
Result	No
*If any has been answered Yes, subject must not be included in the study.	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	15
----------------------------	----

Exclusion Criterion	The subject is an employee of the investigational site or any other parties involved in the study or of their first-degree relatives (parent, sibling, or child).
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	16
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Exclusion Criterion	The subject has participated in a clinical study within 3 months prior to the Screening Visit.	<input checked="" type="radio"/>
---------------------	--	----------------------------------

Result	No	<input type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	17
----------------------------	----

Exclusion Criterion	The subject has previously participated in the same study at a different time (i.e. each subject can be included in the study population only once).
---------------------	--

Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	18
----------------------------	----

Exclusion Criterion	Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.	<input checked="" type="radio"/>
---------------------	--	----------------------------------

Result	No	<input checked="" type="radio"/>
--------	----	----------------------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	19
----------------------------	----

Exclusion Criterion	Subject does not agree to use an acceptable method of effective contraception <input checked="" type="radio"/>
---------------------	--

Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Demographics

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

Date of Birth	(b) (6)
Sex	Female <input checked="" type="radio"/>
Race	White <input checked="" type="radio"/>
Other, specify	
Ethnicity	Caucasian <input checked="" type="radio"/>
Date the Subject signed the Main Informed Consent	06 JUL 2013 DD/MMM/YYYY
Time the Subject signed the Main Informed Consent	08:37 hour:min 24-hour clock
Age(Derived)	22

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Date of collection

06 JUL 2013
DD/MMM/YYYY

Has the subject experienced any past and/ or
concomitant diseases?

Yes ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Date of collection	06 JUL 2013 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	1
--------	---

Diagnosis Description	GLASSES CORRECTION FOR MYOPIA
-----------------------	----------------------------------

Onset Date DD/MMM/YYYY	UN UNK UNK
---------------------------	------------

Stop Date DD/MMM/YYYY	
--------------------------	--

Ongoing?	True
----------	------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Date of collection	06 JUL 2013 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	2
--------	---

Diagnosis Description	APPENDECTOMY
-----------------------	--------------

Onset Date DD/MMM/YYYY	UN UNK 1999
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 1999
--------------------------	-------------

Ongoing?	False
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Vital Signs Screening

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Date of assessment

06 JUL 2013
DD/MMM/YYYY

Time of assessment

09:50
hour:min 24-hour clock

Pulse rate

64
beats per minute

Respiratory rate

15
breaths per minute

Blood Pressure (systolic)

114
mmHg

Blood Pressure (diastolic)

78
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (1)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

General Appearance ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (2)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome

Abnormal ☒

Abnormal, please specify

MYOPIA, LEFT TONSILL
ENLARGED

Clinically significant

No ☒

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (3)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (4)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (5)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (6)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Lungs ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (7)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (8)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Cardiovascular System ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (9)

Data signed: (k.jarus) 30 May 2014 12:25:57

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Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (10)

Data signed: (k.jarus) 30 May 2014 12:25:57

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Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Skin ☒

Outcome

Abnormal ☒

Abnormal, please specify

POSTAPPENDECTOMY SCAR

Clinically significant

No ☒

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (11)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (12)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (13)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (14)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (15)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (16)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (17)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (18)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Physical Examination screening (19)

Data signed: (k.jarus) 30 May 2014 12:25:57

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

Has the subject received advices on the risks of smoking?

Yes ☐

Has a debriefing been performed about THS 2.2?

Yes ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

Date	06 JUL 2013 DD/MMM/YYYY
------	----------------------------

Brand name	LM BLUE LIGHT
------------	---------------

ISO Tar Yield	8 MG
---------------	---------

ISO Nicotine Yield	0.6 MG
--------------------	-----------

ISO CO Yield	9 MG
--------------	---------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: THS 2.2 product demonstration

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

Has the subject seen a THS 2.2 product demonstration?

Yes ☒

If the subject did not see the demonstration please
explain

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Smoking History

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

Date of Assessment

06 JUL 2013
DD/MMM/YYYY

1. Does the subject plan to quit smoking during the next 3 months?

No ☐

2. Did the subject smoke for at least 3 consecutive years?

Yes ☐

3. How many cigarettes per day has the subject smoked on average during the last 4 weeks?

10 to 19 ☐

4. Did the subject smoke menthol cigarettes in the last 4 weeks?

No ☐

5. The subject has used nicotine-containing products other than commercially available CC (either tobacco-based products or nicotine-replacement therapy [NRT]), electronic cigarettes and similar devices, within 4 weeks prior to assessment.

No ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: FTND Questionnaire

Generated On: 15 Dec 2014 17:19:50

Type	FTND
------	------

Date of Birth
YYYY MMM DD

--- X ---

Date of assessment=
YYYY MMM DD

2013 JUL 06
YYYY MMM DD

Time of assessment=
hour:min 24-hour clock

11:08
hour:min 24-hour clock

Assessment Status

Completed ☒

1. How soon after you wake up do you smoke your first cigarette?

6-30 minutes ☒

2. Do you find it difficult to refrain from smoking in places where it is forbidden?

No ☒

3. Which cigarette would you hate most to give up?

Any other ☒

4. How many cigarettes per day do you smoke?

11-20 ☒

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?

Yes ☒

6. Do you smoke even if you are so ill that you are in bed most of the day?

Yes ☒

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(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Weight and Height

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

Weight

81
kg

Height

170
cm

BMI (Derived)

28.0
kg/m2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: ECG (12-Lead Standard) screening

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment:

06 JUL 2013
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

80
beats per minute

QRS Interval

85
msec

QT Interval

360
msec

QTcB Interval

413
msec

PR Interval

180
msec

Interpretation

Normal ☒

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: ECG (12-Lead Standard) screening

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

If Not Clinically significant or clinically Significant, Please
specify the finding(s)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Spirometry (1)

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Date of assessment DD/MMM/YYYY 06 JUL 2013

Time of assessment 10:45

Predicted FVC value 4.15 L

Best measured FVC value 4.73 L

Percent of predicted FVC value 114 %

Best measured FEV1 value 3.91 L

Predicted FEV1 value 3.58 L

Percent of predicted FEV1 value 109 %

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Spirometry (1)

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

Calculated ratio between FEV1/FVC	0.83
-----------------------------------	------

Interpretation	Normal <input checked="" type="radio"/>
----------------	---

If Abnormal, Clinical Significance	Not clinically significant <input type="radio"/>
	Clinically significant <input type="radio"/>

If Not Clinically Significant or Clinically Significant, Please specify the finding(s) _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Spirometry (2)

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category ☒ With short-acting bronchodilator

Date of assessment 06 JUL 2013
DD/MMM/YYYY

Time of assessment 11:35

Name of bronchodilator VENTOLIN

Dose 400
MG

Predicted FVC value 4.15
L

Best measured FVC value 4.69
L

Percent of predicted FVC value 113
%

Best measured FEV1 value 3.86
L

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Spirometry (2)

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

Predicted FEV1 value	3.58 L
----------------------	-----------

Percent of predicted FEV1 value	107 %
---------------------------------	----------

Calculated ratio between FEV1/FVC	0.82
-----------------------------------	------

Interpretation	Normal <input checked="" type="radio"/>
----------------	---

If Abnormal, Clinical Significance	Not clinically significant <input type="checkbox"/>
	Clinically significant <input type="checkbox"/>

If Not Clinically Significant or Clinically Significant, Please specify the finding(s) _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Chest X-Ray

Data signed: (k.jarus) 30 May 2014 12:26:01

Generated On: 15 Dec 2014 17:19:50

Was a chest X-Ray with anterior-posterior and left lateral views performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant

No ☐

Yes ☐

Abnormal, please specify: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Haematology

Data signed: (k.jarus) 30 May 2014 12:26:02

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 8 hours at time of sample collection?

Yes ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Urine analysis

Data signed: (k.jarus) 30 May 2014 12:26:02

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

Yes ☒

If No, please specify the reason:

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Clinical Chemistry

Data signed: (k.jarus) 30 May 2014 12:26:02

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 8 hours at time of
sample collection?

Yes ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (k.jarus) 30 May 2014 12:26:02

Generated On: 15 Dec 2014 17:19:50

Experiment Type	SEROLOGY
-----------------	----------

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Urine Drug Screen screening

Data signed: (k.jarus) 30 May 2014 12:26:02

Generated On: 15 Dec 2014 17:19:50

Not Done?	False
-----------	-------

If Not Done, please specify the reason: _____

Date of sample collection	06 JUL 2013 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	09:03 hour:min 24-hour clock
---------------------------	---------------------------------

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative

Final version 7.0 (Main CRF) (577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Urine Drug Screen screening (4)

Data signed: (k.jarus) 30 May 2014 12:26:02

Generated On: 15 Dec 2014 17:19:50

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Alcohol Breath Test screening

Data signed: (k.jarus) 30 May 2014 12:26:02

Generated On: 15 Dec 2014 17:19:50

Was the alcohol breath test performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 JUL 2013
DD/MMM/YYYY

Time of assessment

09:38
hour:min 24-hour clock

Result

Negative ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Urine Pregnancy Test screening

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Not Done False

If Not Done, specify reason _____

Date of Test 06 JUL 2013
DD/MMM/YYYY

Time of Test 09:10
hour:min 24-hour clock

Specify result Negative ☒

If unclear, please confirm with FSH test

Specify result of FSH test < 20 IU/L ☐
>= 20 IU/L ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Urine Cotinine Test screening

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Category	Cotinine Screening <input checked="" type="radio"/>
----------	---

Not Done	False
----------	-------

If Not Done, please specify the reason:	<hr/>
---	-------

Date of Sample Collection	06 JUL 2013 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	09:03 hour:min 24-hour clock
---------------------------	---------------------------------

Result	Positive >=200 ng/ml <input checked="" type="radio"/>
--------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type

BIOCHEMISTRY

Date of Sample Collection

2013 07 06

Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	ALT
Result	7
Unit	U/L
Lower limit	<
Upper limit	31
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	ALBUMIN
Result	50
Unit	G/L
Lower limit	35
Upper limit	52
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	ALP
Result	65
Unit	U/L
Lower limit	35
Upper limit	104
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	AST
Result	15
Unit	U/L
Lower limit	<
Upper limit	32
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	BILIRUBIN, TOTAL
Result	0.4
Unit	MG/DL
Lower limit	<
Upper limit	1.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	CREATININE
Result	0.7
Unit	MG/DL
Lower limit	0.5
Upper limit	0.9
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	POTASSIUM
Result	4.1
Unit	MMOL/L
Lower limit	3.5
Upper limit	5.1
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	PROTEIN, TOTAL
Result	72
Unit	G/L
Lower limit	64
Upper limit	83
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	SODIUM
Result	141
Unit	MMOL/L
Lower limit	136
Upper limit	146
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	GLUCOSE
Result	87
Unit	MG/DL
Lower limit	70
Upper limit	105
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	LDH
Result	272
Unit	U/L
Lower limit	240
Upper limit	480
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	GGT
Result	14
Unit	U/L
Lower limit	5
Upper limit	36
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	TOTAL CHOLESTEROL
Result	128
Unit	MG/DL
Lower limit	<
Upper limit	200
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	TRIGLYCERIDES
Result	65
Unit	MG/DL
Lower limit	50
Upper limit	200
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU BIOCHEMISTRY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:03

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	DIRECT BILIRUBIN
Result	0.2
Unit	MG/DL
Lower limit	<
Upper limit	0.3
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type

HEMATOLOGY

Date of Sample Collection

2013 07 06

Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	ERYTHROCYTES
Result	4.27
Unit	T/L
Lower limit	3.50
Upper limit	5.00
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	HEMATOCRIT
Result	38.9
Unit	%
Lower limit	37.0
Upper limit	47.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	HEMOGLOBIN
Result	13.4
Unit	G/DL
Lower limit	12.0
Upper limit	16.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	LEUKOCYTES
Result	10.41
Unit	G/L
Lower limit	3.50
Upper limit	10.00
Flag	High <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	PLATELETS
Result	185
Unit	G/L
Lower limit	125
Upper limit	400
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	ABSOLUTE BASOPHILS
Result	0.01
Unit	G/L
Lower limit	<
Upper limit	0.20
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	BASOPHILS (%)
Result	0.1
Unit	%
Lower limit	<
Upper limit	1.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	EOSINOPHILS (%)
Result	1.0
Unit	%
Lower limit	<
Upper limit	5.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	ABSOLUTE EOSINOPHILS
Result	0.10
Unit	G/L
Lower limit	<
Upper limit	0.45
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	LYMPHOCYTES (%)
Result	11.2
Unit	%
Lower limit	20.0
Upper limit	45.0
Flag	Low <input checked="" type="radio"/>
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	NEUTROPHILES (%)
Result	81.6
Unit	%
Lower limit	45.0
Upper limit	70.0
Flag	High <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	ABSOLUTE LYMPHOCYTES
Result	1.17
Unit	G/L
Lower limit	1.00
Upper limit	5.00
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	MONOCYTES (%)
Result	6.1
Unit	%
Lower limit	4.0
Upper limit	12.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	ABSOLUTE NEUTROPHILS
Result	8.50
Unit	G/L
Lower limit	1.80
Upper limit	7.70
Flag	High <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	ABSOLUTE MONOCYTES
Result	0.63
Unit	G/L
Lower limit	<
Upper limit	0.80
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	MCH
Result	31.4
Unit	PG
Lower limit	28.0
Upper limit	34.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	MCV
Result	91.1
Unit	FL
Lower limit	83.0
Upper limit	103.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	MCHC
Result	34.4
Unit	G/DL
Lower limit	31.0
Upper limit	35.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Lab-BU SEROLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type

SEROLOGY

Date of Sample Collection

2013 07 06

Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU SEROLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	SEROLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	ANTI-HCV
Result	NEGATIVE
Unit	
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU SEROLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	SEROLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	HBS AG
Result	NEGATIVE
Unit	
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU SEROLOGY(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:04

Generated On: 15 Dec 2014 17:19:50

Experiment Type	SEROLOGY
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:20
Analyte Name	ANTI-HIV1/2
Result	NEGATIVE
Unit	
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Lab-BU URINALYSIS(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Experiment Type

URINALYSIS

Date of Sample Collection

2013 07 06

Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU URINALYSIS(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:03
Analyte Name	U-PROTEIN
Result	NEGATIVE
Unit	MG/DL
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU URINALYSIS(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:03
Analyte Name	U-GLUCOSE
Result	NEGATIVE
Unit	MG/DL
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU URINALYSIS(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:03
Analyte Name	U-BILIRUBIN
Result	NEGATIVE
Unit	MG/DL
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Lab-BU URINALYSIS(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:03
Analyte Name	U-ERYTHROCYTES
Result	25
Unit	ERYT./μL
Lower limit	
Upper limit	NEGATIVE
Flag	Abnormal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU URINALYSIS(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:03
Analyte Name	U-PH
Result	6.0
Unit	
Lower limit	5.0
Upper limit	8.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU URINALYSIS(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:03
Analyte Name	U-NITRITE
Result	NEGATIVE
Unit	
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU URINALYSIS(2013 07 06)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 06
Time of Sample Collection	09:03
Analyte Name	U-DENSITY
Result	1015
Unit	G/L
Lower limit	1010
Upper limit	1030
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Screening

Form: Lab-BU URINE SEDIMENTATION(2013 07 06)

Generated On: 15 Dec 2014 17:19:50

Experiment Type

URINE SEDIMENTATION

Date of Sample Collection

2013-07-06

Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU URINE SEDIMENTATION(2013 07 06)

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINE SEDIMENTATION
-----------------	---------------------

Date of Sample Collection	2013-07-06
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Time of Sample Collection	09:03
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Analyte Name	U LEUKOCYTES
--------------	--------------

Result	0-5
--------	-----

Unit	
------	--

Lower limit	
-------------	--

Upper limit	0-5
-------------	-----

Flag	Normal <input checked="" type="radio"/>
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Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
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Comment	
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Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU URINE SEDIMENTATION(2013 07 06)

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINE SEDIMENTATION
-----------------	---------------------

Date of Sample Collection	2013-07-06
---------------------------	------------

Time of Sample Collection	09:03
---------------------------	-------

Analyte Name	U ERYTHROCYTES (FRESH)
--------------	-----------------------------------

Result	2-5
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Unit	
------	--

Lower limit	
-------------	--

Upper limit	0-2
-------------	-----

Flag	Abnormal <input checked="" type="radio"/>
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Clinically Significant?	No <input checked="" type="radio"/>
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Comment	
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Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU URINE SEDIMENTATION(2013 07 06)

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINE SEDIMENTATION
-----------------	---------------------

Date of Sample Collection	2013-07-06
---------------------------	------------

Time of Sample Collection	09:03
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Analyte Name	U SQUAMOUS CELLS
--------------	------------------

Result	1+
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Unit	
------	--

Lower limit	
-------------	--

Upper limit	1+
-------------	----

Flag	Normal <input checked="" type="radio"/>
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Clinically Significant?	No <input type="radio"/>
	Yes <input type="radio"/>

Comment	
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Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU URINE SEDIMENTATION(2013 07 06)

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINE SEDIMENTATION
-----------------	---------------------

Date of Sample Collection	2013-07-06
---------------------------	------------

Time of Sample Collection	09:03
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Analyte Name	U BACTERIA
--------------	------------

Result	2+
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Unit	
------	--

Lower limit	
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Upper limit	NEGATIVE
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Flag	Abnormal <input checked="" type="radio"/>
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Clinically Significant?	No <input checked="" type="radio"/>
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Comment	
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Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Screening

Form: Lab-BU URINE SEDIMENTATION(2013 07 06)

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINE SEDIMENTATION
-----------------	---------------------

Date of Sample Collection	2013-07-06
---------------------------	------------

Time of Sample Collection	09:03
---------------------------	-------

Analyte Name	U-MUCUS
--------------	---------

Result	1+
--------	----

Unit	
------	--

Lower limit	
-------------	--

Upper limit	NEGATIVE
-------------	----------

Flag	Abnormal <input checked="" type="radio"/>
------	---

Clinically Significant?	No <input checked="" type="radio"/>
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Comment	
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Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU URINE SEDIMENTATION(2013 07 06)

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINE SEDIMENTATION
-----------------	---------------------

Date of Sample Collection	2013-07-06
---------------------------	------------

Time of Sample Collection	09:03
---------------------------	-------

Analyte Name	U-ERYTHROCYTES (DYSMORPHIC)
--------------	--------------------------------

Result	0-2
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Unit	
------	--

Lower limit	
-------------	--

Upper limit	0-2
-------------	-----

Flag	Normal <input checked="" type="radio"/>
------	---

Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
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Comment	
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Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Screening

Form: Lab-BU URINE SEDIMENTATION(2013 07 06)

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINE SEDIMENTATION
-----------------	---------------------

Date of Sample Collection	2013-07-06
---------------------------	------------

Time of Sample Collection	09:03
---------------------------	-------

Analyte Name	U YEAST
--------------	---------

Result	1+
--------	----

Unit	
------	--

Lower limit	
-------------	--

Upper limit	NEGATIVE
-------------	----------

Flag	Abnormal <input checked="" type="radio"/>
------	---

Clinically Significant?	No <input checked="" type="radio"/>
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Comment	
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Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Date of Visit

24 JUL 2013
DD/MMM/YYYY

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Inclusion Criteria-Admission

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Inclusion Criteria-Admission (1)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Inclusion Criterion Number	4
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Inclusion Criterion	Smoking, healthy subject as judged by the Investigator based on all available assessments in the Screening period/day of Admission	<input checked="" type="radio"/>
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Result	Yes	<input checked="" type="radio"/>
--------	-----	----------------------------------

*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Inclusion Criteria-Admission (2)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Inclusion Criterion Number	5
----------------------------	---

Inclusion Criterion	Subject is a current smoker (based on self-reporting), who for the last 4 weeks has smoked at least 10 commercially available non-menthol CCs per day (no brand restrictions) with a maximum yield of 1 mg nicotine ISO per cigarette, as labeled on the cigarette package. Furthermore, the subject has smoked for at least the last 3 consecutive years. The smoking status will be verified with a urinary cotinine test (cotinine 200 ng/ml).
---------------------	---

Result	Yes <input checked="" type="radio"/>
--------	--------------------------------------

*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Inclusion Criteria-Admission (3)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Inclusion Criterion Number	7
----------------------------	---

Inclusion Criterion	The subject is ready to accept 5 days of SA.	<input checked="" type="radio"/>
---------------------	--	----------------------------------

Result	Yes	<input checked="" type="radio"/>
--------	-----	----------------------------------

*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Inclusion Criteria-Admission (4)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Inclusion Criterion Number	8
----------------------------	---

Inclusion Criterion	The subject is ready to accept using the THS 2.2 product.
---------------------	---

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (1)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	1
Exclusion Criterion	As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason).
Result	No
*If any has been answered Yes, subject must not be included in the study.	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (2)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	3
Exclusion Criterion	The subject has medical condition requiring smoking cessation, or clinically relevant diseases in the judgment of the Investigator.
Result	No
*If any has been answered Yes, subject must not be included in the study.	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (3)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	4
Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥32 kg/m2.
Result	No

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (4)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	5
----------------------------	---

Exclusion Criterion	As per Investigator or designee judgment, the subject has medical conditions which require or will require in the course of the study, a medical intervention (e.g., start of treatment, surgery, hospitalization) which may interfere with the study participation and/or study results.
---------------------	---

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (5)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	6
----------------------------	---

Exclusion Criterion	The subject has used nicotine containing products other than commercially available CC as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment.
---------------------	--

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (6)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	7
----------------------------	---

Exclusion Criterion	The subject has received medication (prescription or over-the-counter) within 14 days or within 5 half lives of the drug (whichever is longer) prior to the Admission Day (Day -2), which has an impact on CYP1A2 or CYP2A6 activity.
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (7)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	8
----------------------------	---

Exclusion Criterion	If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator or designee if these can potentially interfere with the study objectives or subject's safety.
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (8)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	9
----------------------------	---

Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.
---------------------	---

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (9)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	10
----------------------------	----

Exclusion Criterion	The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in the study.
---------------------	---

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (10)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	11
----------------------------	----

Exclusion Criterion	The subject has a positive urine drug test.	<input checked="" type="radio"/>
---------------------	---	----------------------------------

Result	No	<input type="radio"/>
--------	----	-----------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (11)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	13
Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission. <input checked="" type="radio"/>
Result	No <input checked="" type="radio"/>

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (12)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	18
----------------------------	----

Exclusion Criterion	Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding. <input checked="" type="radio"/>
---------------------	---

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Exclusion Criteria-Admission (13)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Exclusion Criterion Number	19
----------------------------	----

Exclusion Criterion	Subject does not agree to use an acceptable method of effective contraception <input checked="" type="radio"/>
---------------------	--

Result	No <input checked="" type="radio"/>
--------	-------------------------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment No ☒

Time of assessment 18:38
hour:min 24-hour clock

Pulse rate 80
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 106
mmHg

Blood Pressure (diastolic) 74
mmHg

Vital Signs Position of Subject Supine ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Has the subject received advices on the risks of smoking?

Yes ☐

Has a debriefing been performed about THS 2.2?

Yes ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

General Appearance ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome

Abnormal ☒

Abnormal, please specify

MYOPIA, LEFT TONSILL
ENLARGED=

Clinically significant

No ☒

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Lungs ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Cardiovascular System ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Skin ☒

Outcome

Abnormal ☒

Abnormal, please specify

POSTAPPENDECTOMY SCAR

Clinically significant

No ☒

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (k.jarus) 30 May 2014 12:26:05

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Brand name	LM BLUE LIGHT
------------	---------------

ISO Tar Yield	8 MG
---------------	---------

ISO Nicotine Yield	0.6 MG
--------------------	-----------

ISO CO Yield	9 MG
--------------	---------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: THS 2.2 product test

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Was the THS 2.2 product trial performed?

Yes ☒

If the THS 2.2 product trial was not performed, please
explain

How many THS 2.2 tobacco sticks did the subject use on
this day?

1

Is the subject willing and able to use the product during
the study?

Yes ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

2. Did the subject smoke for at least 3 consecutive years? Yes ☐

3. How many cigarettes per day has the subject smoked on average during the last 4 weeks? 10 to 19 ☐

4. Did the subject smoke menthol cigarettes in the last 4 weeks? No ☐

5. The subject has used nicotine-containing products other than commercially available CC (either tobacco-based products or nicotine-replacement therapy [NRT]), electronic cigarettes and similar devices, within 4 weeks prior to assessment. No ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Weight

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

17:45
hour:min 24-hour clock

Weight

80.7
kg

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Not Done?	False
-----------	-------

If Not Done, please specify the reason: _____

Time of sample collection	18:13 hour:min 24-hour clock
---------------------------	---------------------------------

Drug type	Result
-----------	--------

Amphetamines	Negative
--------------	----------

Barbiturates	Negative
--------------	----------

Benzodiazepines	Negative
-----------------	----------

Cannabinoids	Negative
--------------	----------

Cocaine	Negative
---------	----------

Final version 7.0 (Main CRF) (577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Drug type	Result
Opiates	Negative

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Alcohol Breath Test

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Was the alcohol breath test performed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

18:08
hour:min 24-hour clock

Result

Negative ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Urine Pregnancy Test

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Not Done False

If Not Done, specify reason _____

Time of Test 18:20
hour:min 24-hour clock

Specify result Negative ☒

If unclear, please confirm with FSH test

Specify result of FSH test < 20 IU/L ☐
>= 20 IU/L ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Urine Cotinine Test

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Time of Sample Collection	18:13
	hour:min 24-hour clock

Result	Positive ≥ 200 ng/ml <input checked="" type="radio"/>
--------	--

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Time of Assessment	19:10
	hour:min 24-hour clock

Result	20
	ppm

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine)

Generated On: 15 Dec 2014 17:19:50

Sample type

URINE

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (1)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111510000316
----------------	----------------

Analyte	3-OH-BAP
---------	----------

Result	114
--------	-----

Result Unit	FG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-07
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (1)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (2)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111470001940
----------------	----------------

Analyte	3-HPMA
---------	--------

Result	237
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-03
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (2)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (3)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111470001940
----------------	----------------

Analyte	CEMA
---------	------

Result	35.8
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-03
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (3)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (4)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111470001940
----------------	----------------

Analyte	HBMA
---------	------

Result	111
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-03
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (4)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (5)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111530000834
----------------	----------------

Analyte	1-NA
---------	------

Result	27.3
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-09
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (5)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (6)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111530000834
----------------	----------------

Analyte	2-NA
---------	------

Result	8.88
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-09
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (6)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (7)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111530000834
----------------	----------------

Analyte	4-ABP
---------	-------

Result	4.38
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-09
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (7)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (8)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111530000834
----------------	----------------

Analyte	Ø-TOL
---------	-------

Result	64.4
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-09
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (8)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (9)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111480000190
----------------	----------------

Analyte	NNAL
---------	------

Result	40.2
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-04
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (9)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (10)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111480000190
----------------	----------------

Analyte	NNN
---------	-----

Result	1.74
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-04
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (10)

Generated On: 15 Dec 2014 17:19:50

Urine End Day

0

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (11)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05113210000652
----------------	----------------

Analyte	MHBMA
---------	-------

Result	0.951
--------	-------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99602-02
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (11)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (12)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05113220000652
----------------	----------------

Analyte	1 OHP
---------	-------

Result	127
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99602-03
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (12)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (13)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05113230000652
----------------	----------------

Analyte	CREATININE
---------	------------

Result	73.7
--------	------

Result Unit	MG/DL
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-14
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (13)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (14)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05113200000652
----------------	----------------

Analyte	SBMA
---------	------

Result	1.90
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99602-01
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (14)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (15)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05113200000652
----------------	----------------

Analyte	SPMA
---------	------

Result	0.477
--------	-------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99602-01
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (15)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (16)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111490000204
----------------	----------------

Analyte	HEMA
---------	------

Result	1.94
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-05
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (16)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (17)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111500000267
----------------	----------------

Analyte	COT
---------	-----

Result	391
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-06
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (17)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (18)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111500000267
----------------	----------------

Analyte	COT-GLUC
---------	----------

Result	2280
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-06
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (18)

Generated On: 15 Dec 2014 17:19:50

Urine End Day

0

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (19)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111500000267
----------------	----------------

Analyte	NIC
---------	-----

Result	325
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-06
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (19)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (20)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111500000267
----------------	----------------

Analyte	NIC-GLUC
---------	----------

Result	490
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-06
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (20)

Generated On: 15 Dec 2014 17:19:50

Urine End Day

0

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (21)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111500000267
----------------	----------------

Analyte	THCOT
---------	-------

Result	814
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-06
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (21)

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (22)

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
-------------	-------

Sample Barcode	05111500000267
----------------	----------------

Analyte	THCOT-GLUC
---------	------------

Result	371
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	
---------------------------	--

Day of Visit	-1
--------------	----

Celerion Study Number	AA99071-06
-----------------------	------------

Date of Collection	2013-JUL-25
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	-1
-----------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Admission (Day -2)

Form: Biomarker(Urine) (22)

Generated On: 15 Dec 2014 17:19:50

Urine End Day

0

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Date of Visit

25 JUL 2013
DD/MMM/YYYY

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment No ☒

Time of assessment 10:22
hour:min 24-hour clock

Pulse rate 78
beats per minute

Respiratory rate 17
breaths per minute

Blood Pressure (systolic) 107
mmHg

Blood Pressure (diastolic) 66
mmHg

Vital Signs Position of Subject Supine ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: COHb Blood Sample

Data signed: (k.jarus) 30 May 2014 12:26:07

Generated On: 15 Dec 2014 17:19:50

Not Done

False

If Not Done, please specify the reason:

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: CO Breath Test <Repeat/> (1)

Data signed: (k.jarus) 30 May 2014 12:26:08

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:42
---	-------

Result(ppm)	13
-------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: CO Breath Test <Repeat/> (2)

Data signed: (k.jarus) 30 May 2014 12:26:08

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 14:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:18
---	-------

Result(ppm)	14
-------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: CO Breath Test <Repeat/> (3)

Data signed: (k.jarus) 30 May 2014 12:26:08

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 18:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:21
---	-------

Result(ppm)	13
-------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: CO Breath Test <Repeat/> (4)

Data signed: (k.jarus) 30 May 2014 12:26:08

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	20:00 - 22:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	20:42
---	-------

Result(ppm)	13
-------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: 24 hour urine collections

Data signed: (k.jarus) 30 May 2014 12:26:08

Generated On: 15 Dec 2014 17:19:50

Start Time	06:07
	hour:min 24-hour clock

End Date	26 JUL 2013
	DD/MMM/YYYY

End Time	06:14
	hour:min 24-hour clock

Volume	2150
--------	------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Sample Urine Collection

Data signed: (k.jarus) 30 May 2014 12:26:08

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

11

How many back up tubes were collected?

11

Date of Sample Collection
DD/MMM/YYYY

Time of Sample Collection

26 JUL 2013

8:25

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Generated On: 15 Dec 2014 17:19:50

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Time of assessment hour:m in 24-hou r clock	Assessment Status	1. I have a desire for a cigarette right now	2. Nothing would be better than smoking a cigarette right now	3. If it were possible I would probably smoke now	4. I could control things better right now if I could smoke	5. All I want right now is a cigarette	6. I have a cigarette now	7. A taste good now	8. I would do almost anything for a cigarette now	9. Smoking would make me less depressed	10. I am going to smoke as soon as possible
QSU	(b) (6)	2013 JUL 25 YYYY MMM DD	20:06 hour:m in 24-hou r clock	Completed	Agree	Somewhat disagree	Agree	Disagree	Somewhat disagree	Agree	Agree	Disagree	Do not agree or disagree	Strongly agree

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU) (Paper)

Generated On: 15 Dec 2014 17:19:50

Type

QUESTIONNAIRE ON
SMOKING URGES

Date of assessment

DD/MMM/YYYY

Time of assessment

hour:min 24-hour clock

1. I have a desire for a cigarette right now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

2. Nothing would be better than smoking a cigarette
right now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU) (Paper)

Generated On: 15 Dec 2014 17:19:50

3. If it were possible I would probably smoke now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

4. I could control things better right now if I could smoke

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

5. All I want right now is a cigarette

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU) (Paper)

Generated On: 15 Dec 2014 17:19:50

6. I have an urge for a cigarette

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

7. A cigarette would taste good now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

8. I would do almost anything for a cigarette now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU) (Paper)

Generated On: 15 Dec 2014 17:19:50

9. Smoking would make me less depressed

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

10. I am going to smoke as soon as possible

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 JUL 25
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

20:08
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Moderately ☒

3. Did you enjoy the sensation in your throat and chest?

Moderately ☒

4. Did smoking calm you down?

Very little ☒

5. Did smoking make you feel more awake?

Very little ☒

6. Did smoking make you feel less irritable?

Very little ☒

7. Did smoking help you concentrate?

Not at all ☒

8. Did smoking reduce your hunger for food?

Little ☒

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

9. Did smoking make you dizzy? Not at all ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a cigarette? Extremely ☐

12. Did you enjoy smoking? Little ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

~~Was smoking satisfying?~~ ☒

Response

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Did cigarettes taste good? ☒

Response

- Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Did you enjoy the sensation in your throat and chest?

☐

Response

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Did smoking calm you down? ☒

Response

- Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Did smoking make you feel more awake? ☒

Response

- Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Did smoking make you feel ☒ less irritable?

Response

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Did smoking help you concentrate? ☒

Response

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)


Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Did smoking reduce your  hunger for food?

Response

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Did smoking make you dizzy? ☒

Response

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Did smoking make you
nauseous? ☒

Response

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Did smoking immediately
relieve your craving for a
cigarette?

☒

Response

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)

Generated On: 15 Dec 2014 17:19:50

Date of assessment

DD/MMM/YYYY

Time of assessment

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Did you enjoy smoking? ☒

Response

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Lab-BU COHB(2013 07 25)

Data signed: (k.jarus) 30 May 2014 12:26:08

Generated On: 15 Dec 2014 17:19:50

Experiment Type

COHB

Date of Sample Collection

2013 07 25

Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Lab-BU COHB(2013 07 25)

Data signed: (k.jarus) 30 May 2014 12:26:08

Generated On: 15 Dec 2014 17:19:50

Experiment Type	COHB
Date of Sample Collection	2013 07 25
Time of Sample Collection	20:44
Analyte Name	COHB
Result	2.2
Unit	%
Lower limit	8.0
Upper limit	9.0
Flag	Low <input checked="" type="radio"/>
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type

URINE

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (1)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113200000652
Analyte	SBMA
Result	1.90
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99602-01
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (1)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (2)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113200000652
Analyte	SPMA
Result	0.477
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99602-01
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (2)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (3)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113220000652
Analyte	1-OHP
Result	127
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99602-03
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (3)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (4)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000267
Analyte	COT
Result	391
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (4)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (5)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000267
Analyte	COT-GLUC
Result	2280
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (5)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (6)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000267
Analyte	NIC
Result	325
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (6)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (7)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000267
Analyte	NIC-GLUC
Result	490
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (7)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (8)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000267
Analyte	THCOT
Result	814
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (8)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
---------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (9)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000267
Analyte	THCOT-GLUC
Result	371
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (9)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (10)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001940
Analyte	3-HPMA
Result	237
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (10)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (11)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001940
Analyte	CEMA
Result	35.8
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (11)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (12)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001940
Analyte	HBMA
Result	111
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (12)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (13)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111490000204
Analyte	HEMA
Result	1.94
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-05
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (13)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (14)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113230000652
Analyte	CREATININE
Result	73.7
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-14
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (14)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (15)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111480000190
Analyte	NNAL
Result	40.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-04
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (15)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day

0

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (16)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111480000190
Analyte	NNN
Result	1.74
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-04
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (16)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (17)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000834
Analyte	1-NA
Result	27.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (17)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (18)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000834
Analyte	2-NA
Result	8.88
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (18)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (19)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000834
Analyte	4-ABP
Result	4.38
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (19)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (20)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000834
Analyte	O-TOL
Result	64.4
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (20)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (21)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113210000652
Analyte	MHBMA
Result	0.951
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99602-02
Date of Collection	2013-JUL-25
Timepoint-minutes	
Urine Start Day	-1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (21)

Data signed: (k.jarus) 30 May 2014 12:26:09

Generated On: 15 Dec 2014 17:19:50

Urine End Day	0
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Date of Visit

26 JUL 2013
DD/MMM/YYYY

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Randomization number (4 digits)	3015
---------------------------------	------

Allocation Arm	THS 2.2 <input checked="" type="radio"/>
----------------	--

Cigarette Consumption	10 – 19 conventional cigarettes per day <input checked="" type="radio"/>
-----------------------	--

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment No ☒

Time of assessment 10:12
hour:min 24-hour clock

Pulse rate 80
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 99
mmHg

Blood Pressure (diastolic) 65
mmHg

Vital Signs Position of Subject Supine ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Spirometry without a short-acting bronchodilator

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Time of assessment 07:23
hour:min 24-hour clock

Predicted FVC value 4.15
L

Best measured FVC value 4.74
L

Percent of predicted FVC value 114
%

Best measured FEV1 value 4.01
L

Predicted FEV1 value 3.58
L

Percent of predicted FEV1 value 111
%

Interpretation Normal ☒

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Spirometry without a short-acting bronchodilator

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s) _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 8 hours at time of
sample collection?

Yes ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

Yes ☒

If No, please specify the reason:

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 8 hours at time of sample collection?

Yes ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

26 JUL 2013

20:44

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

26 JUL 2013

20:44

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: COHb Blood Sample

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Not Done

False

If Not Done, please specify the reason:

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: CO Breath Test <Repeat/> (1)

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	07:27
---	-------

Result(ppm)	8
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: CO Breath Test <Repeat/> (2)

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 14:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:21
---	-------

Result(ppm)	11
-------------	----

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: CO Breath Test <Repeat/> (3)

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 18:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:42
---	-------

Result(ppm)	8
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: CO Breath Test <Repeat/> (4)

Data signed: (k.jarus) 30 May 2014 12:26:10

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	20:00 - 22:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	20:42
---	-------

Result(ppm)	9
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Not Done

False

If Not Done, please specify the reason:

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

26 JUL 2013

06:54

trans-3'-hydroxyc
otinine

26 JUL 2013

06:54

cotinine

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Time of coffee intake	10:52
	hour:min 24-hour clock

Sample collection Not Done	False
----------------------------	-------

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
26 JUL 2013	16:44	Caffeine
26 JUL 2013	16:44	Paraxanthine

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Start Time	06:15
	hour:min 24-hour clock

End Date	27 JUL 2013
	DD/MMM/YYYY

End Time	06:18
	hour:min 24-hour clock

Volume	2300
--------	------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

24

How many back up tubes were collected?

13

Date of Sample Collection
DD/MMM/YYYY

Time of Sample Collection

27 JUL 2013

8:10

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Generated On: 15 Dec 2014 17:19:50

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Time of assessment hour:m in 24-hou r clock	Assess ment Status	1. I have a desire for a cigarette right now	2. Nothing would be better than smoking a cigarette right now	3. If it were possible I would probably smoke now	4. I could control things better right now if I could smoke	5. All I want right now is a cigarette	6. I have a cigarette now	7. A taste good now	8. I would do almost anything for a cigarette now	9. Smoking would make me less depressed	10. I am going to smoke as soon as possible
QSU	(b) (6)	2013 JUL 26 YYYY MMM DD	20:01 hour:m in 24-hou r clock	Comple ted	Disagre e	Disagre e	Disagre e	Disagre e	Disagre e	Disagre e	Disagre e	Strongl y disagree	Disagre e	Somew hat disagree

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 JUL 26
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

06:03
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Slight ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

None ☐

4. Desire or craving to smoke

How have you been feeling over the past 24 hours?

None ☐

5. Difficulty concentrating

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Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? Slight ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

How have you been feeling over the past 24 hours? None ☐

13. Dreaming or nightmares

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Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 JUL 26
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

20:03
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

A lot ☒

2. Did cigarettes taste good?

Moderately ☒

3. Did you enjoy the sensation in your throat and chest?

Little ☒

4. Did smoking calm you down?

Very little ☒

5. Did smoking make you feel more awake?

Little ☒

6. Did smoking make you feel less irritable?

Very little ☒

7. Did smoking help you concentrate?

Not at all ☒

8. Did smoking reduce your hunger for food?

Very little ☒

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

9. Did smoking make you dizzy? Very little ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a cigarette? Moderately ☐

12. Did you enjoy smoking? A lot ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Cough Assessment

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 JUL 26
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

06:01
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Cough Assessment (Paper)

Generated On: 15 Dec 2014 17:19:50

Date of assessment
DD/MMM/YYYY

Time of assessment

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☐

Yes ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☐

Mild ☐

Moderate ☐

Severe ☐

Very severe ☐

Abandoned ☐

Not Applicable ☐

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Rarely ☐

Sometimes ☐

Fairly often ☐

Often ☐

Almost always ☐

Abandoned ☐

Not Applicable ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Cough Assessment (Paper)

Generated On: 15 Dec 2014 17:19:50

Fourth Question: Sputum Production

To what extent do you produce sputum when coughing?

No sputum ☐

A moderate amount of
sputum ☐

A large amount of sputum ☐

A very large amount of
sputum ☐

Abandoned ☐

Not Applicable ☐

Are there any other important observations that you
would like to share with us about you coughing? (open
question)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Date of assessment	26 JUL 2013 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:10 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Agree <input checked="" type="radio"/>
--	--

If you agree or strongly agree, please describe :	THE CIGARETTE IS LESS TASTY
---	--------------------------------

2. You enjoy smoking with the device as much as without it.	Neither agree nor disagree <input type="radio"/>
---	--

If you disagree or strongly disagree, please describe :	
---	--

3. The taste of the conventional cigarettes/products is different with the device.	Strongly agree <input checked="" type="radio"/>
--	---

If you agree or strongly agree, please describe :	THE CIGARETTE SEEMS WEAKER
---	-------------------------------

4. The device is easy to use.	Strongly agree <input checked="" type="radio"/>
-------------------------------	---

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device. Neither agree nor disagree ☒

If you agree or strongly agree, please describe : _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:54
hour:min 24-hour clock

Was the subject fasting for at least 8 hours at time of sample collection?

Yes ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Generated On: 15 Dec 2014 17:19:50

Date of assessment
DD/MMM/YYYY

Time of assessment

Please indicate for each of the items below, how you have been feeling over the past 24 hours

Result

~~1. Angry, irritable, frustrated~~

~~2. Anxious, tense~~

~~3. Depressed Mood, sad~~

~~4. Desire or craving to smoke~~

~~5. Difficulty concentrating~~

Final version 7.0 (Main CRF) (577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (6)

Generated On: 15 Dec 2014 17:19:50

Result

~~6. Increased appetite, hungry, weight gain~~

~~7. Insomnia, sleep problems, awakening at night~~

~~8. Restless~~

~~9. Impatient~~

~~10. Constipation~~

~~11. Dizziness~~

~~12. Coughing~~

~~13. Dreaming or nightmares~~

Final version 7.0 (Main CRF) (577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (14)

Generated On: 15 Dec 2014 17:19:50

Result

~~14. Nausea~~

~~15. Sore throat~~

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

06:54
hour:min 24-hour clock

Was the subject fasting for at least 8 hours at time of
sample collection?

Yes ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type

BIOCHEMISTRY

Date of Sample Collection

2013 07 26

Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	ALT
Result	8
Unit	U/L
Lower limit	<
Upper limit	31
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	ALBUMIN
Result	48
Unit	G/L
Lower limit	35
Upper limit	52
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	ALP
Result	62
Unit	U/L
Lower limit	35
Upper limit	104
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	AST
Result	17
Unit	U/L
Lower limit	<
Upper limit	32
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	BILIRUBIN, TOTAL
Result	0.4
Unit	MG/DL
Lower limit	<
Upper limit	1.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	CREATININE
Result	0.7
Unit	MG/DL
Lower limit	0.5
Upper limit	0.9
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	POTASSIUM
Result	4.1
Unit	MMOL/L
Lower limit	3.5
Upper limit	5.1
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	PROTEIN, TOTAL
Result	70
Unit	G/L
Lower limit	64
Upper limit	83
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	SODIUM
Result	139
Unit	MMOL/L
Lower limit	136
Upper limit	146
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	GLUCOSE
Result	79
Unit	MG/DL
Lower limit	70
Upper limit	105
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	BUN
Result	11.9
Unit	MG/DL
Lower limit	5.0
Upper limit	23.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	LDH
Result	264
Unit	U/L
Lower limit	240
Upper limit	480
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	GGT
Result	14
Unit	U/L
Lower limit	5
Upper limit	36
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	TOTAL CHOLESTEROL
Result	120
Unit	MG/DL
Lower limit	<
Upper limit	200
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	TRIGLYCERIDES
Result	74
Unit	MG/DL
Lower limit	50
Upper limit	200
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU BIOCHEMISTRY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:11

Generated On: 15 Dec 2014 17:19:50

Experiment Type	BIOCHEMISTRY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	DIRECT BILIRUBIN
Result	0.2
Unit	MG/DL
Lower limit	<
Upper limit	0.3
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type

HEMATOLOGY

Date of Sample Collection

2013 07 26

Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	ERYTHROCYTES
Result	4.19
Unit	T/L
Lower limit	3.50
Upper limit	5.00
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	HEMATOCRIT
Result	37.8
Unit	%
Lower limit	37.0
Upper limit	47.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	HEMOGLOBIN
Result	12.8
Unit	G/DL
Lower limit	12.0
Upper limit	16.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	LEUKOCYTES
Result	9.99
Unit	G/L
Lower limit	3.50
Upper limit	10.00
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	PLATELETS
Result	216
Unit	G/L
Lower limit	125
Upper limit	400
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	ABSOLUTE BASOPHILS
Result	0.01
Unit	G/L
Lower limit	<
Upper limit	0.20
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	BASOPHILS (%)
Result	0.1
Unit	%
Lower limit	<
Upper limit	1.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	EOSINOPHILS (%)
Result	2.0
Unit	%
Lower limit	<
Upper limit	5.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	ABSOLUTE EOSINOPHILS
Result	0.20
Unit	G/L
Lower limit	<
Upper limit	0.45
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	LYMPHOCYTES (%)
Result	21.5
Unit	%
Lower limit	20.0
Upper limit	45.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	NEUTROPHILES (%)
Result	70.1
Unit	%
Lower limit	45.0
Upper limit	70.0
Flag	High <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	ABSOLUTE LYMPHOCYTES
Result	2.15
Unit	G/L
Lower limit	1.00
Upper limit	5.00
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	MONOCYTES (%)
Result	6.3
Unit	%
Lower limit	4.0
Upper limit	12.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	ABSOLUTE NEUTROPHILS
Result	7.00
Unit	G/L
Lower limit	1.80
Upper limit	7.70
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	ABSOLUTE MONOCYTES
Result	0.63
Unit	G/L
Lower limit	<
Upper limit	0.80
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	MCH
Result	30.5
Unit	PG
Lower limit	28.0
Upper limit	34.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	MCV
Result	90.2
Unit	FL
Lower limit	83.0
Upper limit	103.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU HEMATOLOGY(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:12

Generated On: 15 Dec 2014 17:19:50

Experiment Type	HEMATOLOGY
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:54
Analyte Name	MCHC
Result	33.9
Unit	G/DL
Lower limit	31.0
Upper limit	35.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU URINALYSIS(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:13

Generated On: 15 Dec 2014 17:19:50

Experiment Type

URINALYSIS

Date of Sample Collection

2013 07 26

Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU URINALYSIS(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:13

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:14
Analyte Name	U-PROTEIN
Result	NEGATIVE
Unit	MG/DL
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU URINALYSIS(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:13

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:14
Analyte Name	U-GLUCOSE
Result	NEGATIVE
Unit	MG/DL
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU URINALYSIS(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:13

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:14
Analyte Name	U-BILIRUBIN
Result	NEGATIVE
Unit	MG/DL
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU URINALYSIS(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:13

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:14
Analyte Name	U-ERYTHROCYTES
Result	NEGATIVE
Unit	ERYT./µL
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU URINALYSIS(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:13

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:14
Analyte Name	U-PH
Result	5.0
Unit	
Lower limit	5.0
Upper limit	8.0
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU URINALYSIS(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:13

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:14
Analyte Name	U-NITRITE
Result	NEGATIVE
Unit	
Lower limit	
Upper limit	NEGATIVE
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU URINALYSIS(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:13

Generated On: 15 Dec 2014 17:19:50

Experiment Type	URINALYSIS
Date of Sample Collection	2013 07 26
Time of Sample Collection	06:14
Analyte Name	U-DENSITY
Result	1020
Unit	G/L
Lower limit	1010
Upper limit	1030
Flag	Normal <input checked="" type="radio"/>
Clinically Significant?	No <input type="radio"/> Yes <input type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU COHB(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Experiment Type

COHB

Date of Sample Collection

2013 07 26

Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Lab-BU COHB(2013 07 26)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Experiment Type	COHB
Date of Sample Collection	2013 07 26
Time of Sample Collection	20:44
Analyte Name	COHB
Result	2.4
Unit	%
Lower limit	8.0
Upper limit	9.0
Flag	Low <input checked="" type="radio"/>
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Sample type

PLASMA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (1)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Sample type	PLASMA
Sample Barcode	05111450000353
Analyte	COTININE
Result	80.9
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99071-01
Date of Collection	2013-JUL-26
Timepoint-minutes	0
Urine Start Day	

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (1)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Urine End Day

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (2)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Sample type	PLASMA
Sample Barcode	05111450000353
Analyte	NICOTINE
Result	6.81
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99071-01
Date of Collection	2013-JUL-26
Timepoint-minutes	0
Urine Start Day	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (2)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Urine End Day

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (3)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Sample type	PLASMA
Sample Barcode	05111520000183
Analyte	CAFFEINE
Result	1110
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	0
Celerion Study Number	AA99071-08
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (3)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Urine End Day

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (4)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Sample type	PLASMA
Sample Barcode	05111520000183
Analyte	PARAXANTHINE
Result	967
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	0
Celerion Study Number	AA99071-08
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (4)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Urine End Day

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (5)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Sample type	PLASMA
Sample Barcode	05111540000183
Analyte	COTININE
Result	61.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99071-10
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (5)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Urine End Day

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (6)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Sample type	PLASMA
Sample Barcode	05111540000183
Analyte	TRANS-3-HYDROXYCOTININE
Result	23.1
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99071-10
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (6)

Data signed: (k.jarus) 30 May 2014 12:26:14

Generated On: 15 Dec 2014 17:19:50

Urine End Day

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type

URINE

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (1)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111510000317
Analyte	3-OH-BAP
Result	98.7
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-07
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (1)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

±

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (2)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001941
Analyte	3-HPMA
Result	216
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (2)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (3)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001941
Analyte	CEMA
Result	33.9
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (3)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (4)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001941
Analyte	HBMA
Result	155
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (4)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (5)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000835
Analyte	1-NA
Result	31.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (5)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (6)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000835
Analyte	2-NA
Result	10.6
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (6)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (7)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000835
Analyte	4-ABP
Result	6.06
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (7)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (8)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000835
Analyte	O-TOL
Result	72.0
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (8)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (9)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111480000191
Analyte	NNAL
Result	42.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-04
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (9)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (10)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111480000191
Analyte	NNN
Result	1.95
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-04
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (10)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (11)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113210000653
Analyte	MHBMA
Result	0.965
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99602-02
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (11)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (12)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113220000653
Analyte	1-OHP
Result	163
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99602-03
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (12)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (13)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113230000653
Analyte	CREATININE
Result	79.4
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-14
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (13)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (14)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05112040000183
Analyte	IPF2A-III
Result	130
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-12
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (14)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (15)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113200000653
Analyte	SBMA
Result	3.37
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99602-01
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (15)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (16)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113200000653
Analyte	SPMA
Result	0.578
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99602-01
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (16)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (17)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111490000205
Analyte	HEMA
Result	2.36
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-05
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (17)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (18)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05112030000183
Analyte	11-DTXB2
Result	348
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-11
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (18)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (19)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000268
Analyte	COT
Result	467
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (19)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (20)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000268
Analyte	COT-GLUC
Result	2700
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (20)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (21)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000268
Analyte	NIC
Result	250
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (21)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (22)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000268
Analyte	NIC-GLUC
Result	602
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (22)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (23)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000268
Analyte	THCOT
Result	904
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (23)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (24)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000268
Analyte	THCOT-GLUC
Result	437
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (24)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (25)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113290000091
Analyte	AMES MUTAGENICITY
Result	8.73
Result Unit	REV/ML
Lab Status	OK
Sample comment	
Detection method	COUNT
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99071-15
Date of Collection	2013-JUL-26
Timepoint-minutes	
Urine Start Day	0

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (25)

Data signed: (k.jarus) 30 May 2014 12:26:15

Generated On: 15 Dec 2014 17:19:50

Urine End Day

1

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Date of Visit

Data signed: (k.jarus) 30 May 2014 12:26:16

Generated On: 15 Dec 2014 17:19:50

Date of Visit

27 JUL 2013
DD/MMM/YYYY

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Vital Signs

Data signed: (k.jarus) 30 May 2014 12:26:16

Generated On: 15 Dec 2014 17:19:50

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Time of assessment

10:21
hour:min 24-hour clock

Pulse rate

76
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

105
mmHg

Blood Pressure (diastolic)

65
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (k.jarus) 30 May 2014 12:26:16

Generated On: 15 Dec 2014 17:19:50

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

27 JUL 2013

20:44

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (k.jarus) 30 May 2014 12:26:17

Generated On: 15 Dec 2014 17:19:50

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

27 JUL 2013

20:44

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: COHb Blood Sample

Data signed: (k.jarus) 30 May 2014 12:26:17

Generated On: 15 Dec 2014 17:19:50

Not Done

False

If Not Done, please specify the reason:

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: CO Breath Test <Repeat/> (1)

Data signed: (k.jarus) 30 May 2014 12:26:17

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:55
---	-------

Result(ppm)	7
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: CO Breath Test <Repeat/> (2)

Data signed: (k.jarus) 30 May 2014 12:26:17

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 14:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:21
---	-------

Result(ppm)	6
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: CO Breath Test <Repeat/> (3)

Data signed: (k.jarus) 30 May 2014 12:26:17

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 18:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:21
---	-------

Result(ppm)	3
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: CO Breath Test <Repeat/> (4)

Data signed: (k.jarus) 30 May 2014 12:26:17

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	20:00 - 22:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	20:42
---	-------

Result(ppm)	3
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: 24 hour urine collections

Data signed: (k.jarus) 30 May 2014 12:26:17

Generated On: 15 Dec 2014 17:19:50

Start Time	06:19
	hour:min 24-hour clock

End Date	28 JUL 2013
	DD/MMM/YYYY

End Time	06:20
	hour:min 24-hour clock

Volume	1850
--------	------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Sample Urine Collection

Data signed: (k.jarus) 30 May 2014 12:26:17

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

11

How many back up tubes were collected?

11

Date of Sample Collection
DD/MMM/YYYY

Time of Sample Collection

28 JUL 2013

7:45

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Generated On: 15 Dec 2014 17:19:50

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Time of assessment hour:m in 24-hou r clock	Assessment Status	1. I have a desire for a cigarette right now	2. Nothing would be better than smoking a cigarette right now	3. If it were possible I would probably smoke now	4. I could control things better right now if I could smoke	5. All I want right now is a cigarette	6. I have a cigarette now	7. A taste good now	8. I would do almost anything for a cigarette now	9. Smoking would make me less depressed	10. I am going to smoke as soon as possible
QSU	(b) (6)	2013 JUL 27 YYYY MMM DD	20:03 hour:m in 24-hou r clock	Completed	Disagree	Disagree	Disagree	Strongly disagree	Strongly disagree	Strongly disagree	Disagree	Strongly disagree	Strongly disagree	Do not agree or disagree

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 JUL 27
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

06:27
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Slight ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

None ☐

4. Desire or craving to smoke

How have you been feeling over the past 24 hours?

None ☐

5. Difficulty concentrating

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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours?

None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours?

None ☐

8. Restless

How have you been feeling over the past 24 hours?

None ☐

9. Impatient

How have you been feeling over the past 24 hours?

None ☐

10. Constipation

How have you been feeling over the past 24 hours?

None ☐

11. Dizziness

How have you been feeling over the past 24 hours?

None ☐

12. Coughing

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

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Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 JUL 27
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

20:05
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Moderately ☒

3. Did you enjoy the sensation in your throat and chest?

Very little ☒

4. Did smoking calm you down?

Not at all ☒

5. Did smoking make you feel more awake?

Very little ☒

6. Did smoking make you feel less irritable?

Very little ☒

7. Did smoking help you concentrate?

Not at all ☒

8. Did smoking reduce your hunger for food?

Very little ☒

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(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

9. Did smoking make you dizzy? Very little ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a cigarette? Moderately ☐

12. Did you enjoy smoking? Moderately ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Cough Assessment

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 JUL 27
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

06:25
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Human Smoking Topography Questionnaire

Generated On: 15 Dec 2014 17:19:50

Type

HUMAN SMOKING
TOPOGRAPHY
QUESTIONNAIRE

Date of assessment

Time of assessment

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products
is different with the device.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you agree or strongly agree, please describe :

2. You enjoy smoking with the device as much as
without it.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you disagree or strongly disagree, please describe :

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Form: Human Smoking Topography Questionnaire

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3. The taste of the conventional cigarettes/products is different with the device.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you agree or strongly agree, please describe : _____

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Folder: Day 1

Form: Lab-BU COHB(2013 07 27)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Experiment Type

COHB

Date of Sample Collection

2013 07 27

Please document clinically relevant abnormalities in the AE form

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Folder: Day 1

Form: Lab-BU COHB(2013 07 27)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Experiment Type	COHB
Date of Sample Collection	2013 07 27
Time of Sample Collection	20:44
Analyte Name	COHB
Result	1.1
Unit	%
Lower limit	8.0
Upper limit	9.0
Flag	Low <input checked="" type="radio"/>
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

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Folder: Day 1

Form: Biomarker(Blood)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type

PLASMA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Blood) (1)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	PLASMA
Sample Barcode	05111450000354
Analyte	COTININE
Result	50.8
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99071-01
Date of Collection	2013-JUL-27
Timepoint-minutes	0
Urine Start Day	

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Folder: Day 1

Form: Biomarker(Blood) (1)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Blood) (2)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	PLASMA
Sample Barcode	05111450000354
Analyte	NICOTINE
Result	2.48
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99071-01
Date of Collection	2013-JUL-27
Timepoint-minutes	0
Urine Start Day	

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Folder: Day 1

Form: Biomarker(Blood) (2)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Biomarker(Urine)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type

URINE

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Folder: Day 1

Form: Biomarker(Urine) (1)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111510000318
Analyte	3-OH-BAP
Result	52.5
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-07
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (1)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (2)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001942
Analyte	3-HPMA
Result	183
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (2)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (3)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001942
Analyte	CEMA
Result	6.36
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (3)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (4)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001942
Analyte	HBMA
Result	87.8
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (4)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (5)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000836
Analyte	1-NA
Result	7.34
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (5)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (6)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000836
Analyte	2-NA
Result	3.50
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (6)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (7)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000836
Analyte	4-ABP
Result	2.91
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (7)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (8)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000836
Analyte	O-TOL
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (8)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (9)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111480000192
Analyte	NNAL
Result	30.0
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-04
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (9)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (10)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111480000192
Analyte	NNN
Result	0.492
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-04
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (10)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (11)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113210000654
Analyte	MHBMA
Result	0.297
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99602-02
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (11)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (12)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113220000654
Analyte	1-OHP
Result	119
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99602-03
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (12)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (13)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113230000654
Analyte	CREATININE
Result	83.9
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-14
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (13)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (14)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113200000654
Analyte	SBMA
Result	1.92
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99602-01
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (14)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (15)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113200000654
Analyte	SPMA
Result	0.317
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99602-01
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (15)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (16)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111490000206
Analyte	HEMA
Result	1.29
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-05
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (16)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (17)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000269
Analyte	COT
Result	325
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (17)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (18)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000269
Analyte	COT-GLUC
Result	2930
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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Folder: Day 1

Form: Biomarker(Urine) (18)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (19)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000269
Analyte	NIC
Result	117
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (19)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (20)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000269
Analyte	NIC-GLUC
Result	304
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (20)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (21)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000269
Analyte	THCOT
Result	963
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (21)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (22)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000269
Analyte	THCOT-GLUC
Result	437
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	1
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-27
Timepoint-minutes	
Urine Start Day	1

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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 1

Form: Biomarker(Urine) (22)

Data signed: (k.jarus) 30 May 2014 12:26:18

Generated On: 15 Dec 2014 17:19:50

Urine End Day

2

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Date of Visit

Data signed: (k.jarus) 30 May 2014 12:26:19

Generated On: 15 Dec 2014 17:19:50

Date of Visit

28 JUL 2013
DD/MMM/YYYY

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Vital Signs

Data signed: (k.jarus) 30 May 2014 12:26:19

Generated On: 15 Dec 2014 17:19:50

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Time of assessment

10:24
hour:min 24-hour clock

Pulse rate

71
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

115
mmHg

Blood Pressure (diastolic)

70
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Plasma Nicotine Sample

Data signed: (k.jarus) 30 May 2014 12:26:20

Generated On: 15 Dec 2014 17:19:50

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

28 JUL 2013

20:44

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Plasma Cotinine Sample

Data signed: (k.jarus) 30 May 2014 12:26:20

Generated On: 15 Dec 2014 17:19:50

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

28 JUL 2013

20:44

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: COHb Blood Sample

Data signed: (k.jarus) 30 May 2014 12:26:20

Generated On: 15 Dec 2014 17:19:50

Not Done

False

If Not Done, please specify the reason:

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: CO Breath Test <Repeat/> (1)

Data signed: (k.jarus) 30 May 2014 12:26:21

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	07:15
---	-------

Result(ppm)	5
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: CO Breath Test <Repeat/> (2)

Data signed: (k.jarus) 30 May 2014 12:26:21

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 14:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:21
---	-------

Result(ppm)	2
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: CO Breath Test <Repeat/> (3)

Data signed: (k.jarus) 30 May 2014 12:26:21

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 18:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:21
---	-------

Result(ppm)	4
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: CO Breath Test <Repeat/> (4)

Data signed: (k.jarus) 30 May 2014 12:26:21

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	20:00 - 22:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	20:42
---	-------

Result(ppm)	5
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: 24 hour urine collections

Data signed: (k.jarus) 30 May 2014 12:26:20

Generated On: 15 Dec 2014 17:19:50

Start Time	06:21
	hour:min 24-hour clock

End Date	29 JUL 2013
	DD/MMM/YYYY

End Time	06:13
	hour:min 24-hour clock

Volume	2000
--------	------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Sample Urine Collection

Data signed: (k.jarus) 30 May 2014 12:26:20

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

11

How many back up tubes were collected?

11

Date of Sample Collection
DD/MMM/YYYY

Time of Sample Collection

29 JUL 2013

7:13

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Generated On: 15 Dec 2014 17:19:50

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Time of assessment hour:m in 24-hou r clock	Assessment Status	1. I have a desire for a cigarette right now	2. Nothing would be better than smoking a cigarette right now	3. If it were possible I would probably smoke now	4. I could control things better right now if I could smoke	5. All I want right now is a cigarette	6. I have a cigarette taste now	7. A cigarette would do almost anything for a cigarette now	8. I would make me less depressed now	9. Smoking would make me less depressed as soon as possible	10. I am going to smoke as soon as possible
QSU	(b) (6)	2013 JUL 28 YYYY MMM DD	20:01 hour:m in 24-hou r clock	Completed	Somewhat disagree	Disagree	Disagree	Strongly disagree	Disagree	Somewhat disagree	Disagree	Strongly disagree	Disagree	Disagree

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 JUL 28
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

06:17
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Slight ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

None ☐

4. Desire or craving to smoke

How have you been feeling over the past 24 hours?

None ☐

5. Difficulty concentrating

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Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? Slight ☐

12. Coughing

How have you been feeling over the past 24 hours? None ☐

13. Dreaming or nightmares

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 JUL 28
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

20:02
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Very little ☐

2. Did cigarettes taste good?

Moderately ☐

3. Did you enjoy the sensation in your throat and chest?

Very little ☐

4. Did smoking calm you down?

Not at all ☐

5. Did smoking make you feel more awake?

Not at all ☐

6. Did smoking make you feel less irritable?

Not at all ☐

7. Did smoking help you concentrate?

Not at all ☐

8. Did smoking reduce your hunger for food?

Not at all ☐

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Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

9. Did smoking make you dizzy? Very little ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a cigarette? Moderately ☐

12. Did you enjoy smoking? Moderately ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Cough Assessment

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 JUL 28
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

06:16
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Lab-BU COHB(2013 07 28)

Data signed: (k.jarus) 30 May 2014 12:26:21

Generated On: 15 Dec 2014 17:19:50

Experiment Type

COHB

Date of Sample Collection

2013 07 28

Please document clinically relevant abnormalities in the AE form

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Lab-BU COHB(2013 07 28)

Data signed: (k.jarus) 30 May 2014 12:26:21

Generated On: 15 Dec 2014 17:19:50

Experiment Type	COHB
Date of Sample Collection	2013 07 28
Time of Sample Collection	20:44
Analyte Name	COHB
Result	1.1
Unit	%
Lower limit	8.0
Upper limit	9.0
Flag	Low <input checked="" type="radio"/>
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Please document clinically relevant abnormalities in the AE form	

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Folder: Day 2

Form: Biomarker(Blood)

Data signed: (k.jarus) 30 May 2014 12:26:21

Generated On: 15 Dec 2014 17:19:50

Sample type

PLASMA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Blood) (1)

Data signed: (k.jarus) 30 May 2014 12:26:21

Generated On: 15 Dec 2014 17:19:50

Sample type	PLASMA
Sample Barcode	05111450000355
Analyte	COTININE
Result	43.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99071-01
Date of Collection	2013-JUL-28
Timepoint-minutes	0
Urine Start Day	

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Folder: Day 2

Form: Biomarker(Blood) (1)

Data signed: (k.jarus) 30 May 2014 12:26:21

Generated On: 15 Dec 2014 17:19:50

Urine End Day

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Blood) (2)

Data signed: (k.jarus) 30 May 2014 12:26:21

Generated On: 15 Dec 2014 17:19:50

Sample type	PLASMA
Sample Barcode	05111450000355
Analyte	NICOTINE
Result	2.14
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99071-01
Date of Collection	2013-JUL-28
Timepoint-minutes	0
Urine Start Day	

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Blood) (2)

Data signed: (k.jarus) 30 May 2014 12:26:21

Generated On: 15 Dec 2014 17:19:50

Urine End Day

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type

URINE

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (1)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111510000319
Analyte	3-OH-BAP
Result	BLQ<(50.0)
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-07
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

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Folder: Day 2

Form: Biomarker(Urine) (1)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (2)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001943
Analyte	3-HPMA
Result	102
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (2)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (3)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001943
Analyte	CEMA
Result	3.37
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

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Folder: Day 2

Form: Biomarker(Urine) (3)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (4)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111470001943
Analyte	HBMA
Result	91.2
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-03
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

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Folder: Day 2

Form: Biomarker(Urine) (4)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (5)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000837
Analyte	1-NA
Result	3.28
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

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Folder: Day 2

Form: Biomarker(Urine) (5)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (6)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000837
Analyte	2-NA
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (6)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (7)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000837
Analyte	4-ABP
Result	1.70
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (7)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (8)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111530000837
Analyte	O-TOL
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-09
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
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Folder: Day 2

Form: Biomarker(Urine) (8)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (9)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111480000193
Analyte	NNAL
Result	23.1
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-04
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (9)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (10)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111480000193
Analyte	NNN
Result	0.308
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-04
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (10)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (11)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113210000655
Analyte	MHBMA
Result	0.154
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99602-02
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (11)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (12)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113220000655
Analyte	1-OHP
Result	87.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99602-03
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (12)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (13)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113230000655
Analyte	CREATININE
Result	77.7
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-14
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (13)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (14)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113200000655
Analyte	SBMA
Result	1.56
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99602-01
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (14)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (15)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05113200000655
Analyte	SPMA
Result	0.155
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99602-01
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (15)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (16)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111490000207
Analyte	HEMA
Result	1.10
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-05
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (16)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (17)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000270
Analyte	COT
Result	267
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (17)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (18)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000270
Analyte	COT-GLUC
Result	2070
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (18)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (19)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000270
Analyte	NIC
Result	104
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (19)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (20)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000270
Analyte	NIC-GLUC
Result	341
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (20)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (21)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000270
Analyte	THCOT
Result	700
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (21)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (22)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Sample type	URINE
Sample Barcode	05111500000270
Analyte	THCOT-GLUC
Result	349
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	2
Celerion Study Number	AA99071-06
Date of Collection	2013-JUL-28
Timepoint-minutes	
Urine Start Day	2

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 2

Form: Biomarker(Urine) (22)

Data signed: (k.jarus) 30 May 2014 12:26:22

Generated On: 15 Dec 2014 17:19:50

Urine End Day

3

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: Date of Visit

Data signed: (k.jarus) 30 May 2014 12:26:23

Generated On: 15 Dec 2014 17:19:50

Date of Visit

29 JUL 2013
DD/MMM/YYYY

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: Vital Signs

Data signed: (k.jarus) 30 May 2014 12:26:23

Generated On: 15 Dec 2014 17:19:50

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Time of assessment

10:13
hour:min 24-hour clock

Pulse rate

79
beats per minute

Respiratory rate

12
breaths per minute

Blood Pressure (systolic)

103
mmHg

Blood Pressure (diastolic)

64
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: Plasma Nicotine Sample

Data signed: (k.jarus) 30 May 2014 12:26:23

Generated On: 15 Dec 2014 17:19:50

Not Done

True

If Not Done, please specify the reason:

SUBJECT RESIGNED

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: Plasma Cotinine Sample

Data signed: (k.jarus) 30 May 2014 12:26:23

Generated On: 15 Dec 2014 17:19:50

Not Done

True

If Not Done, please specify the reason:

SUBJECT RESIGNED

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: COHb Blood Sample

Data signed: (k.jarus) 30 May 2014 12:26:23

Generated On: 15 Dec 2014 17:19:50

Not Done

True

If Not Done, please specify the reason:

SUBJECT RESIGNED

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: CO Breath Test <Repeat/> (1)

Data signed: (k.jarus) 30 May 2014 12:26:24

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	07:11
---	-------

Result(ppm)	6
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: CO Breath Test <Repeat/> (2)

Data signed: (k.jarus) 30 May 2014 12:26:24

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 14:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:21
---	-------

Result(ppm)	5
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: CO Breath Test <Repeat/> (3)

Data signed: (k.jarus) 30 May 2014 12:26:24

Generated On: 15 Dec 2014 17:19:50

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 18:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:21
---	-------

Result(ppm)	4
-------------	---

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: CO Breath Test <Repeat/> (4)

Data signed: (k.jarus) 30 May 2014 12:26:24

Generated On: 15 Dec 2014 17:19:50

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	PATIENT RESIGNED
---	------------------

Scheduled Time	20:00 - 22:00 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
-------------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: 24 hour urine collections

Data signed: (k.jarus) 30 May 2014 12:26:24

Generated On: 15 Dec 2014 17:19:50

Start Time	06:14
	hour:min 24-hour clock

End Date	29 JUL 2013
	DD/MMM/YYYY

End Time	16:23
	hour:min 24-hour clock

Volume	1100
--------	------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: Sample Urine Collection

Data signed: (k.jarus) 30 May 2014 12:26:24

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

11

How many back up tubes were collected?

11

Date of Sample Collection
DD/MMM/YYYY

Time of Sample Collection

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Generated On: 15 Dec 2014 17:19:50

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Time of assessment hour:m in 24-hour clock	Assessment Status	1. I have a desire for a cigarette right now	2. Nothing would be better than smoking a cigarette right now	3. If it were possible I would probably smoke now	4. I could control things better right now if I could smoke	5. All I want now is a cigarette	6. I have an urge for a cigarette now	7. A taste good now	8. I would do almost anything for a cigarette now	9. Smoking would make me less depressed as soon as possible	10. I am going to smoke as soon as possible
------	------------------------------------	---	---	-------------------	--	---	---	---	----------------------------------	---------------------------------------	---------------------	---	---	---

QSU

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 JUL 29
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

06:05
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Slight ☐

4. Desire or craving to smoke

How have you been feeling over the past 24 hours?

None ☐

5. Difficulty concentrating

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Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours?

None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours?

None ☐

8. Restless

How have you been feeling over the past 24 hours?

None ☐

9. Impatient

How have you been feeling over the past 24 hours?

None ☐

10. Constipation

How have you been feeling over the past 24 hours?

None ☐

11. Dizziness

How have you been feeling over the past 24 hours?

Mild ☐

12. Coughing

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

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Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

Date of assessment
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

Assessment Status

Completed ☐

Abandoned ☐

1. Was smoking satisfying?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

2. Did cigarettes taste good?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

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Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

3. Did you enjoy the sensation in your throat and chest?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

4. Did smoking calm you down?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

5. Did smoking make you feel more awake?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

6. Did smoking make you feel less irritable?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

7. Did smoking help you concentrate?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

8. Did smoking reduce your hunger for food?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.: 0085

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

9. Did smoking make you dizzy?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

10. Did smoking make you nauseous?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

11. Did smoking immediately relieve your craving for a cigarette?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.: 0085

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

12. Did you enjoy smoking?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 3

Form: Cough Assessment

Generated On: 15 Dec 2014 17:19:50

Date of Birth YYYY MMM DD	(b) (6)
Date of assessment YYYY MMM DD	2013 JUL 29 YYYY MMM DD
Time of assessment hour:min 24-hour clock	06:03 hour:min 24-hour clock
Assessment Status	Completed <input checked="" type="radio"/>
Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input checked="" type="radio"/>
If YES, please answer the following questions:	
First Question: Cough Impact Scale How much is your cough bothering you?	35
Second Question: Cough Intensity Scale: How intense is your cough?	Mild <input checked="" type="radio"/>
Third Question: Cough Frequency Scale: How frequently do you normally have to cough each day?	Sometimes <input checked="" type="radio"/>
Fourth Question: Sputum Production To what extent do you produce sputum when coughing?	A moderate amount of sputum <input checked="" type="radio"/>

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: Date of Visit

Generated On: 15 Dec 2014 17:19:50

Date of Visit

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 4

Form: Vital Signs

Generated On: 15 Dec 2014 17:19:50

Were Vitals Signs assessed?

No ☐

Yes ☐

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☐

Yes ☐

Time of assessment _____

Pulse rate _____

Respiratory rate _____

Blood Pressure (systolic) _____

Blood Pressure (diastolic) _____

Vital Signs Position of Subject

Supine ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: Plasma Nicotine Sample

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: Plasma Cotinine Sample

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: COHb Blood Sample

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: CO Breath Test <Repeat/> (1)

Generated On: 15 Dec 2014 17:19:50

Assessment not done

If Not Done, please specify the reason:

Scheduled Time

Within 15 min prior to ☒ smoking

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: CO Breath Test <Repeat/> (2)

Generated On: 15 Dec 2014 17:19:50

Assessment not done

If Not Done, please specify the reason:

Scheduled Time

12:00—14:00



Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: CO Breath Test <Repeat/> (3)

Generated On: 15 Dec 2014 17:19:50

Assessment not done

If Not Done, please specify the reason:

Scheduled Time

16:00—18:00



Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: CO Breath Test <Repeat/> (4)

Generated On: 15 Dec 2014 17:19:50

Assessment not done

If Not Done, please specify the reason:

Scheduled Time

20:00—22:00



Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: 24 hour urine collections

Generated On: 15 Dec 2014 17:19:50

Start Time

End Date

End Time

Volume

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: Sample Urine Collection

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

No ☐
Yes ☐

If No, please specify the reason: _____

How many primary tubes were collected? _____

How many back up tubes were collected? _____

Date of Sample Collection
DD/MMM/YYYY

Time of Sample Collection

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Generated On: 15 Dec 2014 17:19:50

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Time of assessment hour:m in 24-hour clock	Assessment Status	1. I have a desire for a cigarette right now	2. Nothing would be better than smoking a cigarette right now	3. If it were possible I would probably smoke now	4. I could control things better right now if I could smoke	5. All I want now is a cigarette	6. I have a cigarette now	7. A taste good now	8. I would do almost anything for a cigarette now	9. Smoking would make me less depressed as soon as possible	10. I am going to smoke as soon as possible
------	------------------------------------	---	---	-------------------	--	---	---	---	----------------------------------	---------------------------	---------------------	---	---	---

QSU

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

Date of assessment
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

Assessment Status

Completed ☐

Abandoned ☐

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

1. Angry, irritable, frustrated

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

How have you been feeling over the past 24 hours?

2. Anxious, nervous

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

3. Depressed Mood, sad

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

4. Desire or craving to smoke

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

5. Difficulty concentrating

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

6. Increased appetite, hungry, weight gain

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

7. Insomnia, sleep problems, awakening at night

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

8. Restless

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

9. Impatient

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

10. Constipation

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

11. Dizziness

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

12. Coughing

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

13. Dreaming or nightmares

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

14. Nausea

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

15. Sore Throat

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

Date of assessment
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

Assessment Status

Completed ☐

Abandoned ☐

1. Was smoking satisfying?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

2. Did cigarettes taste good?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

3. Did you enjoy the sensation in your throat and chest?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

4. Did smoking calm you down?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

5. Did smoking make you feel more awake?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

6. Did smoking make you feel less irritable?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

7. Did smoking help you concentrate?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

8. Did smoking reduce your hunger for food?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

9. Did smoking make you dizzy?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

10. Did smoking make you nauseous?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

11. Did smoking immediately relieve your craving for a cigarette?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.: 0085

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

12. Did you enjoy smoking?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 4

Form: Cough Assessment

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

Date of assessment
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

Assessment Status

Completed ☐

Abandoned ☐

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☐

No ☐

Abandoned ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☐

Mild ☐

Moderate ☐

Severe ☐

Very severe ☐

Abandoned ☐

Not Applicable ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 4

Form: Cough Assessment

Generated On: 15 Dec 2014 17:19:50

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day?

- Rarely ☐
Sometimes ☐
Fairly often ☐
Often ☐
Almost always ☐
Abandoned ☐
Not Applicable ☐

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

- No sputum ☐
A moderate amount of sputum ☐
A large amount of sputum ☐
A very large amount of sputum ☐
Abandoned ☐
Not Applicable ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Generated On: 15 Dec 2014 17:19:50

Type

HUMAN SMOKING
TOPOGRAPHY
QUESTIONNAIRE

Date of assessment

Time of assessment

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products
is different with the device.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you agree or strongly agree, please describe :

2. You enjoy smoking with the device as much as
without it.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you disagree or strongly disagree, please describe :

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Generated On: 15 Dec 2014 17:19:50

3. The taste of the conventional cigarettes/products is different with the device.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Strongly agree ☐
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you agree or strongly agree, please describe : _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Date of Visit

Generated On: 15 Dec 2014 17:19:50

Date of Visit

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 5

Form: Vital Signs

Generated On: 15 Dec 2014 17:19:50

Were Vitals Signs assessed?

No ☐

Yes ☐

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☐

Yes ☐

Time of assessment _____

Pulse rate _____

Respiratory rate _____

Blood Pressure (systolic) _____

Blood Pressure (diastolic) _____

Vital Signs Position of Subject

Supine ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Nicotine Sample

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Nicotine Sample(D5) (1)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T0 - 15 min



ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Nicotine Sample(D5) (2)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T1 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Nicotine Sample(D5) (3)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T2 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Nicotine Sample(D5) (4)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T3 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Nicotine Sample(D5) (5)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T4 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Nicotine Sample(D5) (6)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T5 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Nicotine Sample(D5) (7)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T6 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Nicotine Sample(D5) (8)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T7 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Nicotine Sample(D5) (9)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T8 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Cotinine Sample

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Cotinine Sample(D5) (1)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T0 - 15 min



ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Cotinine Sample(D5) (2)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T1 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Cotinine Sample(D5) (3)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T2 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Cotinine Sample(D5) (4)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T3 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Cotinine Sample(D5) (5)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T4 ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Cotinine Sample(D5) (6)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T5 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Cotinine Sample(D5) (7)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T6 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Cotinine Sample(D5) (8)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

17 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Plasma Cotinine Sample(D5) (9)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T8 

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: COHb Blood Sample<CC/THS Arm/> (1)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Scheduled Time

Within 15 min prior to
smoking

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: COHb Blood Sample<CC/THS Arm/> (2)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Scheduled Time

12:00—14:00 ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: COHb Blood Sample<CC/THS Arm/> (3)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Scheduled Time

16:00—18:00 ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: COHb Blood Sample<CC/THS Arm/> (4)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Scheduled Time

20:00—22:00



ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: CO Breath Test <Repeat/> (1)

Generated On: 15 Dec 2014 17:19:50

Assessment not done

If Not Done, please specify the reason:

Scheduled Time

Within 15 min prior to ☒ smoking

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: CO Breath Test <Repeat/> (2)

Generated On: 15 Dec 2014 17:19:50

Assessment not done

If Not Done, please specify the reason:

Scheduled Time

12:00—14:00 ☒

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: CO Breath Test <Repeat/> (3)

Generated On: 15 Dec 2014 17:19:50

Assessment not done

If Not Done, please specify the reason:

Scheduled Time

16:00—18:00



Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: CO Breath Test <Repeat/> (4)

Generated On: 15 Dec 2014 17:19:50

Assessment not done

If Not Done, please specify the reason:

Scheduled Time

20:00—22:00 ☒

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: CYP1A2 activity Sample

Generated On: 15 Dec 2014 17:19:50

Time of coffee intake

Sample collection Not Done

If Not Done, please specify the reason:

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

Caffeine

Paraxanthine

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: 24 hour urine collections

Generated On: 15 Dec 2014 17:19:50

Start Time

End Date

End Time

Volume

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Sample Urine Collection

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

No ☐
Yes ☐

If No, please specify the reason: _____

How many primary tubes were collected? _____

How many back up tubes were collected? _____

Date of Sample Collection
DD/MMM/YYYY

Time of Sample Collection

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Generated On: 15 Dec 2014 17:19:50

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Time of assessment hour:m in 24-hour clock	Assessment Status	1. I have a desire for a cigarette right now	2. Nothing would be better than smoking a cigarette right now	3. If it were possible I would probably smoke now	4. I could control things better right now if I could smoke	5. All I want now is a cigarette	6. I have a cigarette now	7. A taste good now	8. I would do almost anything for a cigarette now	9. Smoking would make me less depressed as soon as possible	10. I am going to smoke as soon as possible
------	------------------------------------	---	---	-------------------	--	---	---	---	----------------------------------	---------------------------	---------------------	---	---	---

QSU

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

Date of assessment
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

Assessment Status

Completed ☐

Abandoned ☐

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

1. Angry, irritable, frustrated

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

How have you been feeling over the past 24 hours?

2. Anxious, nervous

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

3. Depressed Mood, sad

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

4. Desire or craving to smoke

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

5. Difficulty concentrating

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

6. Increased appetite, hungry, weight gain

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

7. Insomnia, sleep problems, awakening at night

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

8. Restless

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

9. Impatient

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

10. Constipation

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

11. Dizziness

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

12. Coughing

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

13. Dreaming or nightmares

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

14. Nausea

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

15. Sore Throat

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

Date of assessment
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

Assessment Status

Completed ☐

Abandoned ☐

1. Was smoking satisfying?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

2. Did cigarettes taste good?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

3. Did you enjoy the sensation in your throat and chest?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

4. Did smoking calm you down?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

5. Did smoking make you feel more awake?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

6. Did smoking make you feel less irritable?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

7. Did smoking help you concentrate?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

8. Did smoking reduce your hunger for food?

- Not at all ☐
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐
-

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

9. Did smoking make you dizzy?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

10. Did smoking make you nauseous?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

11. Did smoking immediately relieve your craving for a cigarette?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.: 0085

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 15 Dec 2014 17:19:50

12. Did you enjoy smoking?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 5

Form: Cough Assessment

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

Date of assessment
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

Assessment Status

Completed ☐

Abandoned ☐

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☐

No ☐

Abandoned ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☐

Mild ☐

Moderate ☐

Severe ☐

Very severe ☐

Abandoned ☐

Not Applicable ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 5

Form: Cough Assessment

Generated On: 15 Dec 2014 17:19:50

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day?

- Rarely ☐
Sometimes ☐
Fairly often ☐
Often ☐
Almost always ☐
Abandoned ☐
Not Applicable ☐

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

- No sputum ☐
A moderate amount of sputum ☐
A large amount of sputum ☐
A very large amount of sputum ☐
Abandoned ☐
Not Applicable ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: Date of Visit

Generated On: 15 Dec 2014 17:19:50

Date of Visit

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: Plasma Nicotine Sample

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: Plasma Nicotine Sample(D6) (1)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T0 + 20H



ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: Plasma Nicotine Sample(D6) (2)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T0 + 24H



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Folder: Day 6

Form: Plasma Cotinine Sample

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: Plasma Cotinine Sample(D6) (1)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T0 + 20H



ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: Plasma Cotinine Sample(D6) (2)

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Timepoint

T0 + 24H



ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: CYP2A6 activity Sample

Generated On: 15 Dec 2014 17:19:50

Not Done

If Not Done, please specify the reason:

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

~~trans-3'-hydroxycotinine~~

cotinine

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

Date of assessment
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

Assessment Status

Completed ☐

Abandoned ☐

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

1. Angry, irritable, frustrated

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

How have you been feeling over the past 24 hours?

2. Anxious, nervous

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

3. Depressed Mood, sad

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

4. Desire or craving to smoke

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

5. Difficulty concentrating

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

6. Increased appetite, hungry, weight gain

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

7. Insomnia, sleep problems, awakening at night

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

8. Restless

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

9. Impatient

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

10. Constipation

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

11. Dizziness

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

12. Coughing

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

13. Dreaming or nightmares

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

14. Nausea

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 15 Dec 2014 17:19:50

How have you been feeling over the past 24 hours?

15. Sore Throat

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Day 6

Form: Cough Assessment

Generated On: 15 Dec 2014 17:19:50

Date of Birth
YYYY MMM DD

Date of assessment
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

Assessment Status

Completed ☐

Abandoned ☐

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☐

No ☐

Abandoned ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☐

Mild ☐

Moderate ☐

Severe ☐

Very severe ☐

Abandoned ☐

Not Applicable ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Day 6

Form: Cough Assessment

Generated On: 15 Dec 2014 17:19:50

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day?

- Rarely ☐
Sometimes ☐
Fairly often ☐
Often ☐
Almost always ☐
Abandoned ☐
Not Applicable ☐

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

- No sputum ☐
A moderate amount of sputum ☐
A large amount of sputum ☐
A very large amount of sputum ☐
Abandoned ☐
Not Applicable ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: Bio-banking (Transcriptomics)

Generated On: 15 Dec 2014 17:19:50

Was a Bio-banking sample for transcriptomics taken?

No ☐

Yes ☐

Time of Sample Collection

Was the subject fasting for at least 8 hours at time of
sample collection?

No ☐

Yes ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Day 6

Form: Bio-banking (Biomarkers of exposure and risk markers)

Generated On: 15 Dec 2014 17:19:50

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

No ☐
Yes ☐

Time of Sample Collection

Was the subject fasting for at least 8 hours at time of
sample collection?

No ☐
Yes ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Data signed: (k.jarus) 30 May 2014 12:27:29

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0084_01_6RYG.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Data signed: (k.jarus) 30 May 2014 12:27:29

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0084_02_SGP3.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Data signed: (k.jarus) 30 May 2014 12:27:29

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0084_03_8YT1.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Data signed: (k.jarus) 30 May 2014 12:27:29

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0084_04_280S.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Data signed: (k.jarus) 30 May 2014 12:27:29

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0084_05_PDIL.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Data signed: (k.jarus) 30 May 2014 12:27:29

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0084_06_W5EO.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Data signed: (k.jarus) 30 May 2014 12:27:29

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0084_07_F1GE.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Data signed: (k.jarus) 30 May 2014 12:27:29

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0084_08_DNMA.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
---------------------------------	-------------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Data signed: (k.jarus) 30 May 2014 12:27:30

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
-------------	---

Picture File Name	T0100_01_VWEA.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Data signed: (k.jarus) 30 May 2014 12:27:30

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
-------------	---

Picture File Name	T0100_02_9GL8.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Data signed: (k.jarus) 30 May 2014 12:27:30

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	Ashes not anymore visible when shooting picture <input type="checkbox"/>
	No tobacco in plug <input type="checkbox"/>
	Not enough tobacco in the plug to perform the analysis <input type="checkbox"/>
	Tobacco plug destroyed, analysis impossible <input type="checkbox"/>
	No tobacco plug in the vial <input type="checkbox"/>
	Other error <input type="checkbox"/>

Picture File Name	T0100_03_EGSA.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Data signed: (k.jarus) 30 May 2014 12:27:30

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0100_04_XAA9.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Data signed: (k.jarus) 30 May 2014 12:27:30

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0100_05_28QC.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Data signed: (k.jarus) 30 May 2014 12:27:30

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0100_06_FY4M.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Data signed: (k.jarus) 30 May 2014 12:27:30

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
-------------	---

Picture File Name	T0100_07_GNYJ.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Data signed: (k.jarus) 30 May 2014 12:27:30

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0100_08_9DXO.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Data signed: (k.jarus) 30 May 2014 12:27:31

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	Ashes not anymore visible when shooting picture <input type="checkbox"/>
	No tobacco in plug <input type="checkbox"/>
	Not enough tobacco in the plug to perform the analysis <input type="checkbox"/>
	Tobacco plug destroyed, analysis impossible <input type="checkbox"/>
	No tobacco plug in the vial <input type="checkbox"/>
	Other error <input type="checkbox"/>

Picture File Name	T0116_01_XINO.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Data signed: (k.jarus) 30 May 2014 12:27:31

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
-------------	---

Picture File Name	T0116_02_WZ6H.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Data signed: (k.jarus) 30 May 2014 12:27:31

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
-------------	---

Picture File Name	T0116_03_XP4T.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Data signed: (k.jarus) 30 May 2014 12:27:31

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	Ashes not anymore visible when shooting picture <input type="checkbox"/>
	No tobacco in plug <input type="checkbox"/>
	Not enough tobacco in the plug to perform the analysis <input type="checkbox"/>
	Tobacco plug destroyed, analysis impossible <input type="checkbox"/>
	No tobacco plug in the vial <input type="checkbox"/>
	Other error <input type="checkbox"/>

Picture File Name	T0116_04_OR1S.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Data signed: (k.jarus) 30 May 2014 12:27:31

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	<div>Ashes not anymore visible when shooting picture <input type="checkbox"/></div> <div>No tobacco in plug <input type="checkbox"/></div> <div>Not enough tobacco in the plug to perform the analysis <input type="checkbox"/></div> <div>Tobacco plug destroyed, analysis impossible <input type="checkbox"/></div> <div>No tobacco plug in the vial <input type="checkbox"/></div> <div>Other error <input type="checkbox"/></div>
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Picture File Name	T0116_05_PK80.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. o.o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Data signed: (k.jarus) 30 May 2014 12:27:31

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	Ashes not anymore visible when shooting picture <input type="checkbox"/>
	No tobacco in plug <input type="checkbox"/>
	Not enough tobacco in the plug to perform the analysis <input type="checkbox"/>
	Tobacco plug destroyed, analysis impossible <input type="checkbox"/>
	No tobacco plug in the vial <input type="checkbox"/>
	Other error <input type="checkbox"/>

Picture File Name	T0116_06_PVQA.JPG
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Date of analysis DD/MMM/YYYY	18 OCT 2013
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (1)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	24 JUL 2013
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:20
----------------------	-------

Time of butt return	20:26
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (2)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	24 JUL 2013
------------------------------------	-------------

Visit	Day -2 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:53
----------------------	-------

Time of butt return	20:00
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (3)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	24 JUL 2013
------------------------------------	-------------

Visit	Day -2 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:02
----------------------	-------

Time of butt return	21:10
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (4)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	24 JUL 2013
------------------------------------	-------------

Visit	Day -2 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:18
----------------------	-------

Time of butt return	22:26
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (5)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	25 JUL 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:45
----------------------	-------

Time of butt return	06:53
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (6)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	25 JUL 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:41
----------------------	-------

Time of butt return	08:48
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (7)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	25 JUL 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:48
----------------------	-------

Time of butt return	09:53
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (8)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	25 JUL 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:24
----------------------	-------

Time of butt return	11:30
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (9)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	25 JUL 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:46
----------------------	-------

Time of butt return	12:53
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (10)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	25 JUL 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:57
----------------------	-------

Time of butt return	14:03
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (11)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	25 JUL 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:56
----------------------	-------

Time of butt return	16:03
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (12)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	25 JUL 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:10
----------------------	-------

Time of butt return	17:18
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (13)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	25 JUL 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:45
----------------------	-------

Time of butt return	18:52
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (14)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	25 JUL 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:48
----------------------	-------

Time of butt return	20:54
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (15)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	25 JUL 2013
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:54
----------------------	-------

Time of butt return	22:01
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-CC (16)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	26 JUL 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:32
----------------------	-------

Time of butt return	07:39
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0222
----------------------------	------

SODIM file number	03BO0029OWN020222001
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-CC (17)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	26 JUL 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:11
----------------------	-------

Time of butt return	09:18
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0222
----------------------------	------

SODIM file number	03BO0029OWN020222002
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-CC (18)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	26 JUL 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:02
----------------------	-------

Time of butt return	11:11
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0222
----------------------------	------

SODIM file number	03BO0029OWN020222003
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-CC (19)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	26 JUL 2013
------------------------------------	-------------

Visit	Day 0 <input type="radio"/>
-------	-----------------------------

Type of Product Use	Conventional Cigarettes <input type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:29
----------------------	-------

Time of butt return	12:36
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0222
----------------------------	------

SODIM file number	03BO0029OWN020222004
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-CC (20)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	26 JUL 2013
------------------------------------	-------------

Visit	Day 0 <input type="radio"/>
-------	-----------------------------

Type of Product Use	Conventional Cigarettes <input type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	14:13
----------------------	-------

Time of butt return	14:20
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0222
----------------------------	------

SODIM file number	03BO0029OWN020222005
-------------------	----------------------

Comment	
---------	--

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-CC (21)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	26 JUL 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:39
----------------------	-------

Time of butt return	15:47
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0222
----------------------------	------

SODIM file number	03BO0029OWN020222006
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-CC (22)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	26 JUL 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:47
----------------------	-------

Time of butt return	17:54
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0222
----------------------------	------

SODIM file number	03BO0029OWN020222007
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-CC (23)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	26 JUL 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:48
----------------------	-------

Time of butt return	19:55
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0222
----------------------------	------

SODIM file number	03BO0029OWN020222008
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-CC (24)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	26 JUL 2013
------------------------------------	-------------

Visit	Day 0 <input type="radio"/>
-------	-----------------------------

Type of Product Use	Conventional Cigarettes <input type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:57
----------------------	-------

Time of butt return	21:04
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0222
----------------------------	------

SODIM file number	03BO0029OWN020222009
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-CC (25)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	26 JUL 2013
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:59
----------------------	-------

Time of butt return	22:07
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0222
----------------------------	------

SODIM file number	03BO0029OWN020222010
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (26)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	06:59
----------------------	-------

Time of butt return	07:06
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

SODIM file number	03BO0029THS020623001
-------------------	----------------------

Comment	
---------	--

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (27)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	08:57
----------------------	-------

Time of butt return	09:04
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

SODIM file number	03BO0029THS020623002
-------------------	----------------------

Comment	
---------	--

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (28)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:37
----------------------	-------

Time of butt return	10:45
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

SODIM file number	03BO0029THS020623003
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (29)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:37
----------------------	-------

Time of butt return	12:44
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

SODIM file number	03BO0029THS020623004
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (30)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:49
----------------------	-------

Time of butt return	13:56
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

SODIM file number	03BO0029THS020623005
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (31)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:45
----------------------	-------

Time of butt return	17:55
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

SODIM file number	03BO0029THS020623006
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (32)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:34
----------------------	-------

Time of butt return	19:47
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

SODIM file number	03BO0029THS020623007
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-CC (33)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:54
----------------------	-------

Time of butt return	21:02
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

SODIM file number	03BO0029THS020623008
-------------------	----------------------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (34)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day-2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:18
----------------------	-------

Time of butt return	07:25
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (35)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day-2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:56
----------------------	-------

Time of butt return	09:03
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (36)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day-2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:43
----------------------	-------

Time of butt return	10:51
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (37)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day-2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:26
----------------------	-------

Time of butt return	12:33
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (38)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day-2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:57
----------------------	-------

Time of butt return	14:04
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (39)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day-2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:28
----------------------	-------

Time of butt return	16:34
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (40)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day-2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:47
----------------------	-------

Time of butt return	18:55
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (41)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day-2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:55
----------------------	-------

Time of butt return	21:03
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (42)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day-3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:13
----------------------	-------

Time of butt return	07:20
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (43)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day-3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:09
----------------------	-------

Time of butt return	09:17
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (44)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day-3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:27
----------------------	-------

Time of butt return	10:34
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (45)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day-3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:56
----------------------	-------

Time of butt return	12:03
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (46)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day-3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:55
----------------------	-------

Time of butt return	14:02
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-CC (47)

Data signed: (k.jarus) 30 May 2014 12:26:25

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day-3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Conventional Cigarettes <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:29
----------------------	-------

Time of butt return	16:37
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-THS (1)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:59
----------------------	-------

Time of product return	07:06
------------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

Filter kit number	F0084
-------------------	-------

Filter vial number	01
--------------------	----

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	03BO0029THS020623001
-------------------	----------------------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (1)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-THS (2)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	08:57
----------------------	-------

Time of product return	09:04
------------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

Filter kit number	F0084
-------------------	-------

Filter vial number	02
--------------------	----

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	03BO0029THS020623002
-------------------	----------------------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (2)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-THS (3)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	10:37
----------------------	-------

Time of product return	10:45
------------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

Filter kit number	F0084
-------------------	-------

Filter vial number	03
--------------------	----

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	03BO0029THS020623003
-------------------	----------------------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (3)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-THS (4)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	12:37
----------------------	-------

Time of product return	12:44
------------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

Filter kit number	F0084
-------------------	-------

Filter vial number	04
--------------------	----

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	03BO0029THS020623004
-------------------	----------------------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (4)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (5)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	13:49
----------------------	-------

Time of product return	13:56
------------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

Filter kit number	F0084
-------------------	-------

Filter vial number	05
--------------------	----

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	03BO0029THS020623005
-------------------	----------------------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (5)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-THS (6)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	17:45
----------------------	-------

Time of product return	17:55
------------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

Filter kit number	F0084
-------------------	-------

Filter vial number	06
--------------------	----

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	03BO0029THS020623006
-------------------	----------------------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (6)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-THS (7)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	19:34
----------------------	-------

Time of product return	19:47
------------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

Filter kit number	F0084
-------------------	-------

Filter vial number	07
--------------------	----

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	03BO0029THS020623007
-------------------	----------------------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (7)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (8)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	27 JUL 2013
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	20:54
----------------------	-------

Time of product return	21:02
------------------------	-------

SODIM device number	0029
---------------------	------

SODIM sample holder number	0623
----------------------------	------

Filter kit number	F0084
-------------------	-------

Filter vial number	08
--------------------	----

Tobacco plug kit number	T0084
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	03BO0029THS020623008
-------------------	----------------------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (8)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (9)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:18
----------------------	-------

Time of product return	07:25
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Filter kit number	F0100
-------------------	-------

Filter vial number	01
--------------------	----

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	_____
-------------------	-------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (9)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (10)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	08:56
----------------------	-------

Time of product return	09:03
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Filter kit number	F0100
-------------------	-------

Filter vial number	02
--------------------	----

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	
-------------------	--

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (10)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (11)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:43
----------------------	-------

Time of product return	10:51
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Filter kit number	F0100
-------------------	-------

Filter vial number	03
--------------------	----

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	_____
-------------------	-------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (11)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-THS (12)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:26
----------------------	-------

Time of product return	12:33
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Filter kit number	F0100
-------------------	-------

Filter vial number	04
--------------------	----

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	_____
-------------------	-------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (12)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (13)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:57
----------------------	-------

Time of product return	14:04
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Filter kit number	F0100
-------------------	-------

Filter vial number	05
--------------------	----

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	_____
-------------------	-------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (13)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (14)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:29
----------------------	-------

Time of product return	16:34
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Filter kit number	F0100
-------------------	-------

Filter vial number	06
--------------------	----

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	_____
-------------------	-------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (14)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (15)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	18:47
----------------------	-------

Time of product return	18:55
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Filter kit number	F0100
-------------------	-------

Filter vial number	07
--------------------	----

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	
-------------------	--

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (15)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (16)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	28 JUL 2013
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:55
----------------------	-------

Time of product return	21:03
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Filter kit number	F0100
-------------------	-------

Filter vial number	08
--------------------	----

Tobacco plug kit number	T0100
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	_____
-------------------	-------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (16)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (17)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	07:13
----------------------	-------

Time of product return	07:20
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Filter kit number	F0116
-------------------	-------

Filter vial number	01
--------------------	----

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	
-------------------	--

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (17)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (18)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	09:09
----------------------	-------

Time of product return	09:17
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Filter kit number	F0116
-------------------	-------

Filter vial number	02
--------------------	----

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	
-------------------	--

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (18)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (19)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:27
----------------------	-------

Time of product return	10:34
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Filter kit number	F0116
-------------------	-------

Filter vial number	03
--------------------	----

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	_____
-------------------	-------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (19)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (20)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	11:56
----------------------	-------

Time of product return	12:03
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Filter kit number	F0116
-------------------	-------

Filter vial number	04
--------------------	----

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	
-------------------	--

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (20)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (21)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	13:55
----------------------	-------

Time of product return	14:02
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Filter kit number	F0116
-------------------	-------

Filter vial number	05
--------------------	----

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	
-------------------	--

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (21)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (22)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	29 JUL 2013
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	16:29
----------------------	-------

Time of product return	16:37
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Filter kit number	F0116
-------------------	-------

Filter vial number	06
--------------------	----

Tobacco plug kit number	T0116
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	
-------------------	--

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (22)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-THS (23)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use DD/MMM/YYYY	24 JUL 2013
------------------------------------	-------------

Visit	Day -2 <input checked="" type="radio"/>
-------	---

Type of Product Use	Tobacco Heating System <input checked="" type="radio"/>
---------------------	---

If type of Product Use different from the randomization
please explain

Time of distribution	20:20
----------------------	-------

Time of product return	20:26
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Filter kit number	<hr/>
-------------------	-------

Filter vial number	<hr/>
--------------------	-------

Tobacco plug kit number	<hr/>
-------------------------	-------

Tobacco plug vial number	<hr/>
--------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (23)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Comment

Batch Number

B-05875

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (24)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (24)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (25)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (25)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (26)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (26)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (27)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (27)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (28)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (28)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (29)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (29)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (30)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (30)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (31)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (31)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (32)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (32)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (33)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (33)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (34)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (34)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (35)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (35)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (36)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (36)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (37)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (37)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (38)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (38)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (39)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (39)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (40)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (40)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (41)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (41)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (42)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (42)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (43)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (43)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (44)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (44)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (45)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (45)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (46)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (46)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (47)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (47)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (48)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (48)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (49)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (49)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (50)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (50)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (51)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (51)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (52)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (52)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number

Tobacco plug kit number

Tobacco plug vial number

SODIM file number

Comment

Batch Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (53)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (53)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (54)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (54)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (55)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (55)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (56)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (56)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (57)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (57)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (58)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (58)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (59)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (59)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (60)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (60)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (61)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (61)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	<hr/>
Tobacco plug kit number	<hr/>
Tobacco plug vial number	<hr/>
SODIM file number	<hr/>
Comment	<hr/>
Batch Number	<hr/>

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (62)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (62)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number

Tobacco plug kit number

Tobacco plug vial number

SODIM file number

Comment

Batch Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (63)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (63)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (64)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (64)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (65)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (65)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number

Tobacco plug kit number

Tobacco plug vial number

SODIM file number

Comment

Batch Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (66)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (66)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (67)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (67)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (68)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (68)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (69)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (69)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (70)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (70)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (71)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (71)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number

Tobacco plug kit number

Tobacco plug vial number

SODIM file number

Comment

Batch Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (72)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (72)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (73)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (73)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (74)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (74)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (75)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (75)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (76)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (76)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number

Tobacco plug kit number

Tobacco plug vial number

SODIM file number

Comment

Batch Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (77)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (77)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (78)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (78)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (79)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (79)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (80)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (80)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (81)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (81)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (82)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (82)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	<hr/>
Tobacco plug kit number	<hr/>
Tobacco plug vial number	<hr/>
SODIM file number	<hr/>
Comment	<hr/>
Batch Number	<hr/>

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (83)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (83)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (84)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (84)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (85)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
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Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (85)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (86)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
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Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (86)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (87)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
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Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (87)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (88)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
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Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (88)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (89)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (89)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (90)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (90)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (91)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (91)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	_____
Tobacco plug kit number	_____
Tobacco plug vial number	_____
SODIM file number	_____
Comment	_____
Batch Number	_____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (92)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (92)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (93)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (93)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (94)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (94)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	_____
Tobacco plug kit number	_____
Tobacco plug vial number	_____
SODIM file number	_____
Comment	_____
Batch Number	_____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (95)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (95)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (96)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (96)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (97)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (97)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	<hr/>
Tobacco plug kit number	<hr/>
Tobacco plug vial number	<hr/>
SODIM file number	<hr/>
Comment	<hr/>
Batch Number	<hr/>

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (98)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (98)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	<hr/>
Tobacco plug kit number	<hr/>
Tobacco plug vial number	<hr/>
SODIM file number	<hr/>
Comment	<hr/>
Batch Number	<hr/>

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (99)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (99)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	_____
Tobacco plug kit number	_____
Tobacco plug vial number	_____
SODIM file number	_____
Comment	_____
Batch Number	_____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (100)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (100)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (101)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (101)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number

Tobacco plug kit number

Tobacco plug vial number

SODIM file number

Comment

Batch Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (102)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (102)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (103)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (103)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (104)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (104)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (105)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (105)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (106)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (106)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	_____
Tobacco plug kit number	_____
Tobacco plug vial number	_____
SODIM file number	_____
Comment	_____
Batch Number	_____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (107)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (107)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (108)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (108)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	_____
Tobacco plug kit number	_____
Tobacco plug vial number	_____
SODIM file number	_____
Comment	_____
Batch Number	_____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (109)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (109)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number

Tobacco plug kit number

Tobacco plug vial number

SODIM file number

Comment

Batch Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (110)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (110)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	_____
Tobacco plug kit number	_____
Tobacco plug vial number	_____
SODIM file number	_____
Comment	_____
Batch Number	_____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (111)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (111)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (112)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (112)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (113)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (113)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (114)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (114)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Product Use

Form: Product administration-THS (115)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (115)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	_____
Tobacco plug kit number	_____
Tobacco plug vial number	_____
SODIM file number	_____
Comment	_____
Batch Number	_____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (116)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (116)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number

Tobacco plug kit number

Tobacco plug vial number

SODIM file number

Comment

Batch Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (117)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (117)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (118)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (118)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (119)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (119)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (120)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (120)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (121)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (121)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (122)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (122)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	_____
Tobacco plug kit number	_____
Tobacco plug vial number	_____
SODIM file number	_____
Comment	_____
Batch Number	_____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (123)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (123)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (124)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (124)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (125)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (125)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number

Tobacco plug kit number

Tobacco plug vial number

SODIM file number

Comment

Batch Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (126)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (126)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (127)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (127)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number

Tobacco plug kit number

Tobacco plug vial number

SODIM file number

Comment

Batch Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (128)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (128)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (129)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (129)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (130)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (130)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (131)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (131)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (132)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Date of product use
DD/MMM/YYYY

Visit

Screen Failure ☐

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Type of Product Use

Tobacco Heating System ☒

If type of Product Use different from the randomization
please explain

Time of distribution

Time of product return

SODIM device number

SODIM sample holder number

Filter kit number

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Product administration-THS (132)

Data signed: (k.jarus) 30 May 2014 12:26:31

Generated On: 15 Dec 2014 17:19:50

Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (1)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (2)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (3)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (4)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (5)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (6)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (7)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (8)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (9)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (10)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (11)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (12)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (13)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (14)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (15)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (16)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029OWN020222001
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File Status	Error 
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Rejection / Error reason	NB. PUFFS < 3
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Date of analysis DD/MMM/YYYY	16 DEC 2013
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Operator	Valerie Poux 
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (17)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029OWN020222002
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File Status	Rejected 
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Rejection / Error reason	UNEXPECTED ISSUE
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Date of analysis DD/MMM/YYYY	16 DEC 2013
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Operator	Valerie Poux 
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (18)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029OWN020222003
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	16 DEC 2013
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Operator	Valerie Poux 
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (19)

Data signed: (k.jarus) 30 May 2014 12:27:03


Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029OWN020222004
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File Status	Error 
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Rejection / Error reason	NB. PUFFS < 3
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Date of analysis DD/MMM/YYYY	16 DEC 2013
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Operator	Valerie Poux 
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (20)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029OWN020222005
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (21)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029OWN020222006
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (22)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029OWN020222007
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (23)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029OWN020222008
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (24)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029OWN020222009
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux 
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (25)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029OWN020222010
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (26)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623001
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File Status	Accepted <input type="checkbox"/>
	Rejected <input type="checkbox"/>
	Error <input type="checkbox"/>

Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
---------------------------------	-------

Operator	Valerie Poux <input type="checkbox"/>
	Thierry Bachmann <input type="checkbox"/>
	Anthony Bruchet <input type="checkbox"/>

Comment	<hr/>
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Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (27)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623002
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File Status	Accepted <input type="checkbox"/>
	Rejected <input type="checkbox"/>
	Error <input type="checkbox"/>

Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
---------------------------------	-------

Operator	Valerie Poux <input type="checkbox"/>
	Thierry Bachmann <input type="checkbox"/>
	Anthony Bruchet <input type="checkbox"/>

Comment	<hr/>
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Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (28)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623003
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File Status	Accepted <input type="checkbox"/>
	Rejected <input type="checkbox"/>
	Error <input type="checkbox"/>

Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
---------------------------------	-------

Operator	Valerie Poux <input type="checkbox"/>
	Thierry Bachmann <input type="checkbox"/>
	Anthony Bruchet <input type="checkbox"/>

Comment	<hr/>
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Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (29)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623004
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File Status	Accepted <input type="checkbox"/>
	Rejected <input type="checkbox"/>
	Error <input type="checkbox"/>

Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
---------------------------------	-------

Operator	Valerie Poux <input type="checkbox"/>
	Thierry Bachmann <input type="checkbox"/>
	Anthony Bruchet <input type="checkbox"/>

Comment	<hr/>
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Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (30)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623005
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File Status	Accepted <input type="checkbox"/>
	Rejected <input type="checkbox"/>
	Error <input type="checkbox"/>

Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	<hr/>
---------------------------------	-------

Operator	Valerie Poux <input type="checkbox"/>
	Thierry Bachmann <input type="checkbox"/>
	Anthony Bruchet <input type="checkbox"/>

Comment	<hr/>
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Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (31)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623006
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File Status	Accepted <input type="checkbox"/>
	Rejected <input type="checkbox"/>
	Error <input type="checkbox"/>

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	<hr/>
---------------------------------	-------

Operator	Valerie Poux <input type="checkbox"/>
	Thierry Bachmann <input type="checkbox"/>
	Anthony Bruchet <input type="checkbox"/>

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (32)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623007
-------------------	----------------------

File Status	Accepted <input type="checkbox"/>
	Rejected <input type="checkbox"/>
	Error <input type="checkbox"/>

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	<hr/>
---------------------------------	-------

Operator	Valerie Poux <input type="checkbox"/>
	Thierry Bachmann <input type="checkbox"/>
	Anthony Bruchet <input type="checkbox"/>

Comment	<hr/>
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Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (33)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623008
-------------------	----------------------

File Status	Accepted <input type="checkbox"/>
	Rejected <input type="checkbox"/>
	Error <input type="checkbox"/>

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	<hr/>
---------------------------------	-------

Operator	Valerie Poux <input type="checkbox"/>
	Thierry Bachmann <input type="checkbox"/>
	Anthony Bruchet <input type="checkbox"/>

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (34)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (35)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (36)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (37)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Number

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (38)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (39)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (40)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (41)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (42)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (43)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (44)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (45)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (46)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for CC (47)

Data signed: (k.jarus) 30 May 2014 12:27:03

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (1)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623001
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
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Comment	
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Modified File Name	
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (2)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623002
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
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Comment	
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Modified File Name	
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (3)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623003
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
----------	---

Comment	
---------	--

Modified File Name	
--------------------	--

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (4)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623004
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
----------	---

Comment	
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Modified File Name	
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (5)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623005
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
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Comment	
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Modified File Name	
--------------------	--

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (6)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623006
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
----------	---

Comment	
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Modified File Name	
--------------------	--

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (7)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623007
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	16 DEC 2013
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Operator	Valerie Poux 
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Comment	<hr/>
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Modified File Name	<hr/>
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (8)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number	03BO0029THS020623008
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	16 DEC 2013
---------------------------------	-------------

Operator	Valerie Poux <input checked="" type="radio"/>
----------	---

Comment	
---------	--

Modified File Name	
--------------------	--

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (9)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (10)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (11)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (12)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (13)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (14)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (15)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (16)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (17)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (18)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (19)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (20)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (21)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (22)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (23)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (24)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (25)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (26)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (27)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (28)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (29)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (30)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (31)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (32)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (33)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (34)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (35)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (36)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (37)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (38)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (39)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (40)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (41)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (42)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (43)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (44)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (45)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (46)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (47)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (48)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (49)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (50)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (51)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (52)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (53)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (54)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (55)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (56)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (57)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (58)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (59)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (60)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (61)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (62)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (63)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (64)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (65)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (66)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (67)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (68)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (69)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (70)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (71)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (72)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (73)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (74)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (75)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (76)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (77)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (78)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (79)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (80)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (81)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (82)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (83)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (84)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (85)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (86)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (87)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (88)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (89)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (90)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (91)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (92)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (93)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (94)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (95)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (96)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (97)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (98)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (99)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (100)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (101)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (102)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (103)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (104)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (105)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (106)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (107)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (108)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (109)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (110)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (111)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (112)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (113)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (114)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (115)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (116)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (117)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (118)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (119)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (120)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (121)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (122)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (123)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (124)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (125)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment

Modified File Name

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (126)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (127)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (128)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (129)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (130)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (131)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Topography files status for THS (132)

Data signed: (k.jarus) 30 May 2014 12:27:12

Generated On: 15 Dec 2014 17:19:50

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Name _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 15 Dec 2014 17:19:50

Tobacco plug kit number

Tobacco plug vial number

Level

0 ☐

1 ☐

2 ☐

NA ☐

Observation

Ashes not anymore visible
when shooting picture ☐

No tobacco in plug ☐

Not enough tobacco in the
plug to perform the
analysis ☐

Tobacco plug destroyed,
analysis impossible ☐

No tobacco plug in the vial ☐

Other error ☐

Picture File Name

Date of analysis
DD/MMM/YYYY

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Date of Discharge

Data signed: (k.jarus) 30 May 2014 12:27:32

Generated On: 15 Dec 2014 17:19:50

Date of Visit

29 JUL 2013
DD/MMM/YYYY

Discharge Time

18:00
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Vital Signs

Data signed: (k.jarus) 30 May 2014 12:27:32

Generated On: 15 Dec 2014 17:19:50

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Time of assessment

10:13
hour:min 24-hour clock

Pulse rate

79
beats per minute

Respiratory rate

12
breaths per minute

Blood Pressure (systolic)

103
mmHg

Blood Pressure (diastolic)

64
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Advice on the risk of smoking and debriefing

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Has the subject received advices on the risks of
smoking?

No ☐

Yes ☐

Has a debriefing been performed about THS 2.2?

No ☐

Yes ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (1)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

General Appearance ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (2)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome

Abnormal ☒

Abnormal, please specify

MYOPIA, LEFT TONSILL
ENLARGED=

Clinically significant

No ☒

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (3)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (4)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (5)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (6)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Lungs ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (7)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (8)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Cardiovascular System ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (9)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (10)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Skin ☒

Outcome

Abnormal ☒

Abnormal, please specify

POSTAPPENDECTOMY SCAR

Clinically significant

No ☒

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (11)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (12)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (13)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (14)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (15)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (16)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (17)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (18)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Physical Examination (19)

Data signed: (k.jarus) 30 May 2014 12:27:33

Generated On: 15 Dec 2014 17:19:50

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify _____

Clinically significant

No ☐

Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Weight

Data signed: (k.jarus) 30 May 2014 12:27:36

Generated On: 15 Dec 2014 17:19:50

Measurement(s) assessed?

No ☒

If No, please specify the reason:

PATIENT RESIGNED

Time of assessment

Weight

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: ECG (12-Lead Standard)

Data signed: (k.jarus) 30 May 2014 12:27:36

Generated On: 15 Dec 2014 17:19:50

Was the ECG performed?

No ☒

If No, please specify the reason:

PATIENT RESIGNED

Position

Sitting ☐

Standing ☐

Supine ☐

Heart Rate

QRS Interval

QT Interval

QTcB Interval

PR Interval

Interpretation

Normal ☐

Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

If Not Clinically significant or clinically Significant, Please
specify the finding(s)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Spirometry without a short-acting bronchodilator

Data signed: (k.jarus) 30 May 2014 12:27:36

Generated On: 15 Dec 2014 17:19:50

Was the spirometry performed?

No ☒

If No, please specify the reason:

PATIENT RESIGNED

Category

Without short-acting
bronchodilator ☒

Time of assessment

Predicted FVC value

Best measured FVC value

Percent of predicted FVC value

Best measured FEV1 value

Predicted FEV1 value

Percent of predicted FEV1 value

Interpretation

Normal ☐

Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Spirometry without a short-acting bronchodilator

Data signed: (k.jarus) 30 May 2014 12:27:36

Generated On: 15 Dec 2014 17:19:50

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s) _____

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Haematology

Data signed: (k.jarus) 30 May 2014 12:27:37

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

No ☒

If No, please specify the reason:

PATIENT RESIGNED

Was the subject fasting for at least 8 hours at time of
sample collection?

No ☐

Yes ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Urine analysis

Data signed: (k.jarus) 30 May 2014 12:27:37

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

No ☒

If No, please specify the reason:

PATIENT RESIGNED

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: Clinical Chemistry

Data signed: (k.jarus) 30 May 2014 12:27:37

Generated On: 15 Dec 2014 17:19:50

Were samples collected?

No ☒

If No, please specify the reason:

PATIENT RESIGNED

Was the subject fasting for at least 8 hours at time of
sample collection?

No ☐

Yes ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Discharge

Form: Urine Pregnancy Test

Data signed: (k.jarus) 30 May 2014 12:27:37

Generated On: 15 Dec 2014 17:19:50

Not Done	True
----------	------

If Not Done, specify reason	PATIENT RESIGNED
-----------------------------	------------------

Time of Test

Specify result	Negative <input type="checkbox"/>
	Positive <input type="checkbox"/>
	Unclear <input type="checkbox"/>

If unclear, please confirm with FSH test

Specify result of FSH test	< 20 IU/L <input type="checkbox"/>
	>= 20 IU/L <input type="checkbox"/>

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Discharge

Form: CO Breath Test

Data signed: (k.jarus) 30 May 2014 12:27:37

Generated On: 15 Dec 2014 17:19:50

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	PATIENT RESIGNED
---	------------------

Actual Time of Assessment	<hr/>
---------------------------	-------

Result	<hr/>
--------	-------

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (k.jarus) 30 May 2014 12:27:37

Generated On: 15 Dec 2014 17:19:50

Was there any Adverse Event for this subject?

No ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (k.jarus) 30 May 2014 12:27:37

Generated On: 15 Dec 2014 17:19:50

Has the subject taken previous or concomitant
medication?

No ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Device Events

Form: Device report - THS 2.2 Cigarette Holder

Data signed: (k.jarus) 30 May 2014 12:27:37

Generated On: 15 Dec 2014 17:19:50

Were there any events with the device?

No ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Device Events

Form: Device report - THS 2.2 Cigarette Holder (1)

Data signed: (k.jarus) 30 May 2014 12:27:37

Generated On: 15 Dec 2014 17:19:50

Were there any events with the device?

No ☒

Event Log Number

Date of Device Event
DD/MMM/YYYY

Time of
Device Event
hour:min 24-hour clock

Event Relates to Device Type:

THS 2.2 CIGARETTE HOLDER

Unique Device Identifier Serial Number

Event Description

CH stops heating before ☐
end of smoking experience

CH does not charge when ☐
inserted into the Mobil unit

CH heater broken (LED ☐
blinking red)

Smoking experience does ☐
not start when pressing the
button

Electronic malfunction ☐
during
the smoking experience

Other ☐

Other Describe

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Device Events

Form: Device report - THS 2.2 Cigarette Holder (1)

Data signed: (k.jarus) 30 May 2014 12:27:37

Generated On: 15 Dec 2014 17:19:50

Severity of Event

Minor (can be resolved easily) ☐

Major (cannot be resolved. Device needs to be exchanged) ☐

Adverse Event Relationship

Is related to AE ☐

Is not related to AE ☐

If Related to AE, AE Number

Solution Proposed:

Device Replaced ☐

Device Recharged ☐

Device Withdrawn ☐

If the device was replaced, New Device Serial Number:

Date of Device Event Closure
DD/MMM/YYYY

Time of Device Event Closure
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Device Events

Form: Device report - THS 2.2 Charging Unit

Data signed: (k.jarus) 30 May 2014 12:27:38

Generated On: 15 Dec 2014 17:19:50

Were there any events with the device?

No ☒

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Folder: Device Events

Form: Device report - THS 2.2 Charging Unit (1)

Data signed: (k.jarus) 30 May 2014 12:27:38

Generated On: 15 Dec 2014 17:19:50

Were there any events with the device?

No ☒

Event Log Number

Date of Device Event
DD/MMM/YYYY

Time of
Device Event
hour:min 24-hour clock

Event Relates to
Device Type:

THS 2.2 CHARGING UNIT

Unique Device Identifier Serial Number

Event Description

Battery Malfunction ☐

Device Discharged ☐

Other ☐

Other Describe

Severity of Event

Minor (can be resolved easily) ☐

Major (cannot be resolved. Device needs to be exchanged) ☐

Adverse Event
Relationship

Is related to AE ☐

Is not related to AE ☐

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Device Events

Form: Device report - THS 2.2 Charging Unit (1)

Data signed: (k.jarus) 30 May 2014 12:27:38

Generated On: 15 Dec 2014 17:19:50

Solution Proposed:

Device Replaced ☐

Device Recharged ☐

Device Withdrawn ☐

If the device was replaced, New Device Serial Number: _____

Date of Device Event Closure
DD/MMM/YYYY

Time of Device Event Closure
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Device Inventory

Form: Device Inventory - THS 2.2 Cigarette Holder (1)

Data signed: (k.jarus) 30 May 2014 12:27:39

Generated On: 15 Dec 2014 17:19:50

Device Inventory	1
Log Number	

Date of Device Distribution	27 JUL 2013
DD/MMM/YYYY	

Time of	06:59
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1248051
----------------------	---------

Date of Device Collection	29 JUL 2013
DD/MMM/YYYY	

Time of	16:37
Device Collection	
hour:min 24-hour clock	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Device Inventory

Form: Device Inventory - THS 2.2 Cigarette Holder (2)

Data signed: (k.jarus) 30 May 2014 12:27:39

Generated On: 15 Dec 2014 17:19:50

Device Inventory	2
Log Number	

Date of Device Distribution	27 JUL 2013
DD/MMM/YYYY	

Time of	06:59
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1248337
----------------------	---------

Date of Device Collection	29 JUL 2013
DD/MMM/YYYY	

Time of	16:37
Device Collection	
hour:min 24-hour clock	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Device Inventory

Form: Device Inventory - THS 2.2 Charging Unit (1)

Data signed: (k.jarus) 30 May 2014 12:27:39

Generated On: 15 Dec 2014 17:19:50

Device Inventory	1
Log Number	

Date of Device Distribution	27 JUL 2013
DD/MMM/YYYY	

Time of	06:59
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
-------------	-----------------------

Device Serial Number	1316194
----------------------	---------

Date of Device Collection	29 JUL 2013
DD/MMM/YYYY	

Time of	16:37
Device Collection	
hour:min 24-hour clock	

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Folder: Device Inventory

Form: Device Inventory - THS 2.2 Charging Unit (2)

Data signed: (k.jarus) 30 May 2014 12:27:39

Generated On: 15 Dec 2014 17:19:50

Device Inventory
Log Number

Date of Device Distribution
DD/MMM/YYYY

Time of
Device Distribution
hour:min 24-hour clock

Device Type

THS 2.2 CHARGING UNIT

Device Serial Number

Date of Device Collection
DD/MMM/YYYY

Time of
Device Collection
hour:min 24-hour clock

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: End of study

Data signed: (k.jarus) 30 May 2014 12:25:56

Generated On: 15 Dec 2014 17:19:50

End of study date

05 AUG 2013
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Withdrawal by Subject ☒

Details:

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (1)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0084
Vial Number	01
Day Number	01
Sample Collection Date	27 JUL 2013
Group No.	01
Run No.	02
Port No.	09
Sample ID	1302563
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	12 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (1)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	12 AUG 2013
-----------------------	-------------

Absolute UV Absorbance Mouthpiece part of the Filter	NA
--	----

Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
---	----

Absolute UV Absorbance Full Filter	0.4606
------------------------------------	--------

Normalized UV Absorbance Mouthpiece part of the Filter	NA
--	----

Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
---	----

Normalized UV Absorbance Full Filter	2.7636
--------------------------------------	--------

Date of analysis (Nicotine)	13 AUG 2013
-----------------------------	-------------

Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
---	----

Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
--	----

Nicotine Amount Full Filter (mg/ml)	0.2234
-------------------------------------	--------

Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
---	----

Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
--	----

Nicotine Amount Full Filter (mg/filter)	2.2339
---	--------

Comments	
----------	--

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (2)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0084
Vial Number	02
Day Number	01
Sample Collection Date	27 JUL 2013
Group No.	01
Run No.	02
Port No.	09
Sample ID	1302563
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	12 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (2)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	12 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4606
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.7636
Date of analysis (Nicotine)	13 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2234
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.2339
Comments	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (3)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0084
Vial Number	03
Day Number	01
Sample Collection Date	27 JUL 2013
Group No.	01
Run No.	02
Port No.	09
Sample ID	1302563
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	12 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (3)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	12 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4606
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.7636
Date of analysis (Nicotine)	13 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2234
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.2339
Comments	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (4)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0084
Vial Number	04
Day Number	01
Sample Collection Date	27 JUL 2013
Group No.	01
Run No.	02
Port No.	09
Sample ID	1302563
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	12 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (4)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	12 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4606
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.7636
Date of analysis (Nicotine)	13 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2234
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.2339
Comments	

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (5)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0084
Vial Number	05
Day Number	01
Sample Collection Date	27 JUL 2013
Group No.	02
Run No.	02
Port No.	10
Sample ID	1302563
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	12 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (5)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	12 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4979
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.9874
Date of analysis (Nicotine)	13 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2328
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.3280
Comments	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (6)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0084
Vial Number	06
Day Number	01
Sample Collection Date	27 JUL 2013
Group No.	02
Run No.	02
Port No.	10
Sample ID	1302563
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	12 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (6)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	12 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4979
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.9874
Date of analysis (Nicotine)	13 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2328
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.3280
Comments	

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (7)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0084
Vial Number	07
Day Number	01
Sample Collection Date	27 JUL 2013
Group No.	02
Run No.	02
Port No.	10
Sample ID	1302563
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	12 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (7)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	12 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4979
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.9874
Date of analysis (Nicotine)	13 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2328
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.3280
Comments	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (8)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0084
Vial Number	08
Day Number	01
Sample Collection Date	27 JUL 2013
Group No.	02
Run No.	02
Port No.	10
Sample ID	1302563
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	12 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (8)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	12 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4979
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.9874
Date of analysis (Nicotine)	13 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2328
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.3280
Comments	

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (9)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0100
Vial Number	01
Day Number	02
Sample Collection Date	28 JUL 2013
Group No.	01
Run No.	05
Port No.	17
Sample ID	1302579
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	13 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (9)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	13 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4635
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.7810
Date of analysis (Nicotine)	14 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2187
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.1874
Comments	

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (10)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0100
Vial Number	02
Day Number	02
Sample Collection Date	28 JUL 2013
Group No.	01
Run No.	05
Port No.	17
Sample ID	1302579
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	13 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (10)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	13 AUG 2013
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Absolute UV Absorbance Mouthpiece part of the Filter	NA
--	----

Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
---	----

Absolute UV Absorbance Full Filter	0.4635
------------------------------------	--------

Normalized UV Absorbance Mouthpiece part of the Filter	NA
--	----

Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
---	----

Normalized UV Absorbance Full Filter	2.7810
--------------------------------------	--------

Date of analysis (Nicotine)	14 AUG 2013
-----------------------------	-------------

Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
---	----

Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
--	----

Nicotine Amount Full Filter (mg/ml)	0.2187
-------------------------------------	--------

Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
---	----

Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
--	----

Nicotine Amount Full Filter (mg/filter)	2.1874
---	--------

Comments	
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Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (11)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0100
Vial Number	03
Day Number	02
Sample Collection Date	28 JUL 2013
Group No.	01
Run No.	05
Port No.	17
Sample ID	1302579
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	13 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (11)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	13 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4635
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.7810
Date of analysis (Nicotine)	14 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2187
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.1874
Comments	

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (12)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0100
Vial Number	04
Day Number	02
Sample Collection Date	28 JUL 2013
Group No.	01
Run No.	05
Port No.	17
Sample ID	1302579
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	13 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (12)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	13 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4635
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.7810
Date of analysis (Nicotine)	14 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2187
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.1874
Comments	

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (13)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0100
Vial Number	05
Day Number	02
Sample Collection Date	28 JUL 2013
Group No.	02
Run No.	05
Port No.	18
Sample ID	1302579
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	13 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (13)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	13 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4531
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.7186
Date of analysis (Nicotine)	14 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2276
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.2764
Comments	

Final version 7.0 (Main CRF)
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Form: LABSTAT results (14)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0100
Vial Number	06
Day Number	02
Sample Collection Date	28 JUL 2013
Group No.	02
Run No.	05
Port No.	18
Sample ID	1302579
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	13 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (14)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	13 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4531
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.7186
Date of analysis (Nicotine)	14 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2276
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.2764
Comments	

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (15)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0100
Vial Number	07
Day Number	02
Sample Collection Date	28 JUL 2013
Group No.	02
Run No.	05
Port No.	18
Sample ID	1302579
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	13 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (15)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	13 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4531
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.7186
Date of analysis (Nicotine)	14 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2276
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.2764
Comments	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (16)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0100
Vial Number	08
Day Number	02
Sample Collection Date	28 JUL 2013
Group No.	02
Run No.	05
Port No.	18
Sample ID	1302579
Number of Filters	4
Extraction Volume (ml)	40
Date of Extraction	13 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (16)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	13 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4531
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.7186
Date of analysis (Nicotine)	14 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2276
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.2764
Comments	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (17)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0116
Vial Number	01
Day Number	03
Sample Collection Date	29 JUL 2013
Group No.	01
Run No.	09
Port No.	17
Sample ID	1302595
Number of Filters	3
Extraction Volume (ml)	30
Date of Extraction	15 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (17)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	15 AUG 2013
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Absolute UV Absorbance Mouthpiece part of the Filter	NA
--	----

Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
---	----

Absolute UV Absorbance Full Filter	0.4831
------------------------------------	--------

Normalized UV Absorbance Mouthpiece part of the Filter	NA
--	----

Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
---	----

Normalized UV Absorbance Full Filter	2.8986
--------------------------------------	--------

Date of analysis (Nicotine)	15 AUG 2013
-----------------------------	-------------

Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
---	----

Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
--	----

Nicotine Amount Full Filter (mg/ml)	0.2117
-------------------------------------	--------

Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
---	----

Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
--	----

Nicotine Amount Full Filter (mg/filter)	2.1173
---	--------

Comments	
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Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (18)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0116
Vial Number	02
Day Number	03
Sample Collection Date	29 JUL 2013
Group No.	01
Run No.	09
Port No.	17
Sample ID	1302595
Number of Filters	3
Extraction Volume (ml)	30
Date of Extraction	15 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (18)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	15 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4831
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.8986
Date of analysis (Nicotine)	15 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2117
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.1173
Comments	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (19)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0116
Vial Number	03
Day Number	03
Sample Collection Date	29 JUL 2013
Group No.	01
Run No.	09
Port No.	17
Sample ID	1302595
Number of Filters	3
Extraction Volume (ml)	30
Date of Extraction	15 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. z o.o.: 0085

Form: LABSTAT results (19)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	15 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.4831
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	2.8986
Date of analysis (Nicotine)	15 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2117
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.1173
Comments	

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (20)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0116
Vial Number	04
Day Number	03
Sample Collection Date	29 JUL 2013
Group No.	02
Run No.	09
Port No.	18
Sample ID	1302595
Number of Filters	3
Extraction Volume (ml)	30
Date of Extraction	15 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (20)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	15 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.5759
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	3.4554
Date of analysis (Nicotine)	15 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2452
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.4521
Comments	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (21)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0116
Vial Number	05
Day Number	03
Sample Collection Date	29 JUL 2013
Group No.	02
Run No.	09
Port No.	18
Sample ID	1302595
Number of Filters	3
Extraction Volume (ml)	30
Date of Extraction	15 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (21)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	15 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.5759
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	3.4554
Date of analysis (Nicotine)	15 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2452
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.4521
Comments	

Final version 7.0 (Main CRF)
(577)

ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (22)

Generated On: 15 Dec 2014 17:19:50

Cohort Number	02
Kit Number	F0116
Vial Number	06
Day Number	03
Sample Collection Date	29 JUL 2013
Group No.	02
Run No.	09
Port No.	18
Sample ID	1302595
Number of Filters	3
Extraction Volume (ml)	30
Date of Extraction	15 AUG 2013
Sample Volume (ml)	02.00
Dilution Volume (ml)	10.00
Total Volume (ml)	12.00

Final version 7.0 (Main CRF)
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ZRHR-REXC-03-EU: Bio Virtus Research Site Sp. zo. o.: 0085

Form: LABSTAT results (22)

Generated On: 15 Dec 2014 17:19:50

Date of analysis (UV)	15 AUG 2013
Absolute UV Absorbance Mouthpiece part of the Filter	NA
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	0.5759
Normalized UV Absorbance Mouthpiece part of the Filter	NA
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	3.4554
Date of analysis (Nicotine)	15 AUG 2013
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	0.2452
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	NA
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	2.4521
Comments	

Final version 7.0 (Main CRF)
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