

Subject Case Report Forms

PROD 02.001 (MAIN) GMP 05AUG2014 - Case Book

Generated On: 08 Sep 2014 13:44:31

All time stamps listed in this document are displayed in GMT

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Subject (Site level)
Generated On: 08 Sep 2014 13:44:31

Subject (site level)

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Subject

Generated On: 08 Sep 2014 13:44:31

Screening number

Site number

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Deviation Form

Generated On: 08 Sep 2014 13:44:31

Cohort _____

Subject _____

Assessment _____

Visit

Screen Failure ☐

Screening ☐

Admission (Day -2) ☐

Baseline (Day -1) ☐

Baseline (Day 0) ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Discharge ☐

Day 30 ☐

Day 60 ☐

Day 90 ☐

Discharge (ambulatory) ☐

Other ☐

Other, Specify _____

Timepoint _____

Description of Deviation _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Deviation Form

Generated On: 08 Sep 2014 13:44:31

Date Deviation Occurred

DD/MMM/YYYY

Date Deviation Reported

DD/MMM/YYYY

Date Deviation Ended

DD/MMM/YYYY

Resolution of the Deviation

Source of the Deviation

CRA ☐

Site personnel ☐

Sponsor ☐

CRO ☐

Labs ☐

IXRS ☐

ePRO ☐

Deviation Category

Violation ☐

Mis-randomization ☐

Mis-use of product ☐

Concomitant medication ☐

Time deviation ☐

Time missing ☐

Assessment missing ☐

Other ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Deviation Form
Generated On: 08 Sep 2014 13:44:31

Other specify _____

Deviation Type

Major ☐

Minor ☐

If Major, Evaluation Category

Evaluable ☐

Non Evaluable ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Subject Status
Generated On: 08 Sep 2014 13:44:31

Date of 'Screen Failed' Event

Fixed Unit:
DD/MMM/YYYY

Date of 'Discontinued From
Enrollment' Event

Fixed Unit:
DD/MMM/YYYY

Randomization Date

Fixed Unit:
DD/MMM/YYYY

Randomization Time

Fixed Unit:
hour:min 24-hour clock

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Site Accountability
Generated On: 08 Sep 2014 13:44:31

Date of batch dispensed _____

Batch number _____

Category _____ Received ☐

Returned ☐

Batch Expiration Date (only for received event)
DD/MMM/YYYY _____

Number of unused packs returned _____

Number of unused sticks returned (only for returned
event) _____

Number of packs received _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Screen Failure
Generated On: 08 Sep 2014 13:44:31

Reason for Screen Failure

Entry criteria not met ☐

Withdrawal by subject ☐

Adverse Event ☐

Other ☐

If Other, Specify: _____

Is there a pregnancy event?

No ☐

Yes ☐

NA ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Date of Visit<Ambulatory/>
Generated On: 08 Sep 2014 13:44:31

Visit Not Done

If Not Done, Specify Reason

Date of Visit

Fixed Unit:
DD/MMM/YYYY

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Date of Visit
Generated On: 08 Sep 2014 13:44:31

Date of Visit

Fixed Unit:
DD/MMM/YYYY

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Date of Discharge
Generated On: 08 Sep 2014 13:44:31

Date of Visit

Fixed Unit:
DD/MMM/YYYY

Discharge Time

Fixed Unit:
hour:min 24-hour clock

Is the subject continuing in the ambulatory period?

No ☐
Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Additional Informed Consent

Generated On: 08 Sep 2014 13:44:31

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

No ☐
Yes ☐

Consent Date

Fixed Unit:
DD/MMM/YYYY

Has the subject given written informed consent for
Bio-banking for Transcriptomics (Pharmacogenomics),
Nasal Epithelial collection and Buccal Collection?

No ☐
Yes ☐

Consent Date

Fixed Unit:
DD/MMM/YYYY

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Inclusion Criteria

Generated On: 08 Sep 2014 13:44:31

Inclusion Criterion

Subject has signed the ICF ☒ and is able to understand the information provided in the Subject Information Sheet and ICF.

Subject is at a minimum 22 ☐ years of age(inclusive).

Smoking, apparently ☐ healthy subject as judged by the Investigator based on all available assessments from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination, ECG, chest X-ray, and medical history).

Subject smokes at least 10 ☐ commercially available mCCs per day (no brand restrictions), for the last 4 weeks, based on self-reporting.

Furthermore, the subject has been smoking for at least the last 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).

The subject does not plan ☐ to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire.

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Project Name: ZRHM-REXA-08-US

Form: Inclusion Criteria

Generated On: 08 Sep 2014 13:44:31

The subject is ready to ☐
comply with study protocol
(e.g readiness to accept
interruptions of smoking
for up to 91 days and to
use THS 2.2 Menthol).

Result No ☐
Yes ☐

Inclusion Criterion Number 2

Exclusion Criterion

As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason). ☒

A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated). ☐

The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject. ☐

Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) <0.7 and FEV1 <80% predicted value at postbronchodilator spirometry (GOLD, 2013). ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Exclusion Criteria

Generated On: 08 Sep 2014 13:44:31

Subject with asthma ☐
condition (FEV1/FVC <
0.75 and reversibility in
FEV1 > 12% (or > 200
mL) from pre to
post-bronchodilator
values).

Subjects with renal ☐
insufficiency as defined by
serum creatinine levels of
>1.3 mg/dL for females
and >1.5 mg/dL for males.

The subject has a body ☐
mass index (BMI) <18.5 or
≥35 kg/m².

As per Investigator ☐
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.

Any subject with an history ☐
of adverse events linked to
caffeine or caffeine
containing drugs (e.g.,
Vivarin), such as but not
limited to hypersensitivity
or allergy.

The subject has used ☐
nicotine-containing
products other than
commercially available
mCC (either tobacco-based
products or NRT), as well
as electronic cigarettes and
similar devices, within 4
weeks prior to assessment.

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

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 if these
can potentially interfere
with the study objectives
or subject's safety.

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

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Exclusion Criteria

Generated On: 08 Sep 2014 13:44:31

The subject has a positive ☐
urine drug test.

Positive serology test for ☐
human immunodeficiency
virus (HIV)1/2, hepatitis B
or hepatitis C.

Donation or receipt of ☐
whole blood or blood
products within 3 months
prior to Admission.

The subject is a current or ☐
former employee of the
tobacco industry or of their
first-degree relatives
(parent, sibling, child).

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, and child).

The subject has ☐
participated in a clinical
study within 3 months
prior to the Screening Visit.

For women only: Subject is ☐
pregnant (does not have
negative pregnancy tests
at Screening and at
Admission) or is breast
feeding.

For women only : Subject ☐
does not agree to use an
acceptable method of
effective contraception

Result	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
	NA <input type="checkbox"/>

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Randomization

Generated On: 08 Sep 2014 13:44:31

Randomization number (4 digits) _____

Allocation Arm

THS 2.2 menthol ☐

mCC ☐

SA ☐

Cigarette Consumption

10 – 19 conventional
menthol cigarettes per day ☐

Greater than 19 ☐
conventional menthol
cigarettes per day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Demographics

Generated On: 08 Sep 2014 13:44:31

Date of Birth

Fixed Unit:
DD/MMM/YYYY

Sex

Male ☐
Female ☐

Race

White ☐
Black or African American ☐
American Indian or Alaska
Native ☐
Asian ☐
Native Hawaiian or Other
Pacific Islander ☐
Other ☐

Other, specify

Ethnicity

Hispanic ☐
Not Hispanic ☐

Date the Subject signed the Informed Consent

Fixed Unit:
DD/MMM/YYYY

Time the Subject signed the Informed Consent

Fixed Unit:
hour:min 24-hour clock

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Demographics
Generated On: 08 Sep 2014 13:44:31

Age(Derived)

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Medical History/Concomitant Disease
Generated On: 08 Sep 2014 13:44:31

Date of collection

Fixed Unit:
DD/MMM/YYYY

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

No ☐
Yes ☐

Category for Medical History

Medical History

Number

Diagnosis Description

Onset Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing?

H_NOW (Derived):

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Vital Signs<Screening/<

Generated On: 08 Sep 2014 13:44:31

Were Vitals Signs assessed?

No ☐
Yes ☐

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☐
Yes ☐

Date of assessment

Fixed Unit:
DD/MMM/YYYY

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Pulse rate

Fixed Unit:
beats per minute

Respiratory rate

Fixed Unit:
breaths per minute

Blood Pressure (systolic)

Fixed Unit:
mmHg

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Vital Signs<Screening/<
Generated On: 08 Sep 2014 13:44:31

Blood Pressure (diastolic)

Fixed Unit:
mmHg

Vital Signs Position of Subject

Sitting ☐
Standing ☐
Supine ☒

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Vital Signs

Generated On: 08 Sep 2014 13:44:31

Were Vitals Signs assessed?

No ☐
Yes ☐

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☐
Yes ☐

Date of assessment

Fixed Unit:
DD/MMM/YYYY

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Pulse rate

Fixed Unit:
beats per minute

Respiratory rate

Fixed Unit:
breaths per minute

Blood Pressure (systolic)

Fixed Unit:
mmHg

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Vital Signs
Generated On: 08 Sep 2014 13:44:31

Blood Pressure (diastolic)

Fixed Unit:
mmHg

Vital Signs Position of Subject

Sitting ☐
Standing ☐
Supine ☒

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Physical Examination<Screening/>
Generated On: 08 Sep 2014 13:44:31

Was the physical examination performed?

No ☐
Yes ☐

If No, please specify the reason: _____

Date of assessment

Fixed Unit:
DD/MMM/YYYY

System

General Appearance ☒

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

Thyroid Gland ☐

Heart ☐

Chest ☐

Lungs ☐

Gastrointestinal ☐

Cardiovascular System ☐

Neurologic ☐

Skin ☐

Back ☐

Musculoskeletal ☐

Abdomen ☐

Dentition ☐

Other ☐

Other, Specify _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Physical Examination<Screening/>

Generated On: 08 Sep 2014 13:44:31

Outcome Normal ☐
Abnormal ☐

Abnormal, please specify _____

Clinically significant No ☐
Yes ☐

Not Done _____

Not Done; please specify the reason: _____

System	General Appearance <input type="checkbox"/>
	HEENT <input checked="" type="checkbox"/>
	(head, eyes, ears, nose, throat)
	Thyroid Gland <input type="checkbox"/>
	Heart <input type="checkbox"/>
	Chest <input type="checkbox"/>
	Lungs <input type="checkbox"/>
	Gastrointestinal <input type="checkbox"/>
	Cardiovascular System <input type="checkbox"/>
	Neurologic <input type="checkbox"/>
	Skin <input type="checkbox"/>
	Back <input type="checkbox"/>
	Musculoskeletal <input type="checkbox"/>
	Abdomen <input type="checkbox"/>
	Dentition <input type="checkbox"/>
	Other <input type="checkbox"/>

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Product preference
Generated On: 08 Sep 2014 13:44:31

Which Product Arm would you prefer to be randomized to:

THS 2.2 menthol ☐
mCC ☐
SA ☐
No preference ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Advice on the risk of smoking and debriefing
Generated On: 08 Sep 2014 13:44:31

Date

Fixed Unit:
DD/MMM/YYYY

Has the subject received advices on the risks of
smoking?

No ☐
Yes ☐

Has a debriefing been performed about THS 2.2?

No ☐
Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Physical Examination
Generated On: 08 Sep 2014 13:44:31

Was the physical examination performed? No ☐
Yes ☐

If No, please specify the reason: _____

Date of Assessment Fixed Unit:
DD/MMM/YYYY

System	General Appearance <input checked="" type="checkbox"/>
	HEENT <input type="checkbox"/>
	(head, eyes, ears, nose, throat)
	Thyroid Gland <input type="checkbox"/>
	Heart <input type="checkbox"/>
	Chest <input type="checkbox"/>
	Lungs <input type="checkbox"/>
	Gastrointestinal <input type="checkbox"/>
	Cardiovascular System <input type="checkbox"/>
	Neurologic <input type="checkbox"/>
	Skin <input type="checkbox"/>
	Back <input type="checkbox"/>
	Musculoskeletal <input type="checkbox"/>
	Abdomen <input type="checkbox"/>
	Dentition <input type="checkbox"/>
	Other <input type="checkbox"/>

Other, Specify _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Identification of Current Cigarette Brand
Generated On: 08 Sep 2014 13:44:31

Date

Fixed Unit:
DD/MMM/YYYY

Brand name

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: THS 2.2 menthol product test
Generated On: 08 Sep 2014 13:44:31

Was the THS 2.2 menthol product trial performed?

No ☐
Yes ☐

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

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

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

No ☐
Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: THS 2.2 menthol product demonstration
Generated On: 08 Sep 2014 13:44:31

Has the subject seen a THS 2.2 menthol product demonstration?

No ☐
Yes ☐

If the subject did not see the demonstration please explain

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product administration-mCC

Generated On: 08 Sep 2014 13:44:31

H_NOW (Derived):

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

Date of product use
DD/MMM/YYYY

Visit

Day -2 ☐
Day -1 ☐
Day 0 ☐
Day 1 ☐
Day 2 ☐
Day 3 ☐
Day 4 ☐
Day 5 ☐
Day 6 ☐
Day 30 ☐
Day 60 ☐
Day 90 ☐

Type of Product Use

mCC ☒
THS 2.2 Menthol ☐

If type of Product Use different from the randomization
please explain

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Product administration-mCC
Generated On: 08 Sep 2014 13:44:31

Time of distribution	<hr/>
<hr/>	
Time of butt return	<hr/>
<hr/>	
CC with SODIM?	<hr/>
<hr/>	
CC not compatible?	<hr/>
<hr/>	
SODIM device number	<hr/>
<hr/>	
SODIM sample holder number	<hr/>
<hr/>	
SODIM file number	<hr/>
<hr/>	
Comment	<hr/>
<hr/>	

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Product administration-THS menthol
Generated On: 08 Sep 2014 13:44:31

H_NOW (Derived): _____

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

Date of product use
DD/MMM/YYYY _____

Visit

Day -2 ☐

Day 0 ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Day 30 ☐

Day 60 ☐

Day 90 ☐

Type of Product Use

mCC ☐

THS 2.2 Menthol ☒

If type of Product Use different from the randomization
please explain _____

Time of distribution _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Product administration-THS menthol
Generated On: 08 Sep 2014 13:44:31

Time of product return	<hr/>
<hr/>	
SODIM device number	<hr/>
<hr/>	
SODIM sample holder number	<hr/>
<hr/>	
Tobacco plug kit number	<hr/>
<hr/>	
Tobacco plug vial number	<hr/>
<hr/>	
SODIM file number	<hr/>
<hr/>	
Comment	<hr/>
<hr/>	
Batch Number	<hr/>
<hr/>	

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Smoking History

Generated On: 08 Sep 2014 13:44:31

Date of Assessment

Fixed Unit:
DD/MMM/YYYY

1. Does the subject plan to quit smoking during the next 6 months?

No ☐
Yes ☐

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

No ☐
Yes ☐

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

<10 ☐
10 to 19 ☐
>19 ☐

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

No ☐
Yes ☐

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

No ☐
Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: HST 4 hours

Generated On: 08 Sep 2014 13:44:31

Now (Derived):

Visit

Day 30 ☒

Day 60 ☐

Day 90 ☐

Not Done

If Not Done, please specify

Date

DD/MMM/YYYY

SODIM device distribution time

hour:min 24-hour clock

SODIM device collection time

hour:min 24-hour clock

Visit

Day 30 ☐

Day 60 ☒

Day 90 ☐

Not Done

If Not Done, please specify

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Topography files status for mCC

Generated On: 08 Sep 2014 13:44:31

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 _____

H_NOW (Derived): _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Topography files status for THS menthol
Generated On: 08 Sep 2014 13:44:31

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 _____

H_NOW (Derived): _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Visual Inspection of the Tobacco Plugs Results for THS

Generated On: 08 Sep 2014 13:44:31

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 _____

H_NOW (Derived): _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Weight and Height

Generated On: 08 Sep 2014 13:44:31

Measurement(s) assessed?

No ☐

Yes ☐

If No, please specify the reason: _____

Date of assessment

Fixed Unit:
DD/MMM/YYYY

Weight

Fixed Unit:
kg

Height

Fixed Unit:
cm

BMI (Derived)

Fixed Unit:
kg/m2

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Weight

Generated On: 08 Sep 2014 13:44:31

Measurement(s) assessed?

No ☐
Yes ☐

If No, please specify the reason: _____

Date of Assessment

Fixed Unit:
DD/MMM/YYYY

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Weight

Fixed Unit:
kg

Waist circumference

Fixed Unit:
cm

BMI

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: ECG (12-Lead Standard) <Screening/>
Generated On: 08 Sep 2014 13:44:31

Method of ECG Test 12 Lead Placement Cabrera ☐

Was the ECG performed? No ☐
Yes ☐

If No, please specify the reason: _____

Date of assessment: Fixed Unit:
DD/MMM/YYYY

Position Sitting ☐
Standing ☐
Supine ☒

Heart Rate Fixed Unit:
beats per minute

Heart Rate unit beats per minute

QRS Interval Fixed Unit:
msec

QRS Interval unit msec

QT Interval Fixed Unit:
msec

PROD 02.001 (MAIN) GMP 05AUG2014 (649) 400 of 768

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: ECG (12-Lead Standard) <Screening/>
Generated On: 08 Sep 2014 13:44:31

QT Interval unit msec

QTcB Interval Fixed Unit:
msec

QTcB Interval unit msec

QTcF Interval Fixed Unit:
msec

QTcF Interval unit msec

PR Interval Fixed Unit:
msec

PR Interval unit msec

Interpretation Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance Not clinically significant ☐
Clinically significant ☐

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: ECG (12-Lead Standard)
Generated On: 08 Sep 2014 13:44:31

Method of ECG Test 12 Lead Placement Cabrera ☐

Was the ECG performed? No ☐
Yes ☐

If No, please specify the reason: _____

Date of Assessment Fixed Unit:
DD/MMM/YYYY

Position Sitting ☐
Standing ☐
Supine ☒

Heart Rate Fixed Unit:
beats per minute

Heart Rate unit beats per minute

QRS Interval Fixed Unit:
msec

QRS Interval unit msec

QT Interval Fixed Unit:
msec

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PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: ECG (12-Lead Standard)

Generated On: 08 Sep 2014 13:44:31

QT Interval unit msec

QTcB Interval Fixed Unit:
msec

QTcB Interval unit msec

PR Interval Fixed Unit:
msec

PR Interval unit msec

QTcF Interval Fixed Unit:
msec

QTcF Interval unit msec

Interpretation Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance Not clinically significant ☐
Clinically significant ☐

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Spirometry

Generated On: 08 Sep 2014 13:44:31

Was the spirometry performed?

No ☐

Yes ☐

If No, please specify the reason: _____

Category

With short-acting
bronchodilator ☐

Without short-acting
bronchodilator ☒

Position

SITTING

Has the subject smoked within 1 hour prior to
assessment?

No ☐

Yes ☐

Date of assessment
DD/MMM/YYYY

Time of assessment

Name of bronchodilator

Dose

Predicted FVC value

Fixed Unit:
L

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Spirometry
Generated On: 08 Sep 2014 13:44:31

Best measured FVC value	Fixed Unit: L
-------------------------	------------------

Percent of predicted FVC value	Fixed Unit: %
--------------------------------	------------------

Best measured FEV1 value	Fixed Unit: L
--------------------------	------------------

Predicted FEV1 value	Fixed Unit: L
----------------------	------------------

Percent of predicted FEV1 value	Fixed Unit: %
---------------------------------	------------------

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

MEF 25/75 value	Fixed Unit: L/s
-----------------	--------------------

Interpretation	Normal <input type="radio"/>
	Abnormal <input type="radio"/>

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Spirometry

Generated On: 08 Sep 2014 13:44:31

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

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

Was the spirometry performed?

No ☐

Yes ☐

If No, please specify the reason: _____

Category

With short-acting
bronchodilator ☒
Without short-acting
bronchodilator ☐

Position

SITTING

Has the subject smoked within 1 hour prior to
assessment?

No ☐

Yes ☐

Date of assessment
DD/MMM/YYYY _____

Time of assessment _____

Name of bronchodilator _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Gas Transfer

Generated On: 08 Sep 2014 13:44:31

Was the Gas Transfer performed?

No ☐

Yes ☐

If No, please specify the reason: _____

Category

With short-acting
bronchodilator ☐

Without short-acting
bronchodilator ☐

Position

SITTING

Date of assessment
DD/MMM/YYYY

Time of assessment

DLCO value

Fixed Unit:
ml/min/mmHg

KCO value

Fixed Unit:
mmol/min/kPa/L

DLCO/VA value

Fixed Unit:
mmol/min/kPa/L

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Gas Transfer

Generated On: 08 Sep 2014 13:44:31

Interpretation

Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐
Clinically significant ☐

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Lung Volume Measurements
Generated On: 08 Sep 2014 13:44:31

Were the Lung Volume Measurements performed?

No ☐
Yes ☐

If No, please specify the reason: _____

Category

With short-acting ☐
bronchodilator
Without short-acting ☐
bronchodilator

Position

SITTING

Date of assessment
DD/MMM/YYYY

Time of assessment

VC value

Fixed Unit:
L

TLC value

Fixed Unit:
L

IC value

Fixed Unit:
L

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Lung Volume Measurements
Generated On: 08 Sep 2014 13:44:31

FRC value

Fixed Unit:
L

Interpretation

Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐
Clinically significant ☐

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Spirometry with a short-acting bronchodilator
Generated On: 08 Sep 2014 13:44:31

Was the Spirometry with a short-acting bronchodilator performed?

No ☐
Yes ☐

If No, please specify the reason: _____

Category

With short-acting
bronchodilator ☒
Without short-acting
bronchodilator ☐

Position

SITTING

Date of assessment
DD/MMM/YYYY

Time of assessment

Name of bronchodilator

Dose

Predicted FVC value

Fixed Unit:
L

Best measured FVC value

Fixed Unit:
L

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Spirometry with a short-acting bronchodilator
Generated On: 08 Sep 2014 13:44:31

Percent of predicted FVC value	Fixed Unit: %
--------------------------------	------------------

Best measured FEV1 value	Fixed Unit: L
--------------------------	------------------

Predicted FEV1 value	Fixed Unit: L
----------------------	------------------

Percent of predicted FEV1 value	Fixed Unit: %
---------------------------------	------------------

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

MEF 25/75 value	Fixed Unit: L/s
-----------------	--------------------

Interpretation	Normal <input type="radio"/>
	Abnormal <input type="radio"/>

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Spirometry with a short-acting bronchodilator
Generated On: 08 Sep 2014 13:44:31

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Chest X-Ray

Generated On: 08 Sep 2014 13:44:31

Category for Examination

Chest X-Ray ☐

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

No ☐

Yes ☐

If No, please specify the reason: _____

Date of assessment

Fixed Unit:
DD/MMM/YYYY

System

General Appearance ☐

HEENT ☐

(head, eyes, ears, nose,
throat)

Thyroid Gland ☐

Heart ☐

Chest ☒

Lungs ☐

Gastrointestinal ☐

Cardiovascular System ☐

Neurologic ☐

Skin ☐

Back ☐

Musculoskeletal ☐

Abdomen ☐

Dentition ☐

Other ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Chest X-Ray

Generated On: 08 Sep 2014 13:44:31

Interpretation

Normal ☐
Abnormal ☐

Clinically significant

No ☐
Yes ☐

Abnormal, please specify: _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Socio-Economic Status

Generated On: 08 Sep 2014 13:44:31

Was paper questionnaire used? No ☐
Yes ☐

Reason not done _____

Date _____ Fixed Unit:
DD/MMM/YYYY

Time _____ Fixed Unit:
hour:min 24-hour clock

Q1. What is the highest level of education you have completed? Less than High School ☐
High School Graduate ☐
Some College ☐
College Graduate ☐
Advanced Degree ☐

Q2. What is your current occupational status? Working now ☐
Only temporarily laid off, ☐
sick leave or maternity
leave
Looking for work, ☐
unemployed
Retired ☐
Disabled, permanently or ☐
temporarily
Keeping house ☐
Student ☐
Other ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Socio-Economic Status
Generated On: 08 Sep 2014 13:44:31

SPECIFY _____

Q3. How many people are currently living in your household, including yourself? _____

Q4. Of these people, how many are children? _____

Q5. Of these people, how many are adults? _____

Q6. Of the adults, how many bring income into the household? _____

Q7. Which of these categories best describes your total combined family income for the past 12 months? This should include income (before taxes) from all sources, wages, rent from properties, social security, disability and/or veteran's benefits, unemployment benefits, workman's compensation, help from relatives (including child payments and alimony), and so on.

- Less than \$10,000 ☐
\$10,000 to \$29,999 ☐
\$30,000 through \$44,999 ☐
\$45,000 through \$59,999 ☐
\$60,000 through \$74,999 ☐
\$75,000 through \$99,999 ☐
\$100,000 through \$149,999 ☐
\$150,000 and over ☐
I do not know ☐
No response ☐
-

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Haematology

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☒

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Were samples collected?

No ☐

Yes ☐

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

No ☐

Yes ☐

Please document clinically relevant abnormalities in the AE form

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Clinical Chemistry

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☒

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Were samples collected?

No ☐

Yes ☐

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?

No ☐

Yes ☐

Please document clinically relevant abnormalities in the AE form

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Urine analysis

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☒

Cotinine Screening ☐

Alcohol Test ☐

Were samples collected?

No ☐

Yes ☐

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Serology for HIV and Hepatitis B and C
Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☐
Serology ☒
Pregnancy Testing ☐
Urinalysis ☐
Cotinine Screening ☐
Alcohol Test ☐

Not Done

If Not Done, please specify the reason:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Urine Drug Screen<Screening/>

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☒

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Not Done?

If Not Done, please specify the reason:

Date of sample collection

Fixed Unit:
DD/MMM/YYYY

Time of sample collection

Fixed Unit:
hour:min 24-hour clock

Drug type

Amphetamines ☒

Barbiturates ☐

Benzodiazepines ☐

Cannabinoids ☐

Cocaine ☐

Opiates ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Urine Drug Screen<Screening/>

Generated On: 08 Sep 2014 13:44:31

Result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>

Drug type	Amphetamines	<input type="checkbox"/>
	Barbiturates	<input checked="" type="checkbox"/>
	Benzodiazepines	<input type="checkbox"/>
	Cannabinoids	<input type="checkbox"/>
	Cocaine	<input type="checkbox"/>
	Opiates	<input type="checkbox"/>

Result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>

Drug type	Amphetamines	<input type="checkbox"/>
	Barbiturates	<input type="checkbox"/>
	Benzodiazepines	<input checked="" type="checkbox"/>
	Cannabinoids	<input type="checkbox"/>
	Cocaine	<input type="checkbox"/>
	Opiates	<input type="checkbox"/>

Result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Urine Drug Screen

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☒

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Not Done? _____

If Not Done, please specify the reason: _____

Time of sample collection

Fixed Unit:
hour:min 24-hour clock

Drug type

Amphetamines ☒

Barbiturates ☐

Benzodiazepines ☐

Cannabinoids ☐

Cocaine ☐

Opiates ☐

Result

Negative ☐

Positive ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Alcohol Test<Screening/>

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☒

Was the alcohol test performed?

No ☐

Yes ☐

If No, please specify the reason:

Method used

Urine sample ☐

Breath test ☐

Date of assessment

Fixed Unit:
DD/MMM/YYYY

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Result

Negative ☐

Positive ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Alcohol Test

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☒

Was the alcohol test performed?

No ☐

Yes ☐

If No, please specify the reason: _____

Method used

Urine sample ☐

Breath test ☐

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Result

Negative ☐

Positive ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Urine Pregnancy Test<Screening/>

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☒

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Not Done

If Not Done, specify reason

Date of Test

Fixed Unit:
DD/MMM/YYYY

Time of Test

Fixed Unit:
hour:min 24-hour clock

Specify result

Negative ☐

Positive ☐

Unclear ☐

If unclear, please confirm with FSH test

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Urine Pregnancy Test<Screening/>
Generated On: 08 Sep 2014 13:44:31

Specify result of FSH test

< 20 IU/L ☐

>= 20 IU/L ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Urine Pregnancy Test

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☒

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Not Done

If Not Done, specify reason

Date of Test

Fixed Unit:
DD/MMM/YYYY

Time of Test

Fixed Unit:
hour:min 24-hour clock

Specify result

Negative ☐

Positive ☐

Unclear ☐

If unclear, please confirm with FSH test

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Urine Pregnancy Test
Generated On: 08 Sep 2014 13:44:31

Specify result of FSH test

< 20 IU/L ☐

>= 20 IU/L ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Urine Cotinine Test<Screening/>

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☒

Alcohol Test ☐

Not Done

If Not Done, please specify the reason:

Date of Sample Collection

Fixed Unit:
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit:
hour:min 24-hour clock

Result

Negative <200 ng/ml ☐

Positive >=200 ng/ml ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Plasma Nicotine Sample
Generated On: 08 Sep 2014 13:44:31

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Time
hour:min 24-hour clock _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Plasma Nicotine Samples <Day 5>

Generated On: 08 Sep 2014 13:44:31

Now (Derived):

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T0 -15 min ☒

T1 ☐

T2 ☐

T3 ☐

T4 ☐

T5 ☐

T6 ☐

T7 ☐

T8 ☐

T0 + 20H ☐

T0 + 24H ☐

Time
hour:min 24-hour clock

Not Done

If Not Done, please specify the reason:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Plasma Nicotine Samples <Day 6>

Generated On: 30 Sep 2014 09:41:16

Not Done

If Not Done, please specify the reason:

Date

DD/MMM/YYYY

Scheduled Time

T0 -15 min ☐

T1 ☐

T2 ☐

T3 ☐

T4 ☐

T5 ☐

T6 ☐

T7 ☐

T8 ☐

T0 + 20H ☒

T0 + 24H ☐

Time

hour:min 24-hour clock

Not Done

If Not Done, please specify the reason:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Plasma Cotinine Sample
Generated On: 08 Sep 2014 13:44:31

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Time
hour:min 24-hour clock _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Plasma Cotinine Samples <Day 5>

Generated On: 08 Sep 2014 13:44:31

Now (Derived):

Not Done

If Not Done, please specify the reason:

Date

DD/MMM/YYYY

Scheduled Time

T0 -15 min ☒

T1 ☐

T2 ☐

T3 ☐

T4 ☐

T5 ☐

T6 ☐

T7 ☐

T8 ☐

T0 + 20H ☐

T0 + 24H ☐

Time

hour:min 24-hour clock

Not Done

If Not Done, please specify the reason:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Plasma Cotinine Samples <Day 6>

Generated On: 08 Sep 2014 13:44:31

Not Done

If Not Done, please specify the reason:

Date

DD/MMM/YYYY

Scheduled Time

T0 -15 min ☐

T1 ☐

T2 ☐

T3 ☐

T4 ☐

T5 ☐

T6 ☐

T7 ☐

T8 ☐

T0 + 20H ☒

T0 + 24H ☐

Time

hour:min 24-hour clock

Not Done

If Not Done, please specify the reason:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Plasma Cotinine Samples <Day 6>
Generated On: 08 Sep 2014 13:44:31

Date
DD/MMM/YYYY

Scheduled Time

T0 -15 min ☐
T1 ☐
T2 ☐
T3 ☐
T4 ☐
T5 ☐
T6 ☐
T7 ☐
T8 ☐
T0 + 20H ☐
T0 + 24H ☒

Time
hour:min 24-hour clock

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: CoHb Blood Sample(SA)

Generated On: 08 Sep 2014 13:44:31

Not Done

If Not Done, please specify the reason:

Date

DD/MMM/YYYY

Scheduled Time

Within 15 min prior to smoking ☐

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☒

Prior to gas transfer assessment ☐

Prior to gas transfer assessment and prior to product use ☐

10:00 - 11:30 ☐

10:00 - 12:30 ☐

Time

hour:min 24-hour clock

Not Done

If Not Done, please specify the reason:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: CoHb Blood Sample(CC/THS)

Generated On: 08 Sep 2014 13:44:31

Not Done

If Not Done, please specify the reason:

Date

DD/MMM/YYYY

Scheduled Time

Within 15 min prior to smoking ☒

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

Prior to gas transfer assessment ☐

Prior to gas transfer assessment and prior to product use ☐

10:00 - 11:30 ☐

10:00 - 12:30 ☐

Time

hour:min 24-hour clock

Not Done

If Not Done, please specify the reason:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: CoHb Blood Sample

Generated On: 08 Sep 2014 13:44:31

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Timepoint	Within 15 min prior to smoking <input type="checkbox"/>
	12:00 - 13:30 <input type="checkbox"/>
	16:00 - 17:30 <input type="checkbox"/>
	20:00 - 21:30 <input checked="" type="checkbox"/>
	08:00 - 09:30 <input type="checkbox"/>
	Prior to gas transfer assessment <input type="checkbox"/>
	Prior to gas transfer assessment and prior to product use <input type="checkbox"/>
	10:00 - 11:30 <input type="checkbox"/>
	10:00 - 12:30 <input type="checkbox"/>

Time
hour:min 24-hour clock _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: CoHb Blood Sample <prior to gas transfer>
Generated On: 08 Sep 2014 13:44:31

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Timepoint	Within 15 min prior to smoking <input type="checkbox"/>
	12:00 - 13:30 <input type="checkbox"/>
	16:00 - 17:30 <input type="checkbox"/>
	20:00 - 21:30 <input type="checkbox"/>
	08:00 - 09:30 <input type="checkbox"/>
	Prior to gas transfer assessment <input checked="" type="checkbox"/>
	Prior to gas transfer assessment and prior to product use <input type="checkbox"/>
	10:00 - 11:30 <input type="checkbox"/>
	10:00 - 12:30 <input type="checkbox"/>

Time
hour:min 24-hour clock _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: CoHb Blood Sample <prior to gas transfer and product>

Generated On: 08 Sep 2014 13:44:31

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Timepoint

Within 15 min prior to smoking	<input type="checkbox"/>
12:00 - 13:30	<input type="checkbox"/>
16:00 - 17:30	<input type="checkbox"/>
20:00 - 21:30	<input type="checkbox"/>
08:00 - 09:30	<input type="checkbox"/>
Prior to gas transfer assessment	<input type="checkbox"/>
Prior to gas transfer assessment and prior to product use	<input checked="" type="checkbox"/>
10:00 - 11:30	<input type="checkbox"/>
10:00 - 12:30	<input type="checkbox"/>

Time
hour:min 24-hour clock _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: CoHb Blood Sample <D30_D60>

Generated On: 08 Sep 2014 13:44:31

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Timepoint

Within 15 min prior to smoking	<input type="checkbox"/>
12:00 - 13:30	<input type="checkbox"/>
16:00 - 17:30	<input type="checkbox"/>
20:00 - 21:30	<input type="checkbox"/>
08:00 - 09:30	<input type="checkbox"/>
Prior to gas transfer assessment	<input type="checkbox"/>
Prior to gas transfer assessment and prior to product use	<input type="checkbox"/>
10:00 - 11:30	<input checked="" type="checkbox"/>
10:00 - 12:30	<input type="checkbox"/>

Time
hour:min 24-hour clock _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: CoHb Blood Sample <D0>

Generated On: 08 Sep 2014 13:44:31

Not Done

If Not Done, please specify the reason:

Date

DD/MMM/YYYY

Timepoint

Within 15 min prior to smoking ☐

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

Prior to gas transfer ☐

assessment ☐

Prior to gas transfer assessment and prior to product use ☒

10:00 - 11:30 ☐

10:00 - 12:30 ☐

Time

hour:min 24-hour clock

Not Done

If Not Done, please specify the reason:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: CoHb Blood Sample <D0>
Generated On: 08 Sep 2014 13:44:31

Date
DD/MMM/YYYY

Timepoint	Within 15 min prior to smoking	<input type="checkbox"/>
	12:00 - 13:30	<input type="checkbox"/>
	16:00 - 17:30	<input type="checkbox"/>
	20:00 - 21:30	<input checked="" type="checkbox"/>
	08:00 - 09:30	<input type="checkbox"/>
	Prior to gas transfer assessment	<input type="checkbox"/>
	Prior to gas transfer assessment and prior to product use	<input type="checkbox"/>
	10:00 - 11:30	<input type="checkbox"/>
	10:00 - 12:30	<input type="checkbox"/>

Time
hour:min 24-hour clock

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: CoHb Blood Sample <D90>
Generated On: 08 Sep 2014 13:44:31

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Timepoint

Within 15 min prior to smoking	<input type="checkbox"/>
12:00 - 13:30	<input type="checkbox"/>
16:00 - 17:30	<input type="checkbox"/>
20:00 - 21:30	<input type="checkbox"/>
08:00 - 09:30	<input type="checkbox"/>
Prior to gas transfer assessment	<input type="checkbox"/>
Prior to gas transfer assessment and prior to product use	<input type="checkbox"/>
10:00 - 11:30	<input type="checkbox"/>
10:00 - 12:30	<input checked="" type="checkbox"/>

Time
hour:min 24-hour clock _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Oxysterols
Generated On: 08 Sep 2014 13:44:31

Not Done _____

If Not Done, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

No ☐

Yes ☐

Date
DD/MMM/YYYY _____

Time
hour:min 24-hour clock _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: CO Breath Test
Generated On: 08 Sep 2014 13:44:31

Assessment not done

If Not Done, please specify the reason:

Actual Date of Assessment

Fixed Unit:
DD/MMM/YYYY

Actual Time of Assessment

Fixed Unit:
hour:min 24-hour clock

Result

Fixed Unit:
ppm

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: CO Breath Test <Repeat/>

Generated On: 08 Sep 2014 13:44:31

Assessment not done

If Not Done, please specify the reason:

Scheduled Time

Within 15 min prior to smoking ☒

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

Prior to gas transfer assessment ☐

Prior to gas transfer assessment and prior to product use ☐

10:00 - 11:30 ☐

10:00 - 12:30 ☐

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

Assessment not done

If Not Done, please specify the reason:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: CO Breath Test <SA arm/>

Generated On: 08 Sep 2014 13:44:31

Assessment not done

If Not Done, please specify the reason:

Scheduled Time

Within 15 min prior to smoking ☐

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☒

Prior to gas transfer assessment ☐

Prior to gas transfer assessment and prior to product use ☐

10:00 - 11:30 ☐

10:00 - 12:30 ☐

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

Assessment not done

If Not Done, please specify the reason:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: CYP2A6 activity Sample

Generated On: 08 Sep 2014 13:44:31

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 ☐

Date of sample collection
DD/MMM/YYYY _____

Time of sample collection
hour:min 24-hour clock _____

Parameter

trans-3'-hydroxycotinine ☐
cotinine ☒

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: CYP1A2 activity Sample

Generated On: 08 Sep 2014 13:44:31

Time of caffeine tablet intake

Fixed Unit:
hour:min 24-hour clock

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 ☐

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

Caffeine ☐
Paraxanthine ☒

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1

Generated On: 08 Sep 2014 13:44:31

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Risk Marker

hs-CRP, fibrinogen, ☒
homocysteine, LDL, HDL
sICAM-1 ☐
HbA1c, Apo A1, and Apo B ☐

Time
hour:min 24-hour clock _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Risk Marker: sICAM-1
Generated On: 08 Sep 2014 13:44:31

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Risk Marker

hs-CRP, fibrinogen, ☐
homocysteine, LDL, HDL
sICAM-1 ☒
HbA1c, Apo A1, and Apo B ☐

Time
hour:min 24-hour clock _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1,
HbA1c, Apo A1, Apo B**

Generated On: 08 Sep 2014 13:44:31

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Risk Marker

hs-CRP, fibrinogen, ☐
homocysteine, LDL, HDL
sICAM-1 ☐
HbA1c, Apo A1, and Apo B ☐

Time
hour:min 24-hour clock

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Product use diary
Generated On: 08 Sep 2014 13:44:31

Type	Product Use
Date of Birth	<hr/>
Date of completion DD/MMM/YYYY	<hr/>
Time of completion hh:mm	<hr/>
Date the questionnaire was completed for DD/MMM/YYYY	<hr/>
Assessment Status	Completed <input type="checkbox"/> Abandoned <input type="checkbox"/>

What tobacco/nicotine product did you use today?

- Abandoned ☐
- THS 2.2 ☐
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary

Generated On: 08 Sep 2014 13:44:31

THS 2.2, Other tobacco product and Electronic cigarette ☐

CC, Other tobacco product and Electronic cigarette ☐

THS 2.2, CC, Other tobacco product and Electronic cigarette ☐

NRT, Other tobacco product and Electronic cigarette ☐

THS 2.2, NRT, Other tobacco product and Electronic cigarette ☐

CC, NRT, Other tobacco product and Electronic cigarette ☐

THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐

How many THS 2.2 tobacco sticks did you use today?

How many CC/ roll-your-own did you smoke today?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary

Generated On: 08 Sep 2014 13:44:31

What NRT product did you used today?

- Nicotine Inhaler ☐
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary

Generated On: 08 Sep 2014 13:44:31

- Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch ☐
- Nicotine Gum and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Gum and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐
- Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler and Other NRT Product ☐
- Nicotine Nasal Spray and Other NRT Product ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary

Generated On: 08 Sep 2014 13:44:31

Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product ☐

Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary

Generated On: 08 Sep 2014 13:44:31

Nicotine Patch and Other ☐
NRT Product

Nicotine Inhaler, Nicotine ☐
Patch and Other NRT
Product

Nicotine Nasal Spray, ☐
Nicotine Patch and Other
NRT Product

Nicotine Inhaler, Nicotine ☐
Nasal Spray, Nicotine Patch
and Other NRT Product

Nicotine Gum, Nicotine ☐
Patch and Other NRT
Product

Nicotine Inhaler, Nicotine ☐
Gum, Nicotine Patch and
Other NRT Product

How many times did you use an inhaler today? _____

How many times did you use a nasal spray today? _____

How many gums did you use today? _____

How many lozenges did you use today? _____

How many patches did you use today? _____

How many times did you use other NRT products today
not listed previously? _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary

Generated On: 08 Sep 2014 13:44:31

What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☐
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Product use diary
Generated On: 08 Sep 2014 13:44:31

How many times did you use chewable/smokeless tobacco today? _____

How many cigars/cigarillos did you smoke today? _____

How many times did you smoke a pipe today? _____

How many times did you use a tobacco product today not listed previously? _____

How many times did you use an electronic cigarette today? _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Adverse Events Y/N
Generated On: 08 Sep 2014 13:44:31

Was there any Adverse Event for this subject?

No ☐
Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Adverse Events
Generated On: 08 Sep 2014 13:44:31

AE Identifier _____

Adverse Event _____

Start Date _____

DD/MMM/YYYY _____

End Date _____

DD/MMM/YYYY _____

Ongoing at final contact No ☐

Yes ☐

Severity Mild Adverse Event ☐

Moderate Adverse Event ☐

Severe Adverse Event ☐

Serious AE No ☐

Yes ☐

Seriousness Criteria Fatal ☐

Is life-threatening ☐

Requires hospitalization ☐

Results in ☐

disability/incapacity

Congenital anomaly/birth defect ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Adverse Events

Generated On: 08 Sep 2014 13:44:31

Treatment given No ☐
Yes ☐

AE related to Study Procedure Related ☐
Not Related ☐

Relationship to mCC/THS Related ☐
Not Related ☐

AE expectedness No ☐
Yes ☐

Action taken with study product Product use Interrupted ☐
Product use Stopped ☐
Product use Reduced ☐
Not Applicable ☐
None ☐

Other action taken _____

Outcome Death Related to Adverse ☐
Event ☐
Not Recovered or Not ☐
Resolved ☐
Recovered or Resolved ☐
Recovered or Resolved ☐
with Sequelae ☐
Recovering or Resolving ☐
Unknown ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Previous and Concomitant Medication Y/N
Generated On: 08 Sep 2014 13:44:31

Has the subject taken previous or concomitant
medication?

No ☐
Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Previous and Concomitant Medication
Generated On: 08 Sep 2014 13:44:31

Brand Name _____

Start Date
DD/MMM/YYYY _____

Stop Date
DD/MMM/YYYY _____

Ongoing at final contact _____

Total Daily dose - Dose _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Previous and Concomitant Medication
Generated On: 08 Sep 2014 13:44:31

Total Daily dose - Unit

- Ampule Dosing Unit ☐
 - Bolus Dosing Unit ☐
 - Capsule Dosing Unit ☐
 - Gram ☐
 - Inhalation Dosing Unit ☐
 - International Unit ☐
 - Milligram ☐
 - Milliliter ☐
 - Nebule Dosing Unit ☐
 - Patch Dosing Unit ☐
 - Puff Dosing Unit ☐
 - Suppository Dosing Unit ☐
 - Tablet Dosing Unit ☐
 - Tablespoon Dosing Unit ☐
 - Teaspoon Dosing Unit ☐
 - Microgram per Day ☐
 - Not Applicable ☐
 - Other Dosing Unit ☐
 - Application ☐
-

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Previous and Concomitant Medication

Generated On: 08 Sep 2014 13:44:31

Route

- Auricular Route of Administration ☐
- Buccal Route of Administration ☐
- Conjunctival Route of Administration ☐
- Cutaneous Route of Administration ☐
- Dental Route of Administration ☐
- Electro-osmosis Route of Administration ☐
- Endocervical Route of Administration ☐
- Endosinusial Route of Administration ☐
- Endotracheal Route of Administration ☐
- Enteral Route of Administration ☐
- Epidural Route of Administration ☐
- Extraamniotic Route of Administration ☐
- Extracorporeal Circulation Route of Administration ☐
- Administration Via Hemodialysis ☐
- Infiltration Route of Administration ☐
- Interstitial Route of Administration ☐
- Intraabdominal Route of Administration ☐
- Intraamniotic Route of Administration ☐
- Intraarterial Route of Administration ☐
- Intraarticular Route of Administration ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Previous and Concomitant Medication

Generated On: 08 Sep 2014 13:44:31

- Intrabiliary Route of Administration ☐
- Intrabronchial Route of Administration ☐
- Intrabursal Route of Administration ☐
- Intracardiac Route of Administration ☐
- Intracartilaginous Route of Administration ☐
- Intracaudal Route of Administration ☐
- Intracavernous Route of Administration ☐
- Intracavitary Route of Administration ☐
- Intracerebral Route of Administration ☐
- Intracisternal Route of Administration ☐
- Intracorneal Route of Administration ☐
- Intracoronar Dental Route of Administration ☐
- Intracoronary Route of Administration ☐
- Intracorporus Cavernosum Route of Administration ☐
- Intradermal Route of Administration ☐
- Intradiscal Route of Administration ☐
- Intraductal Route of Administration ☐
- Intraduodenal Route of Administration ☐
- Intradural Route of Administration ☐
- Intraepidermal Route of Administration ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Previous and Concomitant Medication

Generated On: 08 Sep 2014 13:44:31

- Intraesophageal Route of Administration ☐
- Intragastric Route of Administration ☐
- Intragingival Route of Administration ☐
- Intraileal Route of Administration ☐
- Intralesional Route of Administration ☐
- Intraluminal Route of Administration ☐
- Intralymphatic Route of Administration ☐
- Intramedullary Route of Administration ☐
- Intrameningeal Route of Administration ☐
- Intramuscular Route of Administration ☐
- Intraocular Route of Administration ☐
- Intraovarian Route of Administration ☐
- Intrapericardial Route of Administration ☐
- Intraperitoneal Route of Administration ☐
- Intrapleural Route of Administration ☐
- Intraprostatic Route of Administration ☐
- Intrapulmonary Route of Administration ☐
- Intrasinal Route of Administration ☐
- Intraspinal Route of Administration ☐
- Intrasynovial Route of Administration ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Previous and Concomitant Medication

Generated On: 08 Sep 2014 13:44:31

Intratendinous Route of Administration ☐

Intratesticular Route of Administration ☐

Intrathecal Route of Administration ☐

Endothoracic Route of Administration ☐

Intratubular Route of Administration ☐

Intratumoral Route of Administration ☐

Intratympanic Route of Administration ☐

Intrauterine Route of Administration ☐

Intravascular Route of Administration ☐

Intravenous Route of Administration ☐

Intravenous Bolus ☐

Intravenous Drip ☐

Intraventricular Route of Administration ☐

Intravesical Route of Administration ☐

Intravitreal Route of Administration ☐

Iontophoresis Route of Administration ☐

Irrigation-Route of Administration ☐

Laryngeal Route of Administration ☐

Nasal Route of Administration ☐

Nasogastric Route of Administration ☐

Route of Administration Not Applicable ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Previous and Concomitant Medication

Generated On: 08 Sep 2014 13:44:31

- Occlusive Dressing ☐
- Technique ☐
- Ophthalmic Route of ☐
- Administration ☐
- Oral Route of ☐
- Administration ☐
- Oropharyngeal Route of ☐
- Administration ☐
- Other Route of ☐
- Administration ☐
- Parenteral Route of ☐
- Administration ☐
- Percutaneous Route of ☐
- Administration ☐
- Periarticular Route of ☐
- Administration ☐
- Peridural Route of ☐
- Administration ☐
- Perineural Route of ☐
- Administration ☐
- Periodontal Route of ☐
- Administration ☐
- Rectal Route of ☐
- Administration ☐
- Inhalation Route of ☐
- Administration ☐
- Retrobulbar Route of ☐
- Administration ☐
- Soft Tissue Route Of ☐
- Administration ☐
- Subarachnoid Route of ☐
- Administration ☐
- Subconjunctival Route of ☐
- Administration ☐
- Subcutaneous Route of ☐
- Administration ☐
- Sublingual Route of ☐
- Administration ☐
- Submucosal Route of ☐
- Administration ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Previous and Concomitant Medication

Generated On: 08 Sep 2014 13:44:31

-
- Topical Route of Administration ☐
 - Transdermal Route of Administration ☐
 - Mucosal Route of Administration ☐
 - Transplacental Route of Administration ☐
 - Transtracheal Route of Administration ☐
 - Transtympanic Route of Administration ☐
 - Unassigned Route of Administration ☐
 - Unknown Route of Administration ☐
 - Ureteral Route of Administration ☐
 - Intraurethral Route of Administration ☐
 - Vaginal Route of Administration ☐
-

Indication

Concomitant Disease Number

AE Number

Other

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: End of study

Generated On: 08 Sep 2014 13:44:31

End of study date

Fixed Unit:
DD/MMM/YYYY

Has the subject completed the study ?

No ☐
Yes ☐

If No, please specify the reason:

Adverse Events ☐
Protocol Violation ☐
Withdrawal by Subject ☐
Lost To Follow-up ☐
Other ☐

Details:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Consent Withdrawal
Generated On: 08 Sep 2014 13:44:31

Did the subject withdraw it's consent to the biobanking
for BoExp and risk markers?

No ☐
Yes ☐

Date of withdrawal of consent for biobanking for BoEXP
and risk markers _____

Did the subject withdraw it's consent to the
transcriptomics analysis?

No ☐
Yes ☐

Date of withdrawal of consent for transcriptomics
analysis _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Withdrawal

Generated On: 08 Sep 2014 13:44:31

Date of withdrawal

Fixed Unit: DD/MMM/YYYY

Did the subject withdraw it's consent from the main study?

No ☐
Yes ☐

If available, please provide details

Did the subject withdraw from the Protected Health Information (PHI)?

No ☐
Yes ☐

Did the subject confirm that samples collected up to the time of withdrawal can be analysed?

No ☐
Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: 24 hour urine collections
Generated On: 08 Sep 2014 13:44:31

Start Date	Fixed Unit: DD/MMM/YYYY
------------	----------------------------

Start Time	Fixed Unit: hour:min 24-hour clock
------------	---------------------------------------

End Date	Fixed Unit: DD/MMM/YYYY
----------	----------------------------

End Time	Fixed Unit: hour:min 24-hour clock
----------	---------------------------------------

Volume	Fixed Unit: mL
--------	-------------------

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Sample Urine Collection
Generated On: 08 Sep 2014 13:44:31

Were samples for 24h collected?

No ☐
Yes ☐

If No, please specify the reason: _____

How many primary tubes were collected? _____

How many back up tubes were collected? _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: 4 hour urine collection
Generated On: 08 Sep 2014 13:44:31

Start Date	Fixed Unit: DD/MMM/YYYY
------------	----------------------------

Start Time	Fixed Unit: hour:min 24-hour clock
------------	---------------------------------------

End Time	Fixed Unit: hour:min 24-hour clock
----------	---------------------------------------

Volume	Fixed Unit: mL
--------	-------------------

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Sample Urine Collection (4 Hour collection)
Generated On: 08 Sep 2014 13:44:31

Were samples for 4h collected? No ☐
Yes ☐

If No, please specify the reason: _____

How many primary tubes were collected? _____

How many back up tubes were collected? _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 08 Sep 2014 13:44:31

Type	MNWS
------	------

Type	Behaviour Rating Scale Self-Report
------	---------------------------------------

Date of Birth	<hr/>
---------------	-------

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Assessment Status	Completed <input type="checkbox"/> Abandoned <input type="checkbox"/>
-------------------	--

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 <input type="checkbox"/>
	Slight <input type="checkbox"/>
1. Angry, irritable, frustrated	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 08 Sep 2014 13:44:31

How have you been feeling over the past 24 hours?

2. Anxious, nervous

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 08 Sep 2014 13:44:31

How have you been feeling over the past 24 hours?

6. Increased appetite, hungry, weight gain

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 08 Sep 2014 13:44:31

How have you been feeling over the past 24 hours?

10. Constipation

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 08 Sep 2014 13:44:31

How have you been feeling over the past 24 hours?

14. Nausea

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

15. Sore Throat

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Cough Assessment

Generated On: 08 Sep 2014 13:44:31

Type	VAS for Cough
------	---------------

Date of Birth	<hr/>
---------------	-------

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Assessment Status	Completed <input type="checkbox"/>
-------------------	------------------------------------

Abandoned <input type="checkbox"/>

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input type="checkbox"/>
---	------------------------------

No <input type="checkbox"/>
Abandoned <input type="checkbox"/>

If YES, please answer the following questions:

First Question: Cough Impact Scale How much is your cough bothering you?	<hr/>
---	-------

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Cough Assessment

Generated On: 08 Sep 2014 13:44:31

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 ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Device report - THS 2.2 menthol Cigarette Holder
Generated On: 08 Sep 2014 13:44:31

Were there any events with the device?

No ☐
Yes ☐

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Device report - THS 2.2 menthol Cigarette Holder
Generated On: 08 Sep 2014 13:44:31

Severity of Event	Minor (can be resolved easily) <input type="checkbox"/>
	Major (cannot be resolved. Device needs to be exchanged) <input type="checkbox"/>

Adverse Event Relationship	Is related to AE <input type="checkbox"/>
	Is not related to AE <input type="checkbox"/>

If Related to AE, AE Number

Solution Proposed:	Device Replaced <input type="checkbox"/>
	Device Recharged <input type="checkbox"/>
	Device Withdrawn <input type="checkbox"/>

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Device report - THS 2.2 menthol Charging Unit
Generated On: 08 Sep 2014 13:44:31

Were there any events with the device?

No ☐
Yes ☐

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) ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Device report - THS 2.2 menthol Charging Unit
Generated On: 08 Sep 2014 13:44:31

Adverse Event
Relationship

Is related to AE ☐
Is not related to AE ☐

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Device Inventory - THS 2.2 menthol Cigarette Holder
Generated On: 08 Sep 2014 13:44:31

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 Cigarette Holder

Device Serial Number

Date of Device Collection
DD/MMM/YYYY

Time of
Device Collection
hour:min 24-hour clock

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Device Inventory - THS 2.2 menthol Charging Unit
Generated On: 08 Sep 2014 13:44:31

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Bio-banking (Transcriptomics)
Generated On: 08 Sep 2014 13:44:31

Was a Bio-banking sample for transcriptomics taken?

No ☐
Yes ☐

Date of Sample Collection

Fixed Unit:
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit:
hour:min 24-hour clock

Was the subject fasting for at least 10 hours at time of
sample collection?

No ☐
Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Bio-banking (Biomarkers of exposure and risk markers)

Generated On: 08 Sep 2014 13:44:31

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

No ☐
Yes ☐

Date of Sample Collection

Fixed Unit:
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit:
hour:min 24-hour clock

Was the subject fasting for at least 10 hours at time of
sample collection?

No ☐
Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Bio-banking (nasal epithelial collection/buccal collection)

Generated On: 08 Sep 2014 13:44:31

Was a Bio-banking sample for nasal epithelial
collection/buccal collection taken?

No ☐
Yes ☐

Date of Sample Collection

Fixed Unit:
DD/MMM/YYYY

Time of Buccal Collection

Fixed Unit:
hour:min 24-hour clock

Time of Nasal Epithelial Collection

Fixed Unit:
hour:min 24-hour clock

Was the subject fasting for at least 30 minutes at time of
sample collection?

No ☐
Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Vital Signs<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Date of assessment
DD/MMM/YYYY

Time of assessment
hour:min 24-hour clock

Has the subject smoked within 15 minutes prior to
assessment

No ☐
Yes ☐

Pulse rate
beats per minute

Respiratory rate
breaths per minute

Blood Pressure (systolic)
mmHg

Blood Pressure (diastolic)
mmHg

Vital Signs Position of Subject

Sitting ☐
Standing ☐
Supine ☒

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: ECG (12-Lead Standard)<Unscheduled />
Generated On: 08 Sep 2014 13:44:31

Date of assessment
DD/MMM/YYYY

Position

Sitting ☐
Standing ☐
Supine ☒

Heart Rate
(beats per minute)

QRS Interval
(msec)

QT Interval
(msec)

QTcB Interval
(msec)

QTcF Interval

Fixed Unit:
msec

PR Interval
(msec)

Interpretation

Normal ☐
Abnormal ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: ECG (12-Lead Standard)<Unscheduled />
Generated On: 08 Sep 2014 13:44:31

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Spirometry<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Category

With short-acting
bronchodilator ☐
Without short-acting
bronchodilator ☐

Date of assessment:
DD/MMM/YYYY

Time of assessment:
hour:min 24-hour clock

Position

SITTING

Has the subject smoked within 1 hour prior to
assessment?

No ☐
Yes ☐

Name of bronchodilator

Dose

Predicted FVC value

Fixed Unit:
L

Best measured FVC value

Fixed Unit:
L

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Spirometry<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Percent of predicted FVC value

Fixed Unit:
%

Best measured FEV1 value

Fixed Unit:
L

Predicted FEV1 value

Fixed Unit:
L

Percent of predicted FEV1 value

Fixed Unit:
%

MEF 25-75

Fixed Unit:
L/s

MEF 25-75 unit

Liter ☐
Percentage ☐
Liters per second ☒
Milliliters per minute per
millimeter of mercury ☐
mmol/min/kPa/L ☐
mL/min/mmHg/L ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Spirometry<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Interpretation

Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐
Clinically significant ☐

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

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Physical Examination<Unscheduled />
Generated On: 08 Sep 2014 13:44:31

Date of assessment

Fixed Unit:
DD/MMM/YYYY

System

General Appearance ☒

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

Thyroid Gland ☐

Heart ☐

Chest ☐

Lungs ☐

Gastrointestinal ☐

Cardiovascular System ☐

Neurologic ☐

Skin ☐

Back ☐

Musculoskeletal ☐

Abdomen ☐

Dentition ☐

Other ☐

Other, Specify

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Physical Examination<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Clinically significant No ☐
Yes ☐

Not Done _____

Not Done; please specify the reason: _____

System General Appearance ☐
HEENT ☒
(head, eyes, ears, nose, throat)
Thyroid Gland ☐
Heart ☐
Chest ☐
Lungs ☐
Gastrointestinal ☐
Cardiovascular System ☐
Neurologic ☐
Skin ☐
Back ☐
Musculoskeletal ☐
Abdomen ☐
Dentition ☐
Other ☐

Other, Specify _____

Outcome Normal ☐
Abnormal ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Weight<Unscheduled />
Generated On: 08 Sep 2014 13:44:31

Date of assessment
DD/MMM/YYYY

Time of assessment
hour:min 24-hour clock

Weight

Fixed Unit:
kg

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: X-Ray<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Category for Examination

Chest X-Ray ☐

Date of assessment
DD/MMM/YYYY

System

General Appearance ☐

HEENT ☐

(head, eyes, ears, nose,
throat)

Thyroid Gland ☐

Heart ☐

Chest ☒

Lungs ☐

Gastrointestinal ☐

Cardiovascular System ☐

Neurologic ☐

Skin ☐

Back ☐

Musculoskeletal ☐

Abdomen ☐

Dentition ☐

Other ☐

Interpretation

Normal ☐

Abnormal ☐

Clinically significant

No ☐

Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: X-Ray<Unscheduled />
Generated On: 08 Sep 2014 13:44:31

Abnormal, please specify: _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Urine Drug Screen<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☒

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Date of sample collection

Fixed Unit:
DD/MMM/YYYY

Time of sample collection

Fixed Unit:
hour:min 24-hour clock

Drug type

Amphetamines ☒

Barbiturates ☐

Benzodiazepines ☐

Cannabinoids ☐

Cocaine ☐

Opiates ☐

Result

Negative ☐

Positive ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Alcohol Test<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☒

Method used

Urine sample ☐

Breath test ☐

Date of assessment
DD/MMM/YYYY

Time of assessment
hour:min 24-hour clock

Result

Negative ☐

Positive ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Urine Pregnancy Test<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☒

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Date of Test
DD/MMM/YYYY

Time of Test
hour:min 24-hour clock

Specify result

Negative ☐

Positive ☐

Unclear ☐

Specify result of FSH test

< 20 IU/L ☐

>= 20 IU/L ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: CO Breath Test<Unscheduled />
Generated On: 08 Sep 2014 13:44:31

Date of Assessment
DD/MMM/YYYY

Actual Time of Assessment
hour:min 24-hour clock

Result
ppm

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Lab-BU-LabCorp
Generated On: 08 Sep 2014 13:44:31

Experiment Type _____

Date of Sample Collection
YYYY/MM/DD _____

Subject Number _____

Date of Birth _____

Gender Male ☐
Female ☐

Time of Sample Collection _____

Analyte Name _____

Code _____

Result _____

Unit _____

Lower limit _____

Upper limit _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Lab-BU-LabCorp

Generated On: 08 Sep 2014 13:44:31

Flag

Low ☐

High ☐

Abnormal ☐

Clinically Significant?

No ☐

Yes ☐

Comment

Please document clinically relevant abnormalities in the AE form

Derived Form name(Lab Type-Date)

Requisition or Accession number

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Lab_BU_CCLS
Generated On: 08 Sep 2014 13:44:31

Transmission Type	Cumulative <input type="checkbox"/>
	Incremental <input type="checkbox"/>

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	<hr/>
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Subject Date of Birth	<hr/>
-----------------------	-------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input type="checkbox"/>
	Unscheduled <input type="checkbox"/>

Accession ID	<hr/>
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Actual Collection Date	<hr/>
------------------------	-------

Actual Collection Time	<hr/>
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	<hr/>
------------	-------

Battery Name	<hr/>
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Lab Test ID	<hr/>
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PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Lab_BU_CCLS
Generated On: 08 Sep 2014 13:44:31

Lab Test Name _____

Test ID _____

Test Status Done ☐
Not Performed (Pending) ☐
Cancelled ☐

Reported Text Result _____

Reported Numeric Result _____

Reference Range low _____

Reference Range high _____

Range Units _____

Conventional Text Result _____

Conventional Numeric Result _____

Conventional Reference Range Low _____

Conventional Reference Range High _____

Conventional Units _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Lab_BU_CCLS

Generated On: 08 Sep 2014 13:44:31

SI Text Result _____

SI Numeric Result _____

SI Reference Range Low _____

SI Reference Range High _____

SI Units _____

Reported Result Type

Coded ☐

Numeric ☐

Text ☐

Greater Than (quantifiable limit) ☐

Less Than (quantifiable limit) ☐

Range ☐

Alert Flag

Low Panic ☐

Low Telephone ☐

Low ☐

High ☐

High Telephone ☐

High Panic ☐

Clinically Significant?

No ☐

Yes ☐

Comment _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Oxysterol results
Generated On: 08 Sep 2014 13:44:31

Sample Accession number

Analyte

Analyte code

Result

Result Unit

Comment

Lower limit of quantification

Date of Collection
DD MMM YYYY

Collection time
hh:mm 24 hour clock

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Lab_BU_COHB

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Lab_BU_COHB
Generated On: 08 Sep 2014 13:44:31

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Clinical Chemistry<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Date of Sample Collection

DD/MMM/YYYY

Was the subject fasting for at least 10 hours at time of
sample collection?

No ☐

Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Haematology<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Date of Sample Collection

DD/MMM/YYYY

Was the subject fasting for at least 10 hours at time of
sample collection?

No ☐

Yes ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Cough Assessment (Paper)
Generated On: 08 Sep 2014 13:44:31

Type	Cough Assessment
------	------------------

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	<hr/>
-----------------	-------

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
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Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Cough Assessment (Paper)

Generated On: 08 Sep 2014 13:44:31

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 ☐

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)

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Generated On: 08 Sep 2014 13:44:31

Type	MNWS
------	------

Type	Behaviour Rating Scale Self-Report
------	---------------------------------------

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	<hr/>
-----------------	-------

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	Fixed Unit: hour:min 24-hour clock
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Please indicate for each of the items below, how you have been feeling over the past 24 hours

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Generated On: 08 Sep 2014 13:44:31

-
1. Angry, irritable, frustrated ☒
 2. Anxious, tense ☐
 3. Depressed Mood, sad ☐
 4. Desire or craving to smoke ☐
 5. Difficulty concentrating ☐
 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 ☐
 14. Nausea ☐
 15. Sore throat ☐

Result

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)

Generated On: 08 Sep 2014 13:44:31

Type

Product Use

Was paper questionnaire used?

No ☐

Yes ☐

Reason not done

Date of completion

DD/MMM/YYYY

Time of completion

hh:mm

Date the questionnaire was completed for

DD/MMM/YYYY

What tobacco/nicotine product did you use today?

- Abandoned ☐
- THS 2.2 ☐
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)

Generated On: 08 Sep 2014 13:44:31

THS 2.2, Other tobacco product and Electronic cigarette ☐

CC, Other tobacco product and Electronic cigarette ☐

THS 2.2, CC, Other tobacco product and Electronic cigarette ☐

NRT, Other tobacco product and Electronic cigarette ☐

THS 2.2, NRT, Other tobacco product and Electronic cigarette ☐

CC, NRT, Other tobacco product and Electronic cigarette ☐

THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐

How many THS 2.2 tobacco sticks did you use today? _____

How many CC/ roll-your-own did you smoke today? _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)

Generated On: 08 Sep 2014 13:44:31

What NRT product did you used today?

- Nicotine Inhaler ☐
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)

Generated On: 08 Sep 2014 13:44:31

- Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch ☐
- Nicotine Gum and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Gum and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐
- Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler and Other NRT Product ☐
- Nicotine Nasal Spray and Other NRT Product ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)

Generated On: 08 Sep 2014 13:44:31

Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product ☐

Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)

Generated On: 08 Sep 2014 13:44:31

Nicotine Patch and Other ☐
NRT Product

Nicotine Inhaler, Nicotine ☐
Patch and Other NRT
Product

Nicotine Nasal Spray, ☐
Nicotine Patch and Other
NRT Product

Nicotine Inhaler, Nicotine ☐
Nasal Spray, Nicotine Patch
and Other NRT Product

Nicotine Gum, Nicotine ☐
Patch and Other NRT
Product

Nicotine Inhaler, Nicotine ☐
Gum, Nicotine Patch and
Other NRT Product

How many times did you use an inhaler today? _____

How many times did you use a nasal spray today? _____

How many gums did you use today? _____

How many lozenges did you use today? _____

How many patches did you use today? _____

How many times did you use other NRT products today
not listed previously? _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)

Generated On: 08 Sep 2014 13:44:31

What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☐
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Product use diary(Paper)
Generated On: 08 Sep 2014 13:44:31

How many times did you use chewable/smokeless tobacco today? _____

How many cigars/cigarillos did you smoke today? _____

How many times did you smoke a pipe today? _____

How many times did you use a tobacco product today not listed previously? _____

How many times did you use an electronic cigarette today? _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: FTND Questionnaire
Generated On: 08 Sep 2014 13:44:31

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

Date of Birth	<hr/>
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Date of assessment	Fixed Unit: DD/MMM/YYYY
DD/MMM/YYYY	<hr/>

Time of assessment	Fixed Unit: hour:min 24-hour clock
<hr/>	<hr/>

Assessment Status	Completed <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

1. How soon after you wake up do you smoke your first cigarette?	After 60 minutes <input type="checkbox"/>
	31-60 minutes <input type="checkbox"/>
	6-30 minutes <input type="checkbox"/>
	Within 5 minutes <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: FTND Questionnaire

Generated On: 08 Sep 2014 13:44:31

3. Which cigarette would you hate most to give up? The first in the morning ☐
Any other ☐
Abandoned ☐

4. How many cigarettes per day do you smoke? 10 or less ☐
11-20 ☐
21-30 ☐
31 or more ☐
Abandoned ☐

5. Do you smoke more frequently during the first hours
after awakening than during the
rest of the day? No ☐
Yes ☐
Abandoned ☐

6. Do you smoke even if you are so ill that you are in
bed most of the day? No ☐
Yes ☐
Abandoned ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 08 Sep 2014 13:44:31

Type	MCEQ
------	------

Date of Birth	<hr/>
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Date of assessment	Fixed Unit:
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	Fixed Unit:
	hour:min 24-hour clock

Assessment Status	Completed <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

1. Was smoking satisfying?	Not at all <input type="checkbox"/>
	Very little <input type="checkbox"/>
	Little <input type="checkbox"/>
	Moderately <input type="checkbox"/>
	A lot <input type="checkbox"/>
	Quite a lot <input type="checkbox"/>
	Extremely <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

2. Did cigarettes taste good?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

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 ☐

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 ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 08 Sep 2014 13:44:31

11. Did smoking immediately relieve your craving for a cigarette?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

12. Did you enjoy smoking?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Behavioral Risk Factor Surveillance System Questionnaire

Generated On: 08 Sep 2014 13:44:31

Type	Behavioral Risk Factor Surveillance System Questionnaire
------	--

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	_____
-----------------	-------

Date of assessment	Fixed Unit: DD/MMM/YYYY
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Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Don't know/Not sure <input type="checkbox"/>

Do you now smoke cigarettes every day, some days, or not at all?	Every day <input type="checkbox"/>
	Some days <input type="checkbox"/>
	Not at all <input type="checkbox"/>
	Don't know/Not sure <input type="checkbox"/>

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Behavioral Risk Factor Surveillance System Questionnaire

Generated On: 08 Sep 2014 13:44:31

Yes ☐

No ☐

Don't know/Not sure ☐

How long has it been since you last smoked a cigarette,
even one or two puffs?

Within the past month ☐
(less than 1 month ago)

Within the past 3 months ☐
(1 month but less than 3
months ago)

Within the past 6 months ☐
(3 months but less than 6
months ago)

Within the past year (6 ☐
months but less than 1
year ago)

Within the past 5 years (1 ☐
year but less than 5 years
ago)

Within the past 10 years (5 ☐
years but less than 10
years ago)

10 years or more ☐

Don't know/Not sure ☐

Do you currently use chewing tobacco, snuff, or snus
every day, some days, or not at all?

Every day ☐

Some days ☐

Not at all ☐

NOTE: Snus (Swedish for snuff) is a moist smokeless
tobacco, usually sold in small pouches that are placed
under the lip against the gum.

Do not read. Not at all ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)
Generated On: 08 Sep 2014 13:44:31

Type	Smoking Questionnaire
------	-----------------------

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	<hr/>
-----------------	-------

Date of assessment	Fixed Unit: DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="checkbox"/>
	Occasional smoker (less than one cigarette per day) <input type="checkbox"/>
	Ex-smoker of cigarettes <input type="checkbox"/>
	Non-smoker of cigarettes <input type="checkbox"/>

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)
Generated On: 08 Sep 2014 13:44:31

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly? Fixed Unit: Years

5. If you are an ex-smoker of cigarettes: For how long have you quit now?

Years Fixed Unit: Years

Months Fixed Unit: Months

Days Fixed Unit: Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years Fixed Unit: Years

Months Fixed Unit: Months

Days Fixed Unit: Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Smoking Questionnaire (SQ)

Generated On: 30 Sep 2014 09:41:16

Time

Currently (last 3 months) ☒

1 year ago ☐

5 years ago ☐

10 years ago ☐

15 years ago ☐

20 years ago ☐

More than 20 years ago ☐

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

None ☐

Less than 1 per day ☐

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day?

None ☐

Less than 1 per day ☐

Hand-rolled Cigarettes
per day

8. On average, how many cigars do/did you smoke per
day?

None ☐

Less than 1 per day ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

None ☐

Less than 1 per day ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Smoking Questionnaire (SQ)

Generated On: 30 Sep 2014 09:41:16

Pipes
per day

Time

Currently (last 3 months) ☐

1 year ago ☒

5 years ago ☐

10 years ago ☐

15 years ago ☐

20 years ago ☐

More than 20 years ago ☐

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

None ☐

Less than 1 per day ☐

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day?

None ☐

Less than 1 per day ☐

Hand-rolled Cigarettes
per day

8. On average, how many cigars do/did you smoke per
day?

None ☐

Less than 1 per day ☐

Cigars
per day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Smoking Questionnaire (SQ)

Generated On: 30 Sep 2014 09:41:16

8. On average, how many pipes do/did you smoke per day?

None ☐
Less than 1 per day ☐

Pipes
per day

Time

Currently (last 3 months) ☐
1 year ago ☐
5 years ago ☒
10 years ago ☐
15 years ago ☐
20 years ago ☐
More than 20 years ago ☐

8. On average, how many Manufactured cigarettes do/did you smoke per day?

None ☐
Less than 1 per day ☐

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☐
Less than 1 per day ☐

Hand-rolled Cigarettes
per day

8. On average, how many cigars do/did you smoke per day?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Smoking Questionnaire (SQ)

Generated On: 30 Sep 2014 09:41:16

None ☐

Less than 1 per day ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

None ☐

Less than 1 per day ☐

Pipes
per day

Time

Currently (last 3 months) ☐

1 year ago ☐

5 years ago ☐

10 years ago ☒

15 years ago ☐

20 years ago ☐

More than 20 years ago ☐

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

None ☐

Less than 1 per day ☐

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Smoking Questionnaire (SQ)

Generated On: 30 Sep 2014 09:41:16

None ☐
Less than 1 per day ☐

Hand-rolled Cigarettes
per day

8. On average, how many cigars do/did you smoke per
day?

None ☐
Less than 1 per day ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

None ☐
Less than 1 per day ☐

Pipes
per day

Time

Currently (last 3 months) ☐
1 year ago ☐
5 years ago ☐
10 years ago ☐
15 years ago ☒
20 years ago ☐
More than 20 years ago ☐

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Smoking Questionnaire (SQ)

Generated On: 30 Sep 2014 09:41:16

None ☐

Less than 1 per day ☐

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day? None ☐

Less than 1 per day ☐

Hand-rolled Cigarettes
per day

8. On average, how many cigars do/did you smoke per
day? None ☐

Less than 1 per day ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per
day? None ☐

Less than 1 per day ☐

Pipes
per day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Smoking Questionnaire (SQ)

Generated On: 30 Sep 2014 09:41:16

Time Currently (last 3 months) ☐
1 year ago ☐
5 years ago ☐
10 years ago ☐
15 years ago ☐
20 years ago ☒
More than 20 years ago ☐

8. On average, how many Manufactured cigarettes do/did you smoke per day? None ☐
Less than 1 per day ☐

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☐
Less than 1 per day ☐

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per day? None ☐
Less than 1 per day ☐

Cigars
per day _____

8. On average, how many pipes do/did you smoke per day? None ☐
Less than 1 per day ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Smoking Questionnaire (SQ)

Generated On: 30 Sep 2014 09:41:16

Pipes
per day

Time

Currently (last 3 months) ☐

1 year ago ☐

5 years ago ☐

10 years ago ☐

15 years ago ☐

20 years ago ☐

More than 20 years ago ☒

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

None ☐

Less than 1 per day ☐

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day?

None ☐

Less than 1 per day ☐

Hand-rolled Cigarettes
per day

8. On average, how many cigars do/did you smoke per
day?

None ☐

Less than 1 per day ☐

Cigars
per day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)
Generated On: 30 Sep 2014 09:41:16

8. On average, how many pipes do/did you smoke per day?

None ☐
Less than 1 per day ☐

Pipes
per day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking

Generated On: 08 Sep 2014 13:44:31

Was paper questionnaire used?

No ☐

Yes ☐

Reason not done

Type

Prochaska Stage of Change
Questionnaire: Intention to
Quit Smoking

Date of assessment

Fixed Unit:
DD/MMM/YYYY

Time of assessment

Fixed Unit:
hour:min 24-hour clock

1. Are you currently a smoker?

Yes, I currently smoke ☐

No, I quit within the last 6 ☐
months

No, I quit more than 6 ☐
months ago

No, I have never smoked ☐

2. In the last year, how many times have you quit
smoking for at least 24 hours?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking

Generated On: 08 Sep 2014 13:44:31

3. Are you seriously thinking of quitting smoking?

Yes, within the next 30 ☐
days

Yes, within the next 6 ☐
months

No, not thinking of quitting ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Supplemental Questions
Generated On: 08 Sep 2014 13:44:31

Was paper questionnaire used?

Fixed Unit:
hour:min 24-hour clock

No ☐
Yes ☐

Reason not done

Date of Assessment

Fixed Unit:
DD/MMM/YYYY

Time of assessment

1. How long it takes for the subject to complete the SQ

Fixed Unit: minutes

Comments (open-end)

Question

2. Did the SQ capture your smoking behavior completely? ☒
3. Did the SQ capture your smoking behavior correctly? ☐
4. Did the SQ capture your smoking history completely? ☐
5. Did the SQ capture your smoking history correctly? ☐
6. Was the SQ self-explaining? ☐
7. Was the SQ easy to use? ☐

Answer

Yes ☐

No ☐

Question

2. Did the SQ capture your smoking behavior completely? ☐
3. Did the SQ capture your smoking behavior correctly? ☒
4. Did the SQ capture your smoking history completely? ☐
5. Did the SQ capture your smoking history correctly? ☐
6. Was the SQ self-explaining? ☐
7. Was the SQ easy to use? ☐
-

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Human Smoking Topography Questionnaire
Generated On: 08 Sep 2014 13:44:31

Type	Human Smoking Topography Questionnaire
------	---

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	_____
-----------------	-------

Date of assessment	Fixed Unit: DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	Fixed Unit: 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.	Strongly agree <input type="checkbox"/>
	Agree <input type="checkbox"/>
	Neither agree nor disagree <input type="checkbox"/>
	Disagree <input type="checkbox"/>
	Strongly disagree <input type="checkbox"/>

If you agree or strongly agree, please describe :	_____
---	-------

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Human Smoking Topography Questionnaire
Generated On: 08 Sep 2014 13:44:31

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 : _____

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Human Smoking Topography Questionnaire
Generated On: 08 Sep 2014 13:44:31

If you agree or strongly agree, please describe : _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 08 Sep 2014 13:44:31

Type	Questionnaire on smoking urges
------	-----------------------------------

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	_____
-----------------	-------

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 <input type="checkbox"/>
	Disagree <input type="checkbox"/>
	Somewhat disagree <input type="checkbox"/>
	Do not agree or disagree <input type="checkbox"/>
	Somewhat agree <input type="checkbox"/>
	Agree <input type="checkbox"/>
	Strongly agree <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

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 ☐

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 ☐

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 ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Generated On: 08 Sep 2014 13:44:31

Type	Modifier Cigarette Evaluation Questionnaire
------	--

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	<hr/>
-----------------	-------

Date of assessment	Fixed Unit:
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	Fixed Unit:
	hour:min 24-hour clock

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Generated On: 08 Sep 2014 13:44:31

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Was smoking satisfying? ☒

Did cigarettes taste good? ☐

Did you enjoy the sensation in your throat and chest? ☐

Did smoking calm you down? ☐

Did smoking make you feel more awake? ☐

Did smoking make you feel less irritable? ☐

Did smoking help you concentrate? ☐

Did smoking reduce your hunger for food? ☐

Did smoking make you dizzy? ☐

Did smoking make you nauseous? ☐

Did smoking immediately relieve your craving for a cigarette? ☐

Did you enjoy smoking? ☐

Response

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: FTND Questionnaire (FTND) (Paper)
Generated On: 08 Sep 2014 13:44:31

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

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	
-----------------	--

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

1. How soon after you wake up do you smoke your first cigarette?	After 60 minutes <input type="checkbox"/>
	31-60 minutes <input type="checkbox"/>
	6-30 minutes <input type="checkbox"/>
	Within 5 minutes <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: FTND Questionnaire (FTND) (Paper)
Generated On: 08 Sep 2014 13:44:31

3. Which cigarette would you hate most to give up? The first in the morning ☐
Any other ☐
Abandoned ☐

4. How many cigarettes per day do you smoke? 10 or less ☐
11-20 ☐
21-30 ☐
31 or more ☐
Abandoned ☐

5. Do you smoke more frequently during the first hours
after awakening than during the
rest of the day? No ☐
Yes ☐
Abandoned ☐

6. Do you smoke even if you are so ill that you are in
bed most of the day? No ☐
Yes ☐
Abandoned ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Questionnaire on smoking urges (QSU)
Generated On: 08 Sep 2014 13:44:31

Type	QSU
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Date of Birth	<hr/>
---------------	-------

Date of assessment

DD/MMM/YYYY	<hr/>
-------------	-------

Time of assessment

hour:min 24-hour clock	<hr/>
------------------------	-------

Assessment Status	Completed <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

1. I have a desire for a cigarette right now	Strongly disagree <input type="checkbox"/>
	Disagree <input type="checkbox"/>
	Somewhat disagree <input type="checkbox"/>
	Do not agree or disagree <input type="checkbox"/>
	Somewhat agree <input type="checkbox"/>
	Agree <input type="checkbox"/>
	Strongly agree <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Questionnaire on smoking urges (QSU)

Generated On: 08 Sep 2014 13:44:31

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 ☐

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 ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Questionnaire on smoking urges (QSU)

Generated On: 08 Sep 2014 13:44:31

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 ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Cough Assessment (Paper)<Unscheduled>
Generated On: 08 Sep 2014 13:44:31

Type	Cough Assessment
------	------------------

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
-----------------------------------	----------------------------

Timepoint	Baseline (Day 0) <input type="checkbox"/>
	Day 1 <input type="checkbox"/>
	Day 2 <input type="checkbox"/>
	Day 3 <input type="checkbox"/>
	Day 4 <input type="checkbox"/>
	Day 5 <input type="checkbox"/>
	Day 6 <input type="checkbox"/>
	Day 30 <input type="checkbox"/>
	Day 60 <input type="checkbox"/>
	Day 90 <input type="checkbox"/>

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

If YES, please answer the following questions:

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Cough Assessment (Paper)<Unscheduled>
Generated On: 08 Sep 2014 13:44:31

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 ☐

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) _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Cough Assessment (Paper)<Unscheduled>
Generated On: 08 Sep 2014 13:44:31

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>**

Generated On: 08 Sep 2014 13:44:31

Type	MNWS
------	------

Type	Behaviour Rating Scale Self-Report
------	---------------------------------------

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
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Timepoint	Baseline (Day 0) <input type="checkbox"/>
	Day 1 <input type="checkbox"/>
	Day 2 <input type="checkbox"/>
	Day 3 <input type="checkbox"/>
	Day 4 <input type="checkbox"/>
	Day 5 <input type="checkbox"/>
	Day 6 <input type="checkbox"/>
	Day 30 <input type="checkbox"/>
	Day 60 <input type="checkbox"/>
	Day 90 <input type="checkbox"/>

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Please indicate for each of the items below, how you have been feeling over the past 24 hours

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>

Generated On: 08 Sep 2014 13:44:31

-
1. Angry, irritable, frustrated ☒
 2. Anxious, tense ☐
 3. Depressed Mood, sad ☐
 4. Desire or craving to smoke ☐
 5. Difficulty concentrating ☐
 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 ☐
 14. Nausea ☐
 15. Sore throat ☐

Result

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Product use diary(Paper)<Unscheduled>
Generated On: 08 Sep 2014 13:44:31

Type	Product Use
------	-------------

Date of completion
DD/MMM/YYYY

Timepoint

Discharge ☐
Day 30 ☐
Day 60 ☐
Day 90 ☐

Time of completion
hh:mm

Date the questionnaire was completed for
DD/MMM/YYYY

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)<Unscheduled>

Generated On: 08 Sep 2014 13:44:31

What tobacco/nicotine product did you use today?

- Abandoned ☐
- THS 2.2 ☐
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)<Unscheduled>

Generated On: 08 Sep 2014 13:44:31

THS 2.2, Other tobacco product and Electronic cigarette ☐

CC, Other tobacco product and Electronic cigarette ☐

THS 2.2, CC, Other tobacco product and Electronic cigarette ☐

NRT, Other tobacco product and Electronic cigarette ☐

THS 2.2, NRT, Other tobacco product and Electronic cigarette ☐

CC, NRT, Other tobacco product and Electronic cigarette ☐

THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐

How many THS 2.2 tobacco sticks did you use today?

How many CC/ roll-your-own did you smoke today?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Product use diary(Paper)<Unscheduled>
Generated On: 08 Sep 2014 13:44:31

What NRT product did you used today?

- Nicotine Inhaler ☐
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)<Unscheduled>

Generated On: 08 Sep 2014 13:44:31

- Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch ☐
- Nicotine Gum and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Gum and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐
- Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler and Other NRT Product ☐
- Nicotine Nasal Spray and Other NRT Product ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)<Unscheduled>

Generated On: 08 Sep 2014 13:44:31

Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product ☐

Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)<Unscheduled>

Generated On: 08 Sep 2014 13:44:31

Nicotine Patch and Other ☐
NRT Product

Nicotine Inhaler, Nicotine ☐
Patch and Other NRT
Product

Nicotine Nasal Spray, ☐
Nicotine Patch and Other
NRT Product

Nicotine Inhaler, Nicotine ☐
Nasal Spray, Nicotine Patch
and Other NRT Product

Nicotine Gum, Nicotine ☐
Patch and Other NRT
Product

Nicotine Inhaler, Nicotine ☐
Gum, Nicotine Patch and
Other NRT Product

How many times did you use an inhaler today? _____

How many times did you use a nasal spray today? _____

How many gums did you use today? _____

How many lozenges did you use today? _____

How many patches did you use today? _____

How many times did you use other NRT products today
not listed previously? _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Product use diary(Paper)<Unscheduled>

Generated On: 08 Sep 2014 13:44:31

What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☐
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Product use diary(Paper)<Unscheduled>
Generated On: 08 Sep 2014 13:44:31

How many times did you use chewable/smokeless tobacco today? _____

How many cigars/cigarillos did you smoke today? _____

How many times did you smoke a pipe today? _____

How many times did you use a tobacco product today not listed previously? _____

How many times did you use an electronic cigarette today? _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>

Generated On: 08 Sep 2014 13:44:31

Type	Questionnaire on smoking urges
------	-----------------------------------

Date of assessment

DD/MMM/YYYY

Timepoint

Baseline (Day -1) ☐

Baseline (Day 0) ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 30 ☐

Day 60 ☐

Day 90 ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>

Generated On: 08 Sep 2014 13:44:31

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 ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>

Generated On: 08 Sep 2014 13:44:31

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 ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>

Generated On: 08 Sep 2014 13:44:31

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 ☐

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 ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 08-Sep-2014 13:44:31

Type	Modifier Cigarette Evaluation Questionnaire
------	--

Date of assessment	Fixed Unit:
DD/MMM/YYYY	DD/MMM/YYYY

Timepoint	Baseline (Day -1) <input type="checkbox"/>
	Baseline (Day 0) <input type="checkbox"/>
	Day 1 <input type="checkbox"/>
	Day 2 <input type="checkbox"/>
	Day 3 <input type="checkbox"/>
	Day 4 <input type="checkbox"/>
	Day 5 <input type="checkbox"/>
	Day 30 <input type="checkbox"/>
	Day 60 <input type="checkbox"/>
	Day 90 <input type="checkbox"/>

Time of assessment	Fixed Unit:
	hour:min 24-hour clock

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 08-Sep-2014 13:44:31

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Was smoking satisfying? ☒

Did cigarettes taste good? ☐

Did you enjoy the sensation in your throat and chest? ☐

Did smoking calm you down? ☐

Did smoking make you feel more awake? ☐

Did smoking make you feel less irritable? ☐

Did smoking help you concentrate? ☐

Did smoking reduce your hunger for food? ☐

Did smoking make you dizzy? ☐

Did smoking make you nauseous? ☐

Did smoking immediately relieve your craving for a cigarette? ☐

Did you enjoy smoking? ☐

Response

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>
Generated On: 08 Sep 2014 13:44:31

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

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
-----------------------------------	----------------------------

Timepoint	Screening <input type="checkbox"/>
	Day 90 <input type="checkbox"/>

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

1. How soon after you wake up do you smoke your first cigarette?	After 60 minutes <input type="checkbox"/>
	31-60 minutes <input type="checkbox"/>
	6-30 minutes <input type="checkbox"/>
	Within 5 minutes <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

3. Which cigarette would you hate most to give up?	The first in the morning <input type="checkbox"/>
	Any other <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>
Generated On: 08 Sep 2014 13:44:31

4. How many cigarettes per day do you smoke? 10 or less ☐
11-20 ☐
21-30 ☐
31 or more ☐
Abandoned ☐

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day? No ☐
Yes ☐
Abandoned ☐

6. Do you smoke even if you are so ill that you are in bed most of the day? No ☐
Yes ☐
Abandoned ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Urine analysis<Unscheduled />

Generated On: 08 Sep 2014 13:44:31

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☒

Cotinine Screening ☐

Alcohol Test ☐

Date of sample collection

DD/MMM/YYYY

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking
Post enrolment**

Generated On: 08 Sep 2014 13:44:31

Was paper questionnaire used?

No ☐

Yes ☐

Reason not done

Type

Prochaska Stage of Change
Questionnaire: Intention to
Quit Smoking

Date of assessment

Fixed Unit:
DD/MMM/YYYY

Time of assessment

Fixed Unit:
hour:min 24-hour clock

1. Are you currently a smoker?

Yes, I currently smoke ☐

No, I quit within the last 6 ☐
months

No, I quit more than 6 ☐
months ago

No, I have never smoked ☐

2. In the last year, how many times have you quit
smoking for at least 24 hours?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Behavioral Risk Factor Surveillance System Questionnaire <unscheduled>

Generated On: 08 Sep 2014 13:44:31

Type	Behavioral Risk Factor Surveillance System Questionnaire
------	--

Date of assessment	Fixed Unit: DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/>
	No <input type="radio"/>
	Don't know/Not sure <input type="radio"/>

Do you now smoke cigarettes every day, some days, or not at all?	Every day <input type="radio"/>
	Some days <input type="radio"/>
	Not at all <input type="radio"/>
	Don't know/Not sure <input type="radio"/>

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking?	Yes <input type="radio"/>
	No <input type="radio"/>
	Don't know/Not sure <input type="radio"/>

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Behavioral Risk Factor Surveillance System Questionnaire <unscheduled>

Generated On: 08 Sep 2014 13:44:31

How long has it been since you last smoked a cigarette,
even one or two puffs?

- Within the past month ☐
(less than 1 month ago)
Within the past 3 months ☐
(1 month but less than 3
months ago)
Within the past 6 months ☐
(3 months but less than 6
months ago)
Within the past year (6 ☐
months but less than 1
year ago)
Within the past 5 years (1 ☐
year but less than 5 years
ago)
Within the past 10 years (5 ☐
years but less than 10
years ago)
10 years or more ☐
Don't know/Not sure ☐

Do you currently use chewing tobacco, snuff, or snus
every day, some days, or not at all?

NOTE: Snus (Swedish for snuff) is a moist smokeless
tobacco, usually sold in small pouches that are placed
under the lip against the gum.

- Every day ☐
Some days ☐
Not at all ☐
Do not read. Not at all ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 08 Sep 2014 13:44:31

Type	Smoking Questionnaire
------	-----------------------

Date of assessment	Fixed Unit: DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/> Occasional smoker (less than one cigarette per day) <input type="radio"/> Ex-smoker of cigarettes <input type="radio"/> Non-smoker of cigarettes <input type="radio"/>
--	---

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/> No <input type="radio"/>
--	---

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input type="radio"/> No <input type="radio"/>
--	---

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	Fixed Unit: Years
---	-------------------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 08 Sep 2014 13:44:31

Years	Fixed Unit: Years
-------	-------------------

Months	Fixed Unit: Months
--------	--------------------

Days	Fixed Unit: Days
------	------------------

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years	Fixed Unit: Years
-------	-------------------

Months	Fixed Unit: Months
--------	--------------------

Days	Fixed Unit: Days
------	------------------

7. What brand of cigarettes/hand-rolled tobacco did you
predominantly smoke in the last 12 months of smoking? _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 30 Sep 2014 09:41:16

Time Currently (last 3 months) ☒
1 year ago ☐
5 years ago ☐
10 years ago ☐
15 years ago ☐
20 years ago ☐
More than 20 years ago ☐

8. On average, how many Manufactured cigarettes do/did you smoke per day? None ☐
Less than 1 per day ☐

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☐
Less than 1 per day ☐

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per day? None ☐
Less than 1 per day ☐

Cigars
per day _____

8. On average, how many pipes do/did you smoke per day? None ☐
Less than 1 per day ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 30 Sep 2014 09:41:16

Pipes
per day

Time

Currently (last 3 months) ☐
1 year ago ☒
5 years ago ☐
10 years ago ☐
15 years ago ☐
20 years ago ☐
More than 20 years ago ☐

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

None ☐
Less than 1 per day ☐

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day?

None ☐
Less than 1 per day ☐

Hand-rolled Cigarettes
per day

8. On average, how many cigars do/did you smoke per
day?

None ☐
Less than 1 per day ☐

Cigars
per day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 30 Sep 2014 09:41:16

8. On average, how many pipes do/did you smoke per day? None ☐
Less than 1 per day ☐

Pipes
per day _____

Time Currently (last 3 months) ☐
1 year ago ☐
5 years ago ☒
10 years ago ☐
15 years ago ☐
20 years ago ☐
More than 20 years ago ☐

8. On average, how many Manufactured cigarettes do/did you smoke per day? None ☐
Less than 1 per day ☐

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☐
Less than 1 per day ☐

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per day?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 30 Sep 2014 09:41:16

None ☐
Less than 1 per day ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per day?

None ☐
Less than 1 per day ☐

Pipes
per day

Time

Currently (last 3 months) ☐
1 year ago ☐
5 years ago ☐
10 years ago ☒
15 years ago ☐
20 years ago ☐
More than 20 years ago ☐

8. On average, how many Manufactured cigarettes do/did you smoke per day?

None ☐
Less than 1 per day ☐

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 30 Sep 2014 09:41:16

None ☐
Less than 1 per day ☐

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per
day? None ☐
Less than 1 per day ☐

Cigars
per day _____

8. On average, how many pipes do/did you smoke per
day? None ☐
Less than 1 per day ☐

Pipes
per day _____

Time Currently (last 3 months) ☐
1 year ago ☐
5 years ago ☐
10 years ago ☐
15 years ago ☒
20 years ago ☐
More than 20 years ago ☐

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 30 Sep 2014 09:41:16

None ☐
Less than 1 per day ☐

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day?

None ☐
Less than 1 per day ☐

Hand-rolled Cigarettes
per day

8. On average, how many cigars do/did you smoke per
day?

None ☐
Less than 1 per day ☐

Cigars
per day

8. On average, how many pipes do/did you smoke per
day?

None ☐
Less than 1 per day ☐

Pipes
per day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 30 Sep 2014 09:41:16

Time Currently (last 3 months) ☐
1 year ago ☐
5 years ago ☐
10 years ago ☐
15 years ago ☐
20 years ago ☒
More than 20 years ago ☐

8. On average, how many Manufactured cigarettes do/did you smoke per day? None ☐
Less than 1 per day ☐

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☐
Less than 1 per day ☐

Hand-rolled Cigarettes
per day _____

8. On average, how many cigars do/did you smoke per day? None ☐
Less than 1 per day ☐

Cigars
per day _____

8. On average, how many pipes do/did you smoke per day? None ☐
Less than 1 per day ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 30 Sep 2014 09:41:16

Pipes
per day

Time

Currently (last 3 months) ☐
1 year ago ☐
5 years ago ☐
10 years ago ☐
15 years ago ☐
20 years ago ☐
More than 20 years ago ☒

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

None ☐
Less than 1 per day ☐

Manufactured Cigarettes
per day

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day?

None ☐
Less than 1 per day ☐

Hand-rolled Cigarettes
per day

8. On average, how many cigars do/did you smoke per
day?

None ☐
Less than 1 per day ☐

Cigars
per day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 30 Sep 2014 09:41:16

8. On average, how many pipes do/did you smoke per day?

None ☐
Less than 1 per day ☐

Pipes
per day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Risk Markers(CCLS)

Generated On: 08 Sep 2014 13:44:31

Transmission Type

Cumulative ☐

Incremental ☐

Subject ID or Number

Subject Sex

Subject Date of Birth

Visit Name

Visit Type

Scheduled ☐

Unscheduled ☐

Accession ID

Actual Collection Date

Actual Collection Time

Specimen Condition

Battery ID

Battery Name

Lab Test ID

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Risk Markers(CCLS)
Generated On: 08 Sep 2014 13:44:31

Lab Test Name _____

Test ID _____

Test Status Done ☐
Not Performed (Pending) ☐
Cancelled ☐

Reported Text Result _____

Reported Numeric Result _____

Reference Range low _____

Reference Range high _____

Range Units _____

Conventional Text Result _____

Conventional Numeric Result _____

Conventional Reference Range Low _____

Conventional Reference Range High _____

Conventional Units _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Risk Markers(CCLS)

Generated On: 08 Sep 2014 13:44:31

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Coded ☐

Numeric ☐

Text ☐

Greater Than (quantifiable
limit) ☐

Less Than (quantifiable
limit) ☐

Range ☐

Alert Flag

Low Panic ☐

Low Telephone ☐

Low ☐

High ☐

High Telephone ☐

High Panic ☐

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (CEMA, HPMa, HBMA)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day _____

Urine End Day _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (NNN, NNAL)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (NNN, NNAL)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day _____

Urine End Day _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (HEMA)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (HEMA)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day

Urine End Day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Generated On: 08 Sep 2014 13:44:31

Urine Start Day

Urine End Day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (3-OH BaP)
Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (3-OH BaP)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day

Urine End Day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Plasma (Caffeine, Paraxanthine)
Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Plasma (Caffeine, Paraxanthine)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day

Urine End Day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)
Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day _____

Urine End Day _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (11-dTXb2)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (11-dTXb2)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day

Urine End Day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (iPF2a-III)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (iPF2a-III)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day _____

Urine End Day _____

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (Ames)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (Ames)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day

Urine End Day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (1-OHP)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (1-OHP)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day

Urine End Day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (SPMA, SBMA)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (SPMA, SBMA)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day

Urine End Day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (MHBMA)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (MHBMA)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day

Urine End Day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Urine (Creatinine)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Urine (Creatinine)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day

Urine End Day

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Project Name: ZRHM-REXA-08-US

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 08 Sep 2014 13:44:31

Sample Barcode

Analyte

Sample type

Result

Result Unit

Lab Status

Sample comment

Detection method

Lower limit of quantification

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Project Name: ZRHM-REXA-08-US
Form: Biomarker-Plasma (Nic, Cot, tHCot)
Generated On: 08 Sep 2014 13:44:31

Urine Start Day

Urine End Day
