



## PMI RESEARCH & DEVELOPMENT

### **Study ZRHM-PK-05-JP** **Clinical Study Report Appendix 16.1.2** **Sample Case Report Form, Subject Questionnaire, and** **Subject Smoking Diary**

**Study Title:** A single-center, open-label, randomized, controlled, crossover study to investigate the nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) following single use in smoking, healthy subjects compared to menthol conventional cigarettes and nicotine gum

**Short Title:** Nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol)

**Study Number:** ZRHM-PK-05-JP

**Product Name:** Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol)

**Study Initiated (first subject screened):** 01 August 2013

**Study Completed (last subject last visit):** 16 November 2013

**Principal Investigator and Affiliation:** F. Nobuoka, MD  
Ageo Medical Clinic  
3133 Haraichi, Ageo City  
Saitama 362-0021, Japan

**Sponsor:** Philip Morris Products S.A.  
PMI Research & Development  
Quai Jeanrenaud 5  
2000 Neuchâtel, Switzerland

**Sponsor Signatories:** Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist  
Andrea Donelli, Clinical Scientist  
Nicola Lama, PhD, Biostatistician  
Patrick Picavet, MD, Medical Safety Officer

**Version:** 1.0

**Date:** 12 May 2015

This study was conducted in accordance with Good Clinical Practice.

#### **Confidentiality Statement**

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This document is confidential. Disclosure of any of its contents to third parties is not permitted except by the prior written consent of Philip Morris Products S.A.

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## **16.1.2.1 SAMPLE CASE REPORT FORM**

Subject Case Report Forms

Final 2.0. (Main CRF) - Case Book

Generated On: 07 Nov 2013 16:29:10

All time stamps listed in this document are displayed in GMT

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Subject**  
**Generated On: 07 Nov 2013 16:29:10**

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Screening number

---

Site number

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Subject Status**  
**Generated On: 07 Nov 2013 16:29:10**

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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

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Screen Failure**  
**Generated On: 07 Nov 2013 16:29:10**

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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 ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Date of Visit**  
**Generated On: 07 Nov 2013 16:29:10**

---

Date of Visit

Fixed Unit:  
DD/MMM/YYYY



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Date of Discharge**  
**Generated On: 07 Nov 2013 16:29:10**

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Date of Visit

Fixed Unit:  
DD/MMM/YYYY

---

Discharge Time

Fixed Unit:  
hour:min 24-hour clock

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Inclusion Criteria**  
**Generated On: 07 Nov 2013 16:29:10**

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

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Inclusion/Exclusion Criterion Number	1
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---

Inclusion/Exclusion Criterion

Subject has signed the ICF ☒ and is able to understand the information provided in the Subject Information Sheet and ICF.  
Subject is aged from 23 to ☐ 65 years (inclusive).  
Subject is Japanese. ☐  
Smoking, healthy subject ☐ as judged by the Investigator based on all available assessments in the Screening period/day of Admission (e.g., safety laboratory, spirometry\* [forced expiratory volume in 1 second {FEV1}/forced vital capacity {FVC} >0.7 at post bronchodilator basal spirometry, post bronchodilator FEV1 >80% predicted value, and post bronchodilator FVC >0.8], vital signs, physical examination, ECG, chest X-ray and medical history).

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Inclusion Criteria  
Generated On: 07 Nov 2013 16:29:10

---

Subject smokes at least 10 ☐  
commercially available  
menthol CCs per day (no  
brand restrictions) with a  
maximum yield of 1 mg  
nicotine ISO/mCC, as  
labelled on the cigarette  
package, 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 in the next  
3 months.  
The subject is ready to ☐  
accept interruptions of  
smoking for up to 4 days.  
The subject is ready to ☐  
accept using both the THS  
2.2 Menthol and NRT gum  
products.

---

Result No ☐  
Yes ☐

---

---

Inclusion/Exclusion Criterion Number 2

---

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐  
and is able to understand  
the information provided in  
the Subject Information  
Sheet and ICF.  
Subject is aged from 23 to ☒  
65 years (inclusive).  
Subject is Japanese. ☐  
Smoking, healthy subject ☐  
as judged by the  
Investigator based on all  
available assessments in  
the Screening period/day  
of Admission (e.g., safety  
laboratory, spirometry\*  
[forced expiratory volume  
in 1 second {FEV1}/forced  
vital capacity {FVC} >0.7  
at post bronchodilator  
basal spirometry, post  
bronchodilator FEV1 >80%  
predicted value, and post  
bronchodilator FVC >0.8],  
vital signs, physical  
examination, ECG, chest  
X-ray and medical history).

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Inclusion Criteria  
Generated On: 07 Nov 2013 16:29:10

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Subject smokes at least 10 ☐  
commercially available  
menthol CCs per day (no  
brand restrictions) with a  
maximum yield of 1 mg  
nicotine ISO/mCC, as  
labelled on the cigarette  
package, 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 in the next  
3 months.  
The subject is ready to ☐  
accept interruptions of  
smoking for up to 4 days.  
The subject is ready to ☐  
accept using both the THS  
2.2 Menthol and NRT gum  
products.

---

Result No ☐  
Yes ☐

---

---

Inclusion/Exclusion Criterion Number 3

---

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐  
and is able to understand  
the information provided in  
the Subject Information  
Sheet and ICF.  
Subject is aged from 23 to ☐  
65 years (inclusive).  
Subject is Japanese. ☒  
Smoking, healthy subject ☐  
as judged by the  
Investigator based on all  
available assessments in  
the Screening period/day  
of Admission (e.g., safety  
laboratory, spirometry\*  
[forced expiratory volume  
in 1 second {FEV1}/forced  
vital capacity {FVC} >0.7  
at post bronchodilator  
basal spirometry, post  
bronchodilator FEV1 >80%  
predicted value, and post  
bronchodilator FVC >0.8],  
vital signs, physical  
examination, ECG, chest  
X-ray and medical history).

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Inclusion Criteria  
Generated On: 07 Nov 2013 16:29:10

---

Subject smokes at least 10 ☐  
commercially available  
menthol CCs per day (no  
brand restrictions) with a  
maximum yield of 1 mg  
nicotine ISO/mCC, as  
labelled on the cigarette  
package, 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 in the next  
3 months.  
The subject is ready to ☐  
accept interruptions of  
smoking for up to 4 days.  
The subject is ready to ☐  
accept using both the THS  
2.2 Menthol and NRT gum  
products.

---

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

---

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Inclusion/Exclusion Criterion Number	4
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Inclusion/Exclusion Criterion

Subject has signed the ICF ☐  
and is able to understand  
the information provided in  
the Subject Information  
Sheet and ICF.  
Subject is aged from 23 to ☐  
65 years (inclusive).  
Subject is Japanese. ☐  
Smoking, healthy subject ☒  
as judged by the  
Investigator based on all  
available assessments in  
the Screening period/day  
of Admission (e.g., safety  
laboratory, spirometry\*  
[forced expiratory volume  
in 1 second {FEV1}/forced  
vital capacity {FVC} >0.7  
at post bronchodilator  
basal spirometry, post  
bronchodilator FEV1 >80%  
predicted value, and post  
bronchodilator FVC >0.8],  
vital signs, physical  
examination, ECG, chest  
X-ray and medical history).

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Inclusion Criteria**  
**Generated On: 07 Nov 2013 16:29:10**

---

Subject smokes at least 10 ☐  
commercially available  
menthol CCs per day (no  
brand restrictions) with a  
maximum yield of 1 mg  
nicotine ISO/mCC, as  
labelled on the cigarette  
package, 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 in the next  
3 months.  
The subject is ready to ☐  
accept interruptions of  
smoking for up to 4 days.  
The subject is ready to ☐  
accept using both the THS  
2.2 Menthol and NRT gum  
products.

---

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

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Inclusion/Exclusion Criterion Number	5
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Inclusion/Exclusion Criterion

Subject has signed the ICF ☐  
and is able to understand  
the information provided in  
the Subject Information  
Sheet and ICF.  
Subject is aged from 23 to ☐  
65 years (inclusive).  
Subject is Japanese. ☐  
Smoking, healthy subject ☐  
as judged by the  
Investigator based on all  
available assessments in  
the Screening period/day  
of Admission (e.g., safety  
laboratory, spirometry\*  
[forced expiratory volume  
in 1 second {FEV1}/forced  
vital capacity {FVC} >0.7  
at post bronchodilator  
basal spirometry, post  
bronchodilator FEV1 >80%  
predicted value, and post  
bronchodilator FVC >0.8],  
vital signs, physical  
examination, ECG, chest  
X-ray and medical history).

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Inclusion Criteria  
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Subject smokes at least 10 ☒ commercially available menthol CCs per day (no brand restrictions) with a maximum yield of 1 mg nicotine ISO/mCC, as labelled on the cigarette package, 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 in the next 3 months. The subject is ready to ☐ accept interruptions of smoking for up to 4 days. The subject is ready to ☐ accept using both the THS 2.2 Menthol and NRT gum products.

---

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

---

---

Inclusion/Exclusion Criterion Number	6
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Inclusion/Exclusion Criterion

Subject has signed the ICF ☐  
and is able to understand  
the information provided in  
the Subject Information  
Sheet and ICF.  
Subject is aged from 23 to ☐  
65 years (inclusive).  
Subject is Japanese. ☐  
Smoking, healthy subject ☐  
as judged by the  
Investigator based on all  
available assessments in  
the Screening period/day  
of Admission (e.g., safety  
laboratory, spirometry\*  
[forced expiratory volume  
in 1 second {FEV1}/forced  
vital capacity {FVC} >0.7  
at post bronchodilator  
basal spirometry, post  
bronchodilator FEV1 >80%  
predicted value, and post  
bronchodilator FVC >0.8],  
vital signs, physical  
examination, ECG, chest  
X-ray and medical history).

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Inclusion Criteria  
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---

Subject smokes at least 10 ☐  
commercially available  
menthol CCs per day (no  
brand restrictions) with a  
maximum yield of 1 mg  
nicotine ISO/mCC, as  
labelled on the cigarette  
package, 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 in the next  
3 months.  
The subject is ready to ☐  
accept interruptions of  
smoking for up to 4 days.  
The subject is ready to ☐  
accept using both the THS  
2.2 Menthol and NRT gum  
products.

---

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

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**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Exclusion Criteria**  
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---

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

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---

Inclusion/Exclusion Criterion Number	1
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Inclusion/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, , prisoners or subjects who are involuntarily incarcerated). ☐

The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator. ☐

The subject has a body mass index (BMI) <18.5 or  $\geq 32.0$  kg/m<sup>2</sup>. ☐



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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Exclusion Criteria**  
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The subject has ☐  
participated in a clinical  
study within 3 months  
prior to the Screening Visit.

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

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"/>

---

---

Inclusion/Exclusion Criterion Number	2
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---

Inclusion/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, , prisoners or  
subjects who are  
involuntarily incarcerated).  
The subject has medical ☐  
condition requiring  
smoking cessation, or  
clinically relevant diseases  
(including but not limited  
to gastrointestinal, renal,  
hepatic, neurological,  
hematological, endocrine,  
oncological, urological,  
immunological, pulmonary  
and cardiovascular disease  
or any other medical  
condition [including but not  
limited to clinically relevant  
abnormal laboratory  
parameters]) in the  
judgment of the  
Investigator.  
The subject has a body ☐  
mass index (BMI) <18.5 or  
≥32.0 kg/m<sup>2</sup>.

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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Exclusion Criteria**  
**Generated On: 07 Nov 2013 16:29:10**

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

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

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"/>

---

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Inclusion/Exclusion Criterion Number	3
--------------------------------------	---

---

Inclusion/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, , prisoners or  
subjects who are  
involuntarily incarcerated).  
The subject has medical ☒  
condition requiring  
smoking cessation, or  
clinically relevant diseases  
(including but not limited  
to gastrointestinal, renal,  
hepatic, neurological,  
hematological, endocrine,  
oncological, urological,  
immunological, pulmonary  
and cardiovascular disease  
or any other medical  
condition [including but not  
limited to clinically relevant  
abnormal laboratory  
parameters]) in the  
judgment of the  
Investigator.  
The subject has a body ☐  
mass index (BMI) <18.5 or  
≥32.0 kg/m<sup>2</sup>.



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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
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---

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

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

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"/>

---

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Inclusion/Exclusion Criterion Number	4
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Inclusion/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, , prisoners or  
subjects who are  
involuntarily incarcerated).  
The subject has medical ☐  
condition requiring  
smoking cessation, or  
clinically relevant diseases  
(including but not limited  
to gastrointestinal, renal,  
hepatic, neurological,  
hematological, endocrine,  
oncological, urological,  
immunological, pulmonary  
and cardiovascular disease  
or any other medical  
condition [including but not  
limited to clinically relevant  
abnormal laboratory  
parameters]) in the  
judgment of the  
Investigator.  
The subject has a body ☒  
mass index (BMI) <18.5 or  
≥32.0 kg/m<sup>2</sup>.

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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

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

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

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"/>

---

---

Inclusion/Exclusion Criterion Number	5
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---

Inclusion/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, , prisoners or  
subjects who are  
involuntarily incarcerated).  
The subject has medical ☐  
condition requiring  
smoking cessation, or  
clinically relevant diseases  
(including but not limited  
to gastrointestinal, renal,  
hepatic, neurological,  
hematological, endocrine,  
oncological, urological,  
immunological, pulmonary  
and cardiovascular disease  
or any other medical  
condition [including but not  
limited to clinically relevant  
abnormal laboratory  
parameters]) in the  
judgment of the  
Investigator.  
The subject has a body ☐  
mass index (BMI) <18.5 or  
≥32.0 kg/m<sup>2</sup>.



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.

The subject has used ☐ nicotine containing products other than commercially available mCC (either tobacco-based products or nicotine-replacement therapy) 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 5 half-lives of the drug prior to the Admission Day (Day -1; whichever is longer) that has an impact on CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

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

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

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"/>

---

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Inclusion/Exclusion Criterion Number	6
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Inclusion/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, , prisoners or subjects who are involuntarily incarcerated). ☐
- The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator. ☐
- The subject has a body mass index (BMI) <18.5 or  $\geq 32.0$  kg/m<sup>2</sup>. ☐

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.

The subject has used ☒  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

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

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

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"/>

---

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Inclusion/Exclusion Criterion Number	8
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Inclusion/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, , prisoners or subjects who are involuntarily incarcerated). ☐
- The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator. ☐
- The subject has a body mass index (BMI) <18.5 or  $\geq 32.0$  kg/m<sup>2</sup>. ☐



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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☒
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

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

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

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"/>

---

---

Inclusion/Exclusion Criterion Number	9
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Inclusion/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, , prisoners or  
subjects who are  
involuntarily incarcerated).  
The subject has medical ☐  
condition requiring  
smoking cessation, or  
clinically relevant diseases  
(including but not limited  
to gastrointestinal, renal,  
hepatic, neurological,  
hematological, endocrine,  
oncological, urological,  
immunological, pulmonary  
and cardiovascular disease  
or any other medical  
condition [including but not  
limited to clinically relevant  
abnormal laboratory  
parameters]) in the  
judgment of the  
Investigator.  
The subject has a body ☐  
mass index (BMI) <18.5 or  
≥32.0 kg/m<sup>2</sup>.

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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☒
- 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, child). ☐

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

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

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"/>

---

---

Inclusion/Exclusion Criterion Number	10
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---

Inclusion/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, , prisoners or subjects who are involuntarily incarcerated). ☐
- The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator. ☐
- The subject has a body mass index (BMI) <18.5 or  $\geq 32.0$  kg/m<sup>2</sup>. ☐



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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

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

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

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"/>

---

---

Inclusion/Exclusion Criterion Number	11
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---

Inclusion/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, , prisoners or subjects who are involuntarily incarcerated). ☐
- The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator. ☐
- The subject has a body mass index (BMI) <18.5 or  $\geq 32.0$  kg/m<sup>2</sup>. ☐

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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

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

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

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"/>

---

---

Inclusion/Exclusion Criterion Number	12
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---

Inclusion/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, , prisoners or subjects who are involuntarily incarcerated). ☐
- The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator. ☐
- The subject has a body mass index (BMI) <18.5 or  $\geq 32.0$  kg/m<sup>2</sup>. ☐



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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

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

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

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"/>

---

---

Inclusion/Exclusion Criterion Number	13
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Inclusion/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, , prisoners or  
subjects who are  
involuntarily incarcerated).  
The subject has medical ☐  
condition requiring  
smoking cessation, or  
clinically relevant diseases  
(including but not limited  
to gastrointestinal, renal,  
hepatic, neurological,  
hematological, endocrine,  
oncological, urological,  
immunological, pulmonary  
and cardiovascular disease  
or any other medical  
condition [including but not  
limited to clinically relevant  
abnormal laboratory  
parameters]) in the  
judgment of the  
Investigator.  
The subject has a body ☐  
mass index (BMI) <18.5 or  
≥32.0 kg/m<sup>2</sup>.

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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Exclusion Criteria**  
**Generated On: 07 Nov 2013 16:29:10**

---

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

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

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"/>

---

---

Inclusion/Exclusion Criterion Number	14
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---

Inclusion/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, , prisoners or subjects who are involuntarily incarcerated). ☐
- The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator. ☐
- The subject has a body mass index (BMI) <18.5 or  $\geq 32.0$  kg/m<sup>2</sup>. ☐



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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☒

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Exclusion Criteria**  
**Generated On: 07 Nov 2013 16:29:10**

---

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

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

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"/>

---

---

Inclusion/Exclusion Criterion Number	15
--------------------------------------	----

---

Inclusion/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, , prisoners or subjects who are involuntarily incarcerated). ☐
- The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator. ☐
- The subject has a body mass index (BMI) <18.5 or  $\geq 32.0$  kg/m<sup>2</sup>. ☐

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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Exclusion Criteria  
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---

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

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

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="radio"/>
	Yes <input type="radio"/>
	NA <input type="radio"/>

---

---

Inclusion/Exclusion Criterion Number	16
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---

Inclusion/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, , prisoners or  
subjects who are  
involuntarily incarcerated).  
The subject has medical ☐  
condition requiring  
smoking cessation, or  
clinically relevant diseases  
(including but not limited  
to gastrointestinal, renal,  
hepatic, neurological,  
hematological, endocrine,  
oncological, urological,  
immunological, pulmonary  
and cardiovascular disease  
or any other medical  
condition [including but not  
limited to clinically relevant  
abnormal laboratory  
parameters]) in the  
judgment of the  
Investigator.  
The subject has a body ☐  
mass index (BMI) <18.5 or  
≥32.0 kg/m<sup>2</sup>.



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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Exclusion Criteria  
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---

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

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

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="radio"/>
	Yes <input type="radio"/>
	NA <input type="radio"/>

---

---

Inclusion/Exclusion Criterion Number	17
--------------------------------------	----

---

Inclusion/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, , prisoners or subjects who are involuntarily incarcerated). ☐
- The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator. ☐
- The subject has a body mass index (BMI) <18.5 or  $\geq 32.0$  kg/m<sup>2</sup>. ☐

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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Exclusion Criteria  
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---

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

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

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"/>

---

---

Inclusion/Exclusion Criterion Number	18
--------------------------------------	----

---

Inclusion/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, , prisoners or  
subjects who are  
involuntarily incarcerated).  
The subject has medical ☐  
condition requiring  
smoking cessation, or  
clinically relevant diseases  
(including but not limited  
to gastrointestinal, renal,  
hepatic, neurological,  
hematological, endocrine,  
oncological, urological,  
immunological, pulmonary  
and cardiovascular disease  
or any other medical  
condition [including but not  
limited to clinically relevant  
abnormal laboratory  
parameters]) in the  
judgment of the  
Investigator.  
The subject has a body ☐  
mass index (BMI) <18.5 or  
≥32.0 kg/m<sup>2</sup>.



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.

The subject has used ☐  
nicotine containing  
products other than  
commercially available  
mCC (either tobacco-based  
products or  
nicotine-replacement  
therapy) 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 5  
half-lives of the drug prior  
to the Admission Day (Day  
-1; whichever is longer)  
that has an impact on  
CYP2A6 activity.

- In case the subject received any medication (prescribed or over the counter) within 14 days prior to Screening or prior to the Admission Day (Day -1) it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives and subject's safety. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in study. ☐
- 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, child). ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Exclusion Criteria**  
**Generated On: 07 Nov 2013 16:29:10**

---

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

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

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 ☐  
Yes ☐  
NA ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Randomization**  
**Generated On: 07 Nov 2013 16:29:10**

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Randomization number (4 digits) \_\_\_\_\_

---

Sequence Subject randomised to:

- Sequence 1 THS 2.2 ☐  
Menthol- mCC  
Sequence 2 mCC - THS ☐  
2.2 Menthol  
Sequence 3 NRT gum - ☐  
THS 2.2 Menthol  
Sequence 4 THS 2.2 ☐  
Menthol - NRT gum
- 

Nicotine level

- $\leq 0.6\text{mg}$  ☐  
 $> 0.6\text{mg}$  and  $\leq 1\text{mg}$  ☐
-

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Demographics**  
**Generated On: 07 Nov 2013 16:29:10**

---

Date of Birth

Fixed Unit:  
DD/MMM/YYYY

---

Sex

Male ☐  
Female ☐

---

Is the Subject Japanese?

No ☐  
Yes ☐

---

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

---

Age(Derived)

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: THS 2.2 Menthol product test**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: NRT gum product test**  
**Generated On: 07 Nov 2013 16:29:10**

---

Was the NRT gum product trial performed?

No ☐  
Yes ☐

---

If the NRT gum product trial was not performed, please  
explain \_\_\_\_\_

---

How many NRT gum did the subject take on this day? \_\_\_\_\_

---

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

No ☐  
Yes ☐

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: THS 2.2 Menthol product demonstration**

**Generated On: 07 Nov 2013 16:29:10**

---

Has the subject seen a THS 2.2 Menthol product demonstration?

No ☐  
Yes ☐

---

If the subject did not see the demonstration please explain

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: NRT product demonstration**  
**Generated On: 07 Nov 2013 16:29:10**

---

Has the subject seen a NRT product demonstration?

No ☐  
Yes ☐

---

If the subject did not see the demonstration please  
explain

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Product administration-NRT gum**  
**Generated On: 07 Nov 2013 16:29:10**

---

H\_NOW (Derived):

---

---

Date of product use

Fixed Unit:  
DD/MMM/YYYY

---

Visit

Admission ☐

Day1 ☐

Day 3 ☐

---

Type of Product Use

mCC ☐

NRT Gum ☒

THS 2.2 Menthol ☐

---

If different from the randomization please explain

---

Time of distribution

hour:min 24-hour clock

---

Time of NRT gum intake

hour:min 24-hour clock

---

Time of product return

hour:min 24-hour clock

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Product administration-NRT gum**  
**Generated On: 07 Nov 2013 16:29:10**

---

Time of last chew/removal  
hour:min 24-hour clock

---

Comment

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Product administration-mCC**  
**Generated On: 07 Nov 2013 16:29:10**

H\_NOW (Derived):

Date of product use  
DD/MMM/YYYY

Visit

Admission ☐

Day1 ☐

Day 3 ☐

Type of Product Use

mCC ☒

NRT Gum ☐

THS 2.2 Menthol ☐

If Type of Product Use different from the randomization  
please explain

hour:min 24-hour clockTime of distribution

Time of lighting  
hour:min:sec 24-hour clock

Time of butt return  
hour:min 24-hour clock

Comment

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Product administration-THS 2.2 Menthol**  
**Generated On: 07 Nov 2013 16:29:10**

H\_NOW (Derived): \_\_\_\_\_

Date of product use  
DD/MMM/YYYY \_\_\_\_\_

Visit \_\_\_\_\_ Admission ☐  
Day1 ☐  
Day 3 ☐

Type of Product Use \_\_\_\_\_ mCC ☐  
NRT Gum ☐  
THS 2.2 Menthol ☒

If Type of Product Use different from the randomization  
please explain \_\_\_\_\_

Time of distribution  
hour:min 24-hour clock \_\_\_\_\_

Time of 1st puff taken  
hour:min 24-hour clock \_\_\_\_\_

Time of product return  
hour:min 24-hour clock \_\_\_\_\_

Comment \_\_\_\_\_

Batch Number \_\_\_\_\_

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Identification of Current mCC Brand**  
**Generated On: 07 Nov 2013 16:29:10**

---

Date

Fixed Unit:  
DD/MMM/YYYY

---

Brand name

---

ISO Tar Yield

Fixed Unit: MG

---

ISO Tar Yield unit

Milligram ☒

---

ISO Nicotine Yield

Fixed Unit: MG

---

ISO Nicotine Yield unit

Milligram ☒

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Identification of NRT Gum Brand**  
**Generated On: 07 Nov 2013 16:29:10**

---

Date

Fixed Unit:  
DD/MMM/YYYY

---

Was Nicorette® gum 2 mg assigned?

No ☐  
Yes ☐

---

If no, specify brand name:

---

Nicotine Dosage

Fixed Unit: mg

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Smoking History**  
**Generated On: 07 Nov 2013 16:29:10**

---

Date of Assessment

Fixed Unit:  
DD/MMM/YYYY

---

Time of Assessment

Fixed Unit:  
hour:min 24-hour clock

---

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

No ☐  
Yes ☐

---

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

No ☐  
Yes ☐

---

3. How many 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 CC (either tobacco-based products or nicotine-replacement therapy [NRT]), electronic cigarettes and similar devices, within 4 weeks prior to assessment.

No ☐  
Yes ☐



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: FTND Questionnaire**  
**Generated On: 07 Nov 2013 16:29:10**

---

Type	Fagerstrom Test for Nicotine Dependence
------	---

---

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

---

---

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

---

---

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

---

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

---

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

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: FTND Questionnaire**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

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

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Medical History/Concomitant Disease**  
**Generated On: 07 Nov 2013 16:29:10**

---

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):

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

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 ☐

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Other, Specify \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

System	General Appearance	<input type="checkbox"/>
	HEENT	<input type="checkbox"/>
	(head, eyes, ears, nose, throat)	
	Thyroid Gland	<input checked="" 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 \_\_\_\_\_

---

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

Not Done \_\_\_\_\_

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance	<input type="checkbox"/>
	HEENT	<input type="checkbox"/>
	(head, eyes, ears, nose,	
	throat)	
	Thyroid Gland	<input type="checkbox"/>
	Heart	<input checked="" 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 \_\_\_\_\_

---

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

Abnormal, please specify:

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" 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 \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Abnormal, please specify: \_\_\_\_\_

---

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 \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

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 ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Other, Specify \_\_\_\_\_

---

Outcome

Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant

No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

System	General Appearance	<input 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 checked="" 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 \_\_\_\_\_

---

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

Not Done \_\_\_\_\_

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance	<input 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 checked="" type="checkbox"/>
	Back	<input type="checkbox"/>
	Musculoskeletal	<input type="checkbox"/>
	Abdomen	<input type="checkbox"/>
	Dentition	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

Abnormal, please specify:

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" type="checkbox"/>
	Abdomen <input type="checkbox"/>
	Dentition <input type="checkbox"/>
	Other <input type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" type="checkbox"/>
	Dentition <input type="checkbox"/>
	Other <input type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

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 ☐

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Other, Specify \_\_\_\_\_

---

Outcome

Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant

No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

System	General Appearance	<input 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 checked="" type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

Not Done \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance	<input 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 checked="" type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

---

Abnormal, please specify:

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Abnormal, please specify: \_\_\_\_\_

---

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 \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

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

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="radio"/>
	Yes	<input type="radio"/>

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Advice on the risk of smoking and Debriefing**

**Generated On: 07 Nov 2013 16:29:10**

---

Has the subject received advices on the risks of  
smoking?

No ☐  
Yes ☐

---

Has a debriefing been performed about THS 2.2  
Menthol?

No ☐  
Yes ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Was the physical examination performed? No ☐  
Yes ☐

---

If No, please specify the reason: \_\_\_\_\_

---

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

---

---

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

---

Other, Specify \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

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 ☐

---

---

**Final 2.0. (Main CRF): Case Book**  
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---

Other, Specify \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Physical Examination  
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---

System	General Appearance	<input type="checkbox"/>
	HEENT	<input type="checkbox"/>
	(head, eyes, ears, nose, throat)	
	Thyroid Gland	<input checked="" 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 \_\_\_\_\_

---

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

Not Done \_\_\_\_\_

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

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 ☐

Abnormal, please specify: \_\_\_\_\_

Clinically significant

No ☐  
Yes ☐



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

Abnormal, please specify:

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" 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 \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" 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 \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

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 ☐

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
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**Generated On: 07 Nov 2013 16:29:10**

---

Other, Specify \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Physical Examination  
Generated On: 07 Nov 2013 16:29:10

System	General Appearance	<input 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 checked="" 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 \_\_\_\_\_

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

Abnormal, please specify: \_\_\_\_\_

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

Not Done \_\_\_\_\_

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance	<input 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 checked="" type="checkbox"/>
	Back	<input type="checkbox"/>
	Musculoskeletal	<input type="checkbox"/>
	Abdomen	<input type="checkbox"/>
	Dentition	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

Abnormal, please specify:

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" type="checkbox"/>
	Abdomen <input type="checkbox"/>
	Dentition <input type="checkbox"/>
	Other <input type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" type="checkbox"/>
	Dentition <input type="checkbox"/>
	Other <input type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

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 ☐

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Other, Specify \_\_\_\_\_

---

Outcome

Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant

No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Physical Examination  
Generated On: 07 Nov 2013 16:29:10

System	General Appearance	<input 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 checked="" type="checkbox"/>

Other, Specify \_\_\_\_\_

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

Abnormal, please specify: \_\_\_\_\_

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

Not Done \_\_\_\_\_

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome	Normal <input type="checkbox"/>
	Abnormal <input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

Abnormal, please specify:

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

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

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No <input type="radio"/>
	Yes <input type="radio"/>

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Weight and Height**  
**Generated On: 07 Nov 2013 16:29:10**

---

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/m<sup>2</sup>

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Weight**  
**Generated On: 07 Nov 2013 16:29:10**

---

Measurement(s) assessed?

No ☐  
Yes ☐

---

If No, please specify the reason: \_\_\_\_\_

---

Time of assessment

Fixed Unit:  
hour:min 24-hour clock

---

Weight

Fixed Unit:  
kg

---

BMI (Derived)

Fixed Unit:  
kg/m2

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Vital Signs Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Were vital 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

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Vital Signs Screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Blood Pressure (diastolic)

Fixed Unit:  
mmHg

---

Vital Signs Position of Subject

Sitting ☐  
Standing ☐  
Supine ☒

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Vital Signs**  
**Generated On: 07 Nov 2013 16:29:10**

---

Were vital signs assessed? No ☐  
Yes ☐

---

If No, please specify the reason: \_\_\_\_\_

---

Has the subject smoked within 15 minutes prior to assessment No ☐  
Yes ☐

---

Time of assessment 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  
\_\_\_\_\_

---

Blood Pressure (diastolic) Fixed Unit:  
mmHg  
\_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Vital Signs**  
**Generated On: 07 Nov 2013 16:29:10**

---

Vital Signs Position of Subject

Sitting ☐  
Standing ☐  
Supine ☒

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: ECG (12-Lead Standard) screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

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

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: ECG (12-Lead Standard) screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

QT Interval unit msec

---

QTcB Interval Fixed Unit: msec

---

---

QTcB 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)

---

---

End Date and Time Fixed Unit:  
DD/MMM/YYYY  
hour:min 24-hour clock

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: ECG (12-Lead Standard)**  
**Generated On: 07 Nov 2013 16:29:10**

---

Method of ECG Test 12 Lead Placement Cabrera ☐

---

Was the ECG performed? No ☐  
Yes ☐

---

If No, please specify the reason: \_\_\_\_\_

---

Time of assessment \_\_\_\_\_

---

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

---

QT Interval unit msec

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: ECG (12-Lead Standard)**  
**Generated On: 07 Nov 2013 16:29:10**

---

QTcB Interval	Fixed Unit: msec
---------------	------------------

---

---

QTcB Interval unit	msec
--------------------	------

---

---

PR Interval	Fixed Unit: msec
-------------	------------------

---

---

PR Interval unit	msec
------------------	------

---

---

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

---

---

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

---

---

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

---

---

End Date and Time	Fixed Unit: DD/MMM/YYYY hour:min 24-hour clock
-------------------	--

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Spirometry**  
**Generated On: 07 Nov 2013 16:29:10**

Was the spirometry performed?

No ☐

Yes ☐

If No, please specify the reason: \_\_\_\_\_

Category

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

Date of assessment:  
DD/MMM/YYYY

Time of assessment:  
hour:min 24-hour clock

Name of bronchodilator

Dose

Predicted FVC value  
L

Best measured FVC value  
L

Percent of predicted FVC value  
%

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Spirometry**  
**Generated On: 07 Nov 2013 16:29:10**

---

Best measured FEV1 value  
L

---

Predicted FEV1 value

Fixed Unit:  
L

---

Percent of predicted FEV1 value  
%

---

Calculated ratio between FEV1/FVC

---

Interpretation

Normal ☐  
Abnormal ☐

---

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:

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Spirometry**  
**Generated On: 07 Nov 2013 16:29:10**

Category

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

Date of assessment:  
DD/MMM/YYYY

Time of assessment:  
hour:min 24-hour clock

Name of bronchodilator

Dose

Predicted FVC value  
L

Best measured FVC value  
L

Percent of predicted FVC value  
%

Best measured FEV1 value  
L

Predicted FEV1 value

Fixed Unit:  
L

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Spirometry**  
**Generated On: 07 Nov 2013 16:29:10**

---

Percent of predicted FEV1 value  
%

---

---

Calculated ratio between FEV1/FVC

---

---

Interpretation

Normal ☐  
Abnormal ☐

---

If Abnormal, Clinical Significance

Not clinically significant ☐  
Clinically significant ☐

---

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

---



**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Spirometry without a short-acting bronchodilator**

**Generated On: 07 Nov 2013 16:29:10**

---

Was the spirometry performed?

No ☐  
Yes ☐

---

If No, please specify the reason: \_\_\_\_\_

---

Category

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

---

Date of assessment:

Fixed Unit:  
DD/MMM/YYYY

---

Time of assessment:

Fixed Unit:  
hour:min 24-hour clock

---

Predicted FVC value

Fixed Unit:  
L

---

Best measured FVC value

Fixed Unit:  
L

---

Percent of predicted FVC value

Fixed Unit:  
%

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Spirometry without a short-acting bronchodilator**

**Generated On: 07 Nov 2013 16:29:10**

---

Best measured FEV1 value

Fixed Unit:  
L

---

Predicted FEV1 value

Fixed Unit:  
L

---

Percent of predicted FEV1 value

Fixed Unit:  
%

---

Interpretation

Normal ☐  
Abnormal ☐

---

If Abnormal, Clinical Significance

Not clinically significant ☐  
Clinically significant ☐

---

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

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Chest X-Ray**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 <input type="checkbox"/>
	HEENT <input type="checkbox"/>
	(head, eyes, ears, nose, throat)
	Thyroid Gland <input type="checkbox"/>
	Heart <input type="checkbox"/>
	Chest <input checked="" 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"/>

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Chest X-Ray**  
**Generated On: 07 Nov 2013 16:29:10**

---

Interpretation Normal ☐  
Abnormal ☐

---

Clinically significant No ☐  
Yes ☐

---

Abnormal, please specify: \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Haematology**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine analysis**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

Were samples collected?

No ☐  
Yes ☐

---

If No, please specify the reason: \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Clinical Chemistry**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Serology for HIV and Hepatitis B and C**

**Generated On: 07 Nov 2013 16:29:10**

---

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☒

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Breath Test ☐

---

Not Done

---

If Not Done, please specify the reason:

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

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"/>

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

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

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Result

Negative ☐  
Positive ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

---

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Urine Drug Screen  
Generated On: 07 Nov 2013 16:29:10

---

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"/>

---

---

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

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen**  
**Generated On: 07 Nov 2013 16:29:10**

---

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

---

---

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

---

---

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

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Alcohol Breath Test screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

Was the alcohol breath test performed?

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

---

Result

Negative ☐  
Positive ☐



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Alcohol Breath Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

Was the alcohol breath test performed?

No ☐  
Yes ☐

---

If No, please specify the reason: \_\_\_\_\_

---

Time of assessment

Fixed Unit:  
hour:min 24-hour clock

---

Result

Negative ☐  
Positive ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Pregnancy Test screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

Not Done

---

If Not Done, specify reason

---

Date of Test

Fixed Unit:  
DD/MMM/YYYY

---

Specify result

Negative ☐  
Positive ☐  
Unclear ☐

---

If unclear, please confirm with FSH test

---

Specify result of FSH test

< 20 IU/L ☐  
>= 20 IU/L ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Pregnancy Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

Not Done

---

If Not Done, specify reason

---

Specify result

Negative ☐  
Positive ☐  
Unclear ☐

---

If unclear, please confirm with FSH test

---

Specify result of FSH test

< 20 IU/L ☐  
>= 20 IU/L ☐

---

Time of Test

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Cotinine Test screening**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

Clinical Chemistry ☐  
Drug Screen ☐  
Haematology ☐  
Serology ☐  
Pregnancy Testing ☐  
Urinalysis ☐  
Cotinine Screening ☒  
Alcohol Breath 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 mg/ml ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Cotinine Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

Not Done

---

If Not Done, please specify the reason:

---

Time of Sample Collection

Fixed Unit:  
hour:min 24-hour clock

---

Result

Negative <200 ng/ml ☐  
Positive >=200 mg/ml ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Plasma Nicotine Sample**  
**Generated On: 07 Nov 2013 16:29:10**

---

H\_NOW (Derived): \_\_\_\_\_

---

---

Not Done \_\_\_\_\_

---

---

If Not Done, please specify the reason: \_\_\_\_\_

---

---

Date  
DD/MMM/YYYY \_\_\_\_\_

---

---

Scheduled Time	T0 -15 min <input type="checkbox"/>
	T1 <input type="checkbox"/>
	T2 <input type="checkbox"/>
	T3 <input type="checkbox"/>
	T4 <input type="checkbox"/>
	T5 <input type="checkbox"/>
	T6 <input type="checkbox"/>
	T7 <input type="checkbox"/>
	T8 <input type="checkbox"/>
	T9 <input type="checkbox"/>
	T10 <input type="checkbox"/>
	T11 <input type="checkbox"/>
	T12 <input type="checkbox"/>
	T13 <input type="checkbox"/>
	T14 <input type="checkbox"/>
	T15(T0 + 24) <input checked="" type="checkbox"/>

---

---

Time  
hour:min 24-hour clock \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CoHb Blood Sample**  
**Generated On: 07 Nov 2013 16:29:10**

---

---

Not Done

If Not Done, please specify the reason:

Scheduled Time

T0 -15 min ☒

T1 ☐

T2 ☐

T3 ☐

T4 ☐

T5 ☐

T6 ☐

T7 ☐

T8 ☐

T9 ☐

T10 ☐

T11 ☐

T12 ☐

T13 ☐

T14 ☐

T15(T0 + 24) ☐

---

---

Not Done

If Not Done, please specify the reason:

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CoHb Blood Sample**  
**Generated On: 07 Nov 2013 16:29:10**

---

Scheduled Time

T0 -15 min ☐

T1 ☒

T2 ☐

T3 ☐

T4 ☐

T5 ☐

T6 ☐

T7 ☐

T8 ☐

T9 ☐

T10 ☐

T11 ☐

T12 ☐

T13 ☐

T14 ☐

T15(T0 + 24) ☐

---

Not Done

---

If Not Done, please specify the reason:

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CoHb Blood Sample**  
**Generated On: 07 Nov 2013 16:29:10**

---

Scheduled Time

T0 -15 min ☐

T1 ☐

T2 ☒

T3 ☐

T4 ☐

T5 ☐

T6 ☐

T7 ☐

T8 ☐

T9 ☐

T10 ☐

T11 ☐

T12 ☐

T13 ☐

T14 ☐

T15(T0 + 24) ☐

---

Not Done

---

If Not Done, please specify the reason:

---

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: CoHb Blood Sample  
Generated On: 07 Nov 2013 16:29:10

---

Scheduled Time

T0 -15 min ☐

T1 ☐

T2 ☐

T3 ☒

T4 ☐

T5 ☐

T6 ☐

T7 ☐

T8 ☐

T9 ☐

T10 ☐

T11 ☐

T12 ☐

T13 ☐

T14 ☐

T15(T0 + 24) ☐

---

Not Done

If Not Done, please specify the reason:

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CoHb Blood Sample**  
**Generated On: 07 Nov 2013 16:29:10**

---

Scheduled Time

T0 -15 min ☐  
T1 ☐  
T2 ☐  
T3 ☐  
T4 ☒  
T5 ☐  
T6 ☐  
T7 ☐  
T8 ☐  
T9 ☐  
T10 ☐  
T11 ☐  
T12 ☐  
T13 ☐  
T14 ☐  
T15(T0 + 24) ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CO Breath Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

Assessment not done

---

If not done, please specify the reason:

---

Actual Time of Assessment

Fixed Unit:  
hour:min 24-hour clock

---

Result

Fixed Unit: ppm

---

Unit

ppm

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CO Breath Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

---

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 ☐

---

Actual Time of Assessment  
hour:min 24-hour clock \_\_\_\_\_

---

Result(ppm) \_\_\_\_\_

---

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 ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CO Breath Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

Actual Time of Assessment  
hour:min 24-hour clock

---

Result(ppm)

---

---

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 ☐

---

Actual Time of Assessment  
hour:min 24-hour clock

---

Result(ppm)

---

---

Assessment not done

---

---

If not done, please specify the reason:

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CO Breath Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

Scheduled Time	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"/>

---

Actual Time of Assessment	
hour:min 24-hour clock	<hr/>

---

Result(ppm)	<hr/>
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---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CO Breath Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

---

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 ☒

---

Actual Time of Assessment  
hour:min 24-hour clock \_\_\_\_\_

---

Result(ppm) \_\_\_\_\_

---

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 ☐



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CO Breath Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

Actual Time of Assessment  
hour:min 24-hour clock

---

Result(ppm)

---

---

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 ☐

---

Actual Time of Assessment  
hour:min 24-hour clock

---

Result(ppm)

---

---

Assessment not done

---

---

If not done, please specify the reason:

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CO Breath Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

Scheduled Time	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"/>

---

Actual Time of Assessment	
hour:min 24-hour clock	<hr/>

---

Result(ppm)	<hr/>
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---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CYP2A6 activity samples**  
**Generated On: 07 Nov 2013 16:29:10**

Not Done

If Not Done, please specify the reason:

Was the sample taken prior to smoking?

No ☐

Yes ☐

H\_NOW (Derived):

Date of Sample Collection

Fixed Unit:  
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit:  
hour:min 24-hour clock

Parameter

trans-3'-hydroxycotinine ☒  
cotinine ☐

Date of Sample Collection

Fixed Unit:  
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit:  
hour:min 24-hour clock

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CYP2A6 activity samples**  
**Generated On: 07 Nov 2013 16:29:10**

---

Parameter

trans-3'-hydroxycotinine ☐  
cotinine ☒

---

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Previous and Concomitant Medication Y/N**

**Generated On: 07 Nov 2013 16:29:10**

---

Has the subject taken previous or concomitant  
medication?

No ☐  
Yes ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 07 Nov 2013 16:29:10**

Number	
Brand Name	
Start Date DD/MMM/YYYY	
Stop Date DD/MMM/YYYY	
Ongoing at final contact	
Total Daily dose - Dose	

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐
-

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 07 Nov 2013 16:29:10**

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- 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 ☐

- 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 ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 07 Nov 2013 16:29:10**

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- 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 ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 07 Nov 2013 16:29:10**

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- 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 ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 07 Nov 2013 16:29:10**

---

- 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 \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Adverse Events Y/N**  
**Generated On: 07 Nov 2013 16:29:10**

---

Was there any Adverse Event for this subject?

No ☐  
Yes ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Adverse Events**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

Treatment given

No ☐

Yes ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Adverse Events**  
**Generated On: 07 Nov 2013 16:29:10**

---

Relationship to study procedures Related ☐  
Not Related ☐

---

Relationship (mCC/THS) Related ☐  
Not Related ☐

---

Relationship (NRT) Related ☐  
Not Related ☐

---

AE expectedness (mCC/THS) No ☐  
Yes ☐

---

AE expectedness (NRT) No ☐  
Yes ☐

---

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

---

Other action taken \_\_\_\_\_

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Adverse Events**  
**Generated On: 07 Nov 2013 16:29:10**

---

Outcome

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

---

H\_NOW (Derived):

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: End of study**  
**Generated On: 07 Nov 2013 16:29:10**

---

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:

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Questionnaire on smoking urges (QSU)**  
**Generated On: 07 Nov 2013 16:29:10**

---

Type	QSU
------	-----

---

Date of Birth YYYY MMM DD	Fixed Unit: YYYY MMM DD
------------------------------	----------------------------

---

---

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

---

---

Assessment Window	Initial Assessment QSU <input type="checkbox"/>
	Window 1 <input type="checkbox"/>
	Window 2 <input type="checkbox"/>
	Window 3 <input type="checkbox"/>
	Window 4 <input type="checkbox"/>
	Window 5 <input type="checkbox"/>
	Window 6 <input type="checkbox"/>
	Window 7 <input type="checkbox"/>
	Window 8 <input type="checkbox"/>
	Window 9 <input type="checkbox"/>

---

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

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Questionnaire on smoking urges (QSU)**  
**Generated On: 07 Nov 2013 16:29:10**

---

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"/>

---

2. Nothing would be better than smoking 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"/>

---

3. If it were possible I would probably smoke 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"/>

---

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 ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Questionnaire on smoking urges (QSU)**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

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

**Generated On: 07 Nov 2013 16:29:10**

---

Type	MCEQ
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---

Date of Birth YYYY MMM DD	Fixed Unit: YYYY MMM DD
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---

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

---

Time of assessment hour:min 24-hour clock	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"/>

---



**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

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

**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐
-

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

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

**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

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

**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

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

**Generated On: 07 Nov 2013 16:29:10**

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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 ☐
-

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Cough Assessment**  
**Generated On: 07 Nov 2013 16:29:10**

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Type	VAS for Cough
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Date of Birth YYYY MMM DD	Fixed Unit: YYYY MMM DD
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Date of assessment YYYY MMM DD	Fixed Unit: YYYY MMM DD
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---

---

Time of assessment hour:min 24-hour clock	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?

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Cough Assessment**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Device report - THS 2.2 Menthol Cigarette Holder**

**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Device report - THS 2.2 Menthol Cigarette Holder**

**Generated On: 07 Nov 2013 16:29:10**

---

Other Describe \_\_\_\_\_

---

Severity of Event

Minor (can be resolved easily) ☐

Major (cannot be resolved. Device needs to be exchanged) ☐

---

Adverse Event  
Relationship

Is related to AE ☐

Is not related to AE ☐

---

If Related to AE, AE Number \_\_\_\_\_

---

Solution Proposed:

Device Replaced ☐

Device Recharged ☐

Device Withdrawn ☐

---

If replaced, new device serial number: \_\_\_\_\_

---

Date of Device Event Closure:  
DD/MMM/YYYY

Time of Device Event Closure:  
hour:min 24-hour clock

---



**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Device report - THS 2.2 Menthol Charging Unit**

**Generated On: 07 Nov 2013 16:29:10**

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) ☐

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Device report - THS 2.2 Menthol Charging Unit**

**Generated On: 07 Nov 2013 16:29:10**

---

Adverse Event  
Relationship

Is related to AE ☐  
Is not related to AE ☐

---

Solution Proposed:

Device Replaced ☐  
Device Recharged ☐  
Device Withdrawn ☐

---

If replaced, new device serial number: \_\_\_\_\_

---

Date of Device Event Closure:  
DD/MMM/YYYY \_\_\_\_\_

---

Time of Device Event Closure:  
DD/MMM/YYYY \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Device Inventory - THS 2.2 Menthol Cigarette Holder**

**Generated On: 07 Nov 2013 16:29:10**

---

---

Device Inventory  
Log Number

Visit

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

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Device Inventory - THS 2.2 Menthol Charging Unit**

**Generated On: 07 Nov 2013 16:29:10**

---

---

Device Inventory  
Log Number

---

Visit

---

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

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Vital Signs**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: ECG (12-Lead Standard)**  
**Generated On: 07 Nov 2013 16:29:10**

Date of assessment  
DD/MMM/YYYY

Time of assessment  
hour:min 24-hour clock

Position

Sitting ☐  
Standing ☐  
Supine ☒

Heart Rate  
(beats per minute)

QRS Interval  
(msec)

QT Interval  
(msec)

QTcB Interval  
(msec)

PR Interval  
(msec)

Interpretation

Normal ☐  
Abnormal ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: ECG (12-Lead Standard)**  
**Generated On: 07 Nov 2013 16:29:10**

---

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

---

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

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Spirometry**  
**Generated On: 07 Nov 2013 16:29:10**

---

---

Category	With short-acting bronchodilator <input type="radio"/>
	Without short-acting bronchodilator <input type="radio"/>

---

Date of assessment:  
DD/MMM/YYYY 

---

---

Time of assessment:  
hour:min 24-hour clock 

---

---

Name of bronchodilator 

---

---

Dose 

---

---

Predicted FVC value  
L 

---

---

Best measured FVC value  
L 

---

---

Percent of predicted FVC value  
% 

---

---

Best measured FEV1 value  
L 

---

---

Predicted FEV1 value  
L 

---

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Spirometry**  
**Generated On: 07 Nov 2013 16:29:10**

---

Percent of predicted FEV1 value  
%

---

Interpretation

Normal ☐  
Abnormal ☐

---

If Abnormal, Clinical Significance

Not clinically significant ☐  
Clinically significant ☐

---

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

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

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:

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

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"/>

---

Other, Specify \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input type="checkbox"/>
	HEENT <input type="checkbox"/>
	(head, eyes, ears, nose, throat)
	Thyroid Gland <input checked="" 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 \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

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 ☐

---

---

**Final 2.0. (Main CRF): Case Book**  
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---

Other, Specify \_\_\_\_\_

---

Outcome

Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant

No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Physical Examination  
Generated On: 07 Nov 2013 16:29:10

---

System	General Appearance	<input type="checkbox"/>
	HEENT	<input type="checkbox"/>
	(head, eyes, ears, nose, throat)	
	Thyroid Gland	<input type="checkbox"/>
	Heart	<input type="checkbox"/>
	Chest	<input checked="" 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 \_\_\_\_\_

---

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

Not Done \_\_\_\_\_

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

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 ☐

Abnormal, please specify: \_\_\_\_\_

Clinically significant

No ☐  
Yes ☐



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

Abnormal, please specify:

---

**Final 2.0. (Main CRF): Case Book**  
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---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" 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 \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---

**Final 2.0. (Main CRF): Case Book**  
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**Generated On: 07 Nov 2013 16:29:10**

---

Abnormal, please specify: \_\_\_\_\_

---

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 \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

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 ☐

---

---

**Final 2.0. (Main CRF): Case Book**  
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---

Other, Specify \_\_\_\_\_

---

Outcome

Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant

No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

System	General Appearance	<input 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 checked="" type="checkbox"/>
	Musculoskeletal	<input type="checkbox"/>
	Abdomen	<input type="checkbox"/>
	Dentition	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

Not Done \_\_\_\_\_

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

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 ☐

Abnormal, please specify: \_\_\_\_\_

Clinically significant

No ☐  
Yes ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

Abnormal, please specify:

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" type="checkbox"/>
	Other <input type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome Normal ☐  
Abnormal ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
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**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Outcome Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

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 ☒

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Other, Specify \_\_\_\_\_

---

Outcome

Normal ☐  
Abnormal ☐

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant

No ☐  
Yes ☐

---

Not Done \_\_\_\_\_

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

Final 2.0. (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Physical Examination  
Generated On: 07 Nov 2013 16:29:10

---

System	General Appearance	<input 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 checked="" type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

Not Done \_\_\_\_\_

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Not Done; please specify the reason: \_\_\_\_\_

---

---

System	General Appearance <input 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 checked="" type="checkbox"/>

---

Other, Specify \_\_\_\_\_

---

Outcome	Normal <input type="checkbox"/>
	Abnormal <input type="checkbox"/>

---

Abnormal, please specify: \_\_\_\_\_

---

Clinically significant	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

Abnormal, please specify:

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 07 Nov 2013 16:29:10**

---

Clinically significant

No ☐  
Yes ☐

---

Not Done

---

Not Done; please specify the reason:



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Weight**  
**Generated On: 07 Nov 2013 16:29:10**

---

Date of assessment  
DD/MMM/YYYY

---

Time of assessment  
hour:min 24-hour clock

---

Weight

Fixed Unit:  
kg

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: X-Ray**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category for Examination

Chest X-Ray ☐

---

System

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

---

Date of assessment  
DD/MMM/YYYY

---

Interpretation

Normal ☐  
Abnormal ☐

---

Clinically significant

No ☐  
Yes ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: X-Ray**  
**Generated On: 07 Nov 2013 16:29:10**

---

Abnormal, please specify: \_\_\_\_\_

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Clinical Chemistry**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

Date of Sample Collection  
DD/MMM/YYYY

---

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

No ☐  
Yes ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Haematology**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

Date of Sample Collection  
DD/MMM/YYYY

---

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

No ☐  
Yes ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine analysis**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

Date of sample collection  
DD/MMM/YYYY

---

Time of sample collection

---

Urinalysis

---

Result

---

Unit

---

Lower limit

---

Upper limit

---

Flag

---

Clinically Significant?

No ☐  
Yes ☐

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine analysis**  
**Generated On: 07 Nov 2013 16:29:10**

---

Comment

---

Please document clinically relevant abnormalities in the AE form

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Serology for HIV and Hepatitis B and C**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

Date of Sample Collection

Fixed Unit:  
DD/MMM/YYYY

---

Time of Sample Collection

Fixed Unit:  
hour:min 24-hour clock



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Serology for HIV and Hepatitis B and C**  
**Generated On: 07 Nov 2013 16:29:10**

---

Serology

Haematocrit ☐  
Hemoglobin ☐  
Mean corpuscular ☐  
haemoglobin  
Mean corpuscular ☐  
haemoglobin concentration  
Mean corpuscular volume ☐  
Platelet count ☐  
Red blood cell count ☐  
White blood cell count ☐  
Neutrophils ☐  
Basophils ☐  
Eosinophils ☐  
Lymphocytes ☐  
Monocytes ☐  
Albumin ☐  
Total protein ☐  
Alkaline phosphatase ☐  
Alanine aminotransferase ☐  
Aspartate aminotransferase ☐  
Blood urea nitrogen ☐  
Creatinine ☐  
Gamma-glutamyl ☐  
transferase  
Fasting glucose ☐  
Lactate dehydrogenase ☐  
Potassium ☐  
Sodium ☐  
Total Bilirubin ☐  
Direct Bilirubin ☐  
Total Cholesterol ☐  
Triglycerides ☐

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Serology for HIV and Hepatitis B and C**

**Generated On: 07 Nov 2013 16:29:10**

---

	pH	<input type="checkbox"/>
	Bilirubin	<input type="checkbox"/>
	Glucose	<input type="checkbox"/>
	Nitrite	<input type="checkbox"/>
	Red blood cell traces	<input type="checkbox"/>
	Protein	<input type="checkbox"/>
	Specific gravity	<input type="checkbox"/>
	Hepatitis B surface antigen	<input checked="" type="checkbox"/>
	Hepatitis C virus	<input type="checkbox"/>
	HIV (anti HIV 1/2 and p24 antigen)	<input type="checkbox"/>

---

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

---

Comment	<hr/>
---------	-------

---

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Serology for HIV and Hepatitis B and C**

**Generated On: 07 Nov 2013 16:29:10**

---

Serology

- Haematocrit ☐
- Hemoglobin ☐
- Mean corpuscular ☐
- haemoglobin
- Mean corpuscular ☐
- haemoglobin concentration
- Mean corpuscular volume ☐
- Platelet count ☐
- Red blood cell count ☐
- White blood cell count ☐
- Neutrophils ☐
- Basophils ☐
- Eosinophils ☐
- Lymphocytes ☐
- Monocytes ☐
- Albumin ☐
- Total protein ☐
- Alkaline phosphatase ☐
- Alanine aminotransferase ☐
- Aspartate aminotransferase ☐
- Blood urea nitrogen ☐
- Creatinine ☐
- Gamma-glutamyl ☐
- transferase
- Fasting glucose ☐
- Lactate dehydrogenase ☐
- Potassium ☐
- Sodium ☐
- Total Bilirubin ☐
- Direct Bilirubin ☐
- Total Cholesterol ☐
- Triglycerides ☐

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Serology for HIV and Hepatitis B and C**

**Generated On: 07 Nov 2013 16:29:10**

---

pH ☐  
Bilirubin ☐  
Glucose ☐  
Nitrite ☐  
Red blood cell traces ☐  
Protein ☐  
Specific gravity ☐  
Hepatitis B surface antigen ☐  
Hepatitis C virus ☒  
HIV (anti HIV 1/2 and p24 antigen) ☐

---

Result Negative ☐  
Positive ☐

---

Comment \_\_\_\_\_

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Serology for HIV and Hepatitis B and C**  
**Generated On: 07 Nov 2013 16:29:10**

---

Serology

Haematocrit ☐  
Hemoglobin ☐  
Mean corpuscular ☐  
haemoglobin  
Mean corpuscular ☐  
haemoglobin concentration  
Mean corpuscular volume ☐  
Platelet count ☐  
Red blood cell count ☐  
White blood cell count ☐  
Neutrophils ☐  
Basophils ☐  
Eosinophils ☐  
Lymphocytes ☐  
Monocytes ☐  
Albumin ☐  
Total protein ☐  
Alkaline phosphatase ☐  
Alanine aminotransferase ☐  
Aspartate aminotransferase ☐  
Blood urea nitrogen ☐  
Creatinine ☐  
Gamma-glutamyl ☐  
transferase  
Fasting glucose ☐  
Lactate dehydrogenase ☐  
Potassium ☐  
Sodium ☐  
Total Bilirubin ☐  
Direct Bilirubin ☐  
Total Cholesterol ☐  
Triglycerides ☐

**Final 2.0. (Main CRF): Case Book**

**Project Name: ZRHM-PK-05-JP**

**Form: Serology for HIV and Hepatitis B and C**

**Generated On: 07 Nov 2013 16:29:10**

---

	pH	<input type="checkbox"/>
	Bilirubin	<input type="checkbox"/>
	Glucose	<input type="checkbox"/>
	Nitrite	<input type="checkbox"/>
	Red blood cell traces	<input type="checkbox"/>
	Protein	<input type="checkbox"/>
	Specific gravity	<input type="checkbox"/>
	Hepatitis B surface antigen	<input type="checkbox"/>
	Hepatitis C virus	<input type="checkbox"/>
	HIV (anti HIV 1/2 and p24 antigen)	<input checked="" type="checkbox"/>

---

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

---

Comment	<hr/>
---------	-------

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen**  
**Generated On: 07 Nov 2013 16:29:10**

---

Category

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

---

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen**  
**Generated On: 07 Nov 2013 16:29:10**

---

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"/>

---

---

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

---

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen**  
**Generated On: 07 Nov 2013 16:29:10**

---

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

---

---

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

---

---

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

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Alcohol Breath Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

---

Category

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

---

Date of assessment  
DD/MMM/YYYY

---

Time of assessment  
hour:min 24-hour clock

---

Result

Negative ☐  
Positive ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Pregnancy Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

---

Category

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

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Blood Samples**  
**Generated On: 07 Nov 2013 16:29:10**

---

Date  
DD/MMM/YYYY

---

Time  
hour:min 24-hour clock

---

Scheduled Time

T0 -15 min ☐

T1 ☐

T2 ☐

T3 ☐

T4 ☐

T5 ☐

T6 ☐

T7 ☐

T8 ☐

T9 ☐

T10 ☐

T11 ☐

T12 ☐

T13 ☐

T14 ☐

T15(T0 + 24) ☐

---

Sample Type

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: (INACTIVE) CO Breath Test**  
**Generated On: 07 Nov 2013 16:29:10**

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Protocol Deviation**  
**Generated On: 07 Nov 2013 16:29:10**

Cohort \_\_\_\_\_

Subject \_\_\_\_\_

Assessment \_\_\_\_\_

Visit \_\_\_\_\_

Screen Failure ☐

Screening ☐

Wash-out 1 (Day 0) ☐

Single use 1 (Day 1) ☐

Wash-out 2 (Day 2) ☐

Single use 2 (Day 3) ☐

Day 4 ☐

Discharge ☐

Other ☐

Other, Specify \_\_\_\_\_

Timepoint \_\_\_\_\_

Description of Protocol Deviation \_\_\_\_\_

Date Deviation Occurred

DD/MMM/YYYY \_\_\_\_\_

Date Deviation Reported

DD/MMM/YYYY \_\_\_\_\_

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Protocol Deviation**  
**Generated On: 07 Nov 2013 16:29:10**

---

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 ☐

---

Deviation Type

Major ☐  
Minor ☐

---

If Major, Evaluation Category

Evaluable ☐  
Non Evaluable ☐

---

**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Subject (Site level)**  
**Generated On: 07 Nov 2013 16:29:10**

---

Subject (site level)

---



**Final 2.0. (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Site Accountability**  
**Generated On: 07 Nov 2013 16:29:10**

---

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) \_\_\_\_\_

---



## **16.1.2.2 SUBJECT QUESTIONNAIRE ENGLISH**

### **16.1.2.2.1 Cough Assessment**

## Cough assessment

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?

YES / NO

If YES, please answer the following questions:

### First Question: Cough Impact Scale

How much is your cough bothering you?

VAS: Not Bothering Me at All -----Extremely Bothersome

### Second Question: Cough Intensity Scale:

How intense is your cough?

1 = very mild - 2 = mild - 3 = moderate - 4 = severe - 5 = very severe

### Third Question: Cough Frequency Scale:

How frequently do you normally have to cough each day?

1 = rarely - 2 = sometimes - 3 = fairly often - 4 = often - 5 = almost always

### Fourth Question: Sputum Production

To what extent do you produce sputum when coughing?

0 = no sputum - 1 = a moderate amount of sputum - 2 = a large amount of sputum - 3 = a very large amount of sputum

### Fifth Question:

Are there any other important observations that you would like to share with us about you coughing? (open question)



#### **16.1.2.2.2 Fagerström Test for Nicotine Dependence**

## **Fagerstrom Test for Nicotine Dependence \***

Is smoking “just a habit” or are you addicted? Take this test and find out your level of dependence on nicotine.

1. How soon after you wake up do you smoke your first cigarette?
  - ◆ After 60 minutes (0)
  - ◆ 31-60 minutes (1)
  - ◆ 6-30 minutes (2)
  - ◆ Within 5 minutes (3)
2. Do you find it difficult to refrain from smoking in places where it is forbidden?
  - ◆ No (0)
  - ◆ Yes (1)
3. Which cigarette would you hate most to give up?
  - ◆ The first in the morning (1)
  - ◆ Any other (0)
4. How many cigarettes per day do you smoke?
  - ◆ 10 or less (0)
  - ◆ 11-20 (1)
  - ◆ 21-30 (2)
  - ◆ 31 or more (3)
5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?
  - ◆ No (0)
  - ◆ Yes (1)
6. Do you smoke even if you are so ill that you are in bed most of the day?
  - ◆ No (0)
  - ◆ Yes (1)

\* Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: A revision of the Fagerstrom Tolerance Questionnaire. British Journal of Addictions 1991;86:1119-27

## **Fagerstrom Test for Nicotine Dependence (cont.)**

Your score was: \_\_\_\_\_

Your level of dependence on nicotine is:

0-2 Very low dependence

3-4 Low dependence

5 Medium dependence

6-7 High dependence

8-10 Very high dependence

Scores under 5: "Your level of nicotine dependence is still low. You should act now before your level of dependence increases."

Score of 5: "Your level of nicotine dependence is moderate. If you don't quit soon, your level of dependence on nicotine will increase until you may be seriously addicted. Act now to end your dependence on nicotine."

Score over 7: "Your level of dependence is high. You aren't in control of your smoking – it is in control of you! When you make the decision to quit, you may want to talk with your doctor about nicotine replacement therapy or other medications to help you break your addiction."



### **16.1.2.2.3 ModifieX Cigarette Evaluation Questionnaire**

## Modified Cigarette Evaluation Questionnaire (mCEQ)

Date and time of assessment  
(24-hour clock)

/    /      
D D M M Y Y Y Y

☐ Tick if same as  
visit date

:    
hour min

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

1. Was smoking satisfying?

Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Did cigarettes taste good?

Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Did you enjoy the sensation in your throat and chest?

Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Did smoking calm you down?

Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



### Modified Cigarette Evaluation Questionnaire

5. Did smoking make you feel more awake?

<b>Not at all</b>	<b>Very little</b>	<b>Little</b>	<b>Moderately</b>	<b>A lot</b>	<b>Quite a lot</b>	<b>Extremely</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Did smoking make you feel less irritable?

<b>Not at all</b>	<b>Very little</b>	<b>Little</b>	<b>Moderately</b>	<b>A lot</b>	<b>Quite a lot</b>	<b>Extremely</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. Did smoking help you concentrate?

<b>Not at all</b>	<b>Very little</b>	<b>Little</b>	<b>Moderately</b>	<b>A lot</b>	<b>Quite a lot</b>	<b>Extremely</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. Did smoking reduce your hunger for food?

<b>Not at all</b>	<b>Very little</b>	<b>Little</b>	<b>Moderately</b>	<b>A lot</b>	<b>Quite a lot</b>	<b>Extremely</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. Did smoking make you dizzy?

<b>Not at all</b>	<b>Very little</b>	<b>Little</b>	<b>Moderately</b>	<b>A lot</b>	<b>Quite a lot</b>	<b>Extremely</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. Did smoking make you nauseous?

<b>Not at all</b>	<b>Very little</b>	<b>Little</b>	<b>Moderately</b>	<b>A lot</b>	<b>Quite a lot</b>	<b>Extremely</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Modified Cigarette Evaluation Questionnaire</b>
11. Did smoking immediately relieve your craving for a cigarette?
<b>Not at all    Very little    Little    Moderately    A lot    Quite a lot    Extremely</b>
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
12. Did you enjoy smoking?
<b>Not at all    Very little    Little    Moderately    A lot    Quite a lot    Extremely</b>
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>



#### **16.1.2.2.4 Questionnaire on Smoking Urges**

## Questionnaire on smoking urges (QSU)

Date and time of assessment (24-hour clock)  /  /  ☐ Tick if same as visit date  
    DD     MM     YY YY YY YY  
     :   
    hour     min

1. I have a desire for a cigarette right now

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

2. Nothing would be better than smoking a cigarette right now

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

3. If it were possible I would probably smoke now

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

### Questionnaire on smoking urges (QSU)

4. I could control things better right now if I could smoke

**Strongly  
disagree**

**Strongly  
agree**

☐☐☐☐☐☐☐

5. All I want right now is a cigarette

**Strongly  
disagree**

**Strongly  
agree**

☐☐☐☐☐☐☐

6. I have an urge for a cigarette

**Strongly  
disagree**

**Strongly  
agree**

☐☐☐☐☐☐☐

7. A cigarette would taste good now

**Strongly  
disagree**

**Strongly  
agree**

☐☐☐☐☐☐☐

8. I would do almost anything for a cigarette now

**Strongly  
disagree**

**Strongly  
agree**

☐☐☐☐☐☐☐

### Questionnaire on smoking urges (QSU)

9. Smoking would make me less depressed

**Strongly  
disagree**

**Strongly  
agree**

☐☐☐☐☐☐☐

10. I am going to smoke as soon as possible

**Strongly  
disagree**

**Strongly  
agree**

☐☐☐☐☐☐☐



### **16.1.2.3 SUBJECT QUESTIONNAIRE LOCAL LANGUAGE**

#### **16.1.2.3.1 Cough Assessment**




TRANSPERFECT

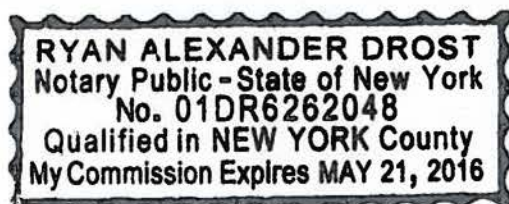
City of New York, State of New York, County of New York

I, Gaby Grijalva, hereby certify that the following is, to the best of my knowledge and belief, a true and accurate translation of the document titled "Cough assessment\_VAS" from English into Japan (Japanese) following Covance's process of concept definition, Dual Forward Translation, Reconciliation, Back Translation, Resolution, Covance cognitive interviewing with 5 adult smokers, final proofreading, and formatting.

  
Gaby Grijalva, Project Coordinator

Sworn to before me this  
Wednesday, May 15, 2013

  
Signature, Notary Public



Stamp, Notary Public

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## 咳の評価

過去 24 時間に、日常的に(例えば、数回)咳をしましたか？

はい／いいえ

「はい」の場合、以下の質問にお答えください：

### 第 1 問：咳の影響のスケール

あなたは咳によってどのくらい悩まされていますか？

VAS(視覚的アナログ尺度)：全く悩まされていない ----- 非常に悩まされている

### 第 2 問：咳の激しさのスケール：

あなたの咳はどのくらい激しいですか？

1 = 非常に軽い      2 = 軽い      3 = 中程度      4 = 激しい      5 = 非常に激しい

### 第 3 問：咳の頻度のスケール：

あなたは毎日通常どのくらいの頻度で咳をしますか？

1 = まれ      2 = 時々      3 = やや頻繁に      4 = 頻繁に      5 = ほとんど常に

### 第 4 問：痰の分泌

咳をする時に、どのくらい痰が出ますか？

0 = 痰は出ない   1 = 中程度の量の痰   2 = 大量の痰   3 = 非常に大量の痰

### 第 5 問：

あなたの咳について他に気が付いたことがあれば書いてください。(自由回答式の質問)



#### **16.1.2.3.2 Fagerström Test for Nicotine Dependence**




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I, Gaby Grijalva, hereby certify that the following is, to the best of my knowledge and belief, a true and accurate translation of the document titled "Fagerstrom-Nicotine-Dependence-Test" from English into Japan (Japanese) following Covance's process of concept definition, Dual Forward Translation, Reconciliation, Back Translation, Resolution, Covance cognitive interviewing with 5 adult smokers, final proofreading, and formatting.

  
Gaby Grijalva, Project Coordinator

Sworn to before me this  
Wednesday, May 15, 2013

  
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## ファガストロームニコチン依存度テスト\*

喫煙は「ただの習慣」ですか、それともあなたは中毒になっていますか？このテストを受けて、あなたのニコチン依存のレベルを知ってください。

1. 起床後何分で最初の喫煙をしますか？
  - ◆ 61分以降(0)
  - ◆ 31～60分(1)
  - ◆ 6～30分(2)
  - ◆ 5分以内(3)
2. 喫煙が禁じられている場所でタバコを吸わないでいることがつらいと感じますか？
  - ◆ いいえ(0)
  - ◆ はい(1)
3. 喫煙の中でどれが一番やめにくいですか？
  - ◆ 朝の最初の1本(1)
  - ◆ それ以外(0)
4. あなたは1日に何本タバコを吸いますか？
  - ◆ 10本以下(0)
  - ◆ 11～20本(1)
  - ◆ 21～30本(2)
  - ◆ 31本以上(3)
5. 他の時間帯より起床後数時間内に多く喫煙しますか？
  - ◆ いいえ(0)
  - ◆ はい(1)
6. ほとんど1日中寝込んでいるような病気の時でも喫煙しますか？
  - ◆ いいえ(0)
  - ◆ はい(1)

\* Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: A revision of the Fagerstrom Tolerance Questionnaire. British Journal of Addictions 1991;86:1119-27




### **16.1.2.3.3 ModifieX Cigarette Evaluation Questionnaire**

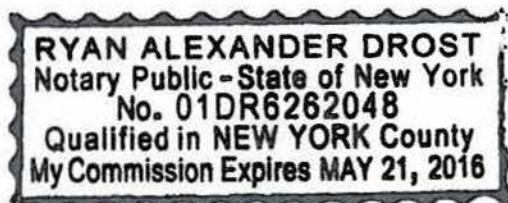
City of New York, State of New York, County of New York

I, Gaby Grijalva, hereby certify that the following is, to the best of my knowledge and belief, a true and accurate translation of the document titled "mCEQ United Kingdom (English)\_Final\_Clean" from English into Japan (Japanese) following Covance's process of concept definition, Dual Forward Translation, Reconciliation, Back Translation, Resolution, Covance cognitive interviewing with 5 adult smokers, final proofreading, and formatting.

  
Gaby Grijalva, Project Coordinator

Sworn to before me this  
Wednesday, May 15, 2013

  
Signature, Notary Public



Stamp, Notary Public

## 改訂版タバコ評価質問票(mCEQ)

評価の日時  
(24 時間制)

□□ / □□ / □□□□  
日 月 年 年 年 年

□□ : □□  
時 分

☐ 来院日と同じ場合はチェックマークを入れてください

本質問票を前回記入してから喫煙した場合は、タバコを吸ってどのように感じたかを最も表しているものにチェックマークを付けてください。

1. タバコを吸って満足した。

全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. タバコの味はおいしかった。

全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. 喉や胸への刺激を堪能した。

全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. タバコを吸ったら気持ちが落ち着いた。

全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## 改訂版タバコ評価質問票(mCEQ)

5. タバコを吸ったらより頭が冴えた感じになった。

全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. タバコを吸ったらイライラ感が少なくなった。

全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. タバコを吸ったら集中しやすくなった。

全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. タバコを吸ったら食欲が低下した。

全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. タバコを吸ったらめまいがした。

全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. タバコを吸ったら吐き気がした。

全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



# 改訂版タバコ評価質問票(mCEQ)

11. タバコを吸ったら、タバコを吸いたい気持ちがすぐにおさまった。

全く あてはまら ない	ほとんど あてはまら ない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. タバコを吸って楽しかった。


全く あてはまら ない	ほとんど あてはまら ない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



#### **16.1.2.3.4 Questionnaire on Smoking Urges**

City of New York, State of New York, County of New York

I, Gaby Grijalva, hereby certify that the following is, to the best of my knowledge and belief, a true and accurate translation of the document titled "QSU-brief United Kingdom (English)\_Final\_Clean" from English into Japan (Japanese) following Covance's process of concept definition, Dual Forward Translation, Reconciliation, Back Translation, Resolution, Covance cognitive interviewing with 5 adult smokers, final proofreading, and formatting.



---

Gaby Grijalva, Project Coordinator

Sworn to before me this  
Wednesday, May 15, 2013



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Signature, Notary Public



Stamp, Notary Public

## 喫煙衝動に関する質問票(QSU)

評価の日時  
(24 時間制)

/   /      
 日 日      月 月      年 年 年 年

:    
 時                  分

☐ 来院日と同じ場合は  
 チェックマークを  
 入れてください

1. 今タバコを吸いたいと思っている

全く同意し  
ない

☐      ☐      ☐      ☐      ☐      ☐

強く同意  
する

☐

2. 今、一番したいことはタバコを吸うことである

全く同意し  
ない

☐      ☐      ☐      ☐      ☐      ☐

強く同意  
する

☐

3. 今タバコが吸えるのであれば、吸うと思う

全く同意し  
ない

☐      ☐      ☐      ☐      ☐      ☐

強く同意  
する

☐

## 喫煙衝動に関する質問票(QSU)

4. 今タバコが吸えれば、もっとうまく物事に対処できる

全く同意し  
ない

強く同意  
する

☐ ☐ ☐ ☐ ☐ ☐ ☐

5. 今欲しいものはタバコだけだ

全く同意し  
ない

強く同意  
する

☐ ☐ ☐ ☐ ☐ ☐ ☐

6. とてもタバコが吸いたい

全く同意し  
ない

強く同意  
する

☐ ☐ ☐ ☐ ☐ ☐ ☐

7. 今タバコを吸ったらおいしいだろうと思う

全く同意し  
ない

強く同意  
する

☐ ☐ ☐ ☐ ☐ ☐ ☐

8. 今タバコのためなら、たいていのことはする

全く同意し  
ない

強く同意  
する

☐ ☐ ☐ ☐ ☐ ☐ ☐

## 喫煙衝動に関する質問票(QSU)

9. タバコを吸ったら憂鬱さが軽減するだろう

全く同意し  
ない

強く同意  
する

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

10. 私はできるだけすぐタバコを吸うつもりである

全く同意し  
ない

強く同意  
する

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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#### **16.1.2.4 SUBJECT SMOKING DIARY ENGLISH**

Not applicable.



### **16.1.2.5 SUBJECT SMOKING DIARY LOCAL LANGUAGE**

Not applicable.