

Subject Case Report Forms

Final 7.0 (Main CRF) - Case Book

Generated On: 14 Jul 2014 10:16:01

All time stamps listed in this document are displayed in GMT

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Subject**  
**Generated On: 14 Jul 2014 10:16:01**

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Screening number

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Site number

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**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Subject Status**  
**Generated On: 14 Jul 2014 10:16:01**

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Date of 'Screen Failed' Event

Fixed Unit:  
DD/MMM/YYYY

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Date of 'Discontinued From  
Enrollment' Event

Fixed Unit:  
DD/MMM/YYYY

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Randomization Date

Fixed Unit:  
DD/MMM/YYYY

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Randomization Time

Fixed Unit:  
hour:min 24-hour clock

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**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Screen Failure**  
**Generated On: 14 Jul 2014 10:16:01**

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Reason for Screen Failure

Entry criteria not met ☐

Withdrawal by subject ☐

Adverse Event ☐

Other ☐

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If Other, Specify: \_\_\_\_\_

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Is there a pregnancy event?

No ☐

Yes ☐

NA ☐

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**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Date of Visit**  
**Generated On: 14 Jul 2014 10:16:01**

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Date of Visit

Fixed Unit:  
DD/MMM/YYYY

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**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Date of Visit**  
**Generated On: 14 Jul 2014 10:16:01**

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Date of Visit

Fixed Unit:  
DD/MMM/YYYY

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Date of Discharge**  
**Generated On: 14 Jul 2014 10:16:01**

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Date of Visit

Fixed Unit:  
DD/MMM/YYYY

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Discharge Time

Fixed Unit:  
hour:min 24-hour clock

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Inclusion Criteria**  
**Generated On: 14 Jul 2014 10:16:01**

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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.

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

---

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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  $\geq 32.0$  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 7.0 (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Exclusion Criteria  
Generated On: 14 Jul 2014 10:16:01

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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.

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

---

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Inclusion/Exclusion Criterion Number	2
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**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Randomization**  
**Generated On: 14 Jul 2014 10:16:01**

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

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Sequence Subject randomised to:

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

Nicotine level

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

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Demographics**  
**Generated On: 14 Jul 2014 10:16:01**

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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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: THS 2.2 Menthol product test**  
**Generated On: 14 Jul 2014 10:16:01**

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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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: NRT gum product test**  
**Generated On: 14 Jul 2014 10:16:01**

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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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: THS 2.2 Menthol product demonstration**  
**Generated On: 14 Jul 2014 10:16:01**

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Has the subject seen a THS 2.2 Menthol product demonstration?

No ☐  
Yes ☐

---

If the subject did not see the demonstration please explain

---

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: NRT product demonstration**  
**Generated On: 14 Jul 2014 10:16:01**

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Has the subject seen a NRT product demonstration?

No ☐  
Yes ☐

---

If the subject did not see the demonstration please  
explain

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Product administration-NRT gum**  
**Generated On: 14 Jul 2014 10:16:01**

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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 \_\_\_\_\_

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---

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

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---

Time of NRT gum intake  
hour:min 24-hour clock \_\_\_\_\_

---

---

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

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Product administration-NRT gum**  
**Generated On: 14 Jul 2014 10:16:01**

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

---

Comment

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Product administration-mCC**  
**Generated On: 14 Jul 2014 10:16:01**

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Product administration-THS 2.2 Menthol**  
**Generated On: 14 Jul 2014 10:16:01**

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Identification of Current mCC Brand**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Identification of NRT Gum Brand**  
**Generated On: 14 Jul 2014 10:16:01**

---

Date

Fixed Unit:  
DD/MMM/YYYY

---

Was Nicorette® gum 2 mg used?

No ☐  
Yes ☐

---

If no, specify brand name:

---

Nicotine Dosage

Fixed Unit: mg

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Smoking History**  
**Generated On: 14 Jul 2014 10:16:01**

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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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: FTND Questionnaire**  
**Generated On: 14 Jul 2014 10:16:01**

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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="checkbox"/>
	31-60 minutes <input type="checkbox"/>
	6-30 minutes <input type="checkbox"/>
	Within 5 minutes <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

---

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

---

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

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Medical History/Concomitant Disease**  
**Generated On: 14 Jul 2014 10:16:01**

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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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 14 Jul 2014 10:16:01**

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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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination Screening**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 ☐

---

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**Final 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

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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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 14 Jul 2014 10:16:01**

---

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

---

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

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Weight and Height**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Weight**  
**Generated On: 14 Jul 2014 10:16:01**

---

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/m<sup>2</sup>

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Vital Signs Screening**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Vital Signs Screening**  
**Generated On: 14 Jul 2014 10:16:01**

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Blood Pressure (diastolic)

Fixed Unit:  
mmHg

---

Vital Signs Position of Subject

Sitting ☐  
Standing ☐  
Supine ☒

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Vital Signs**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Vital Signs**  
**Generated On: 14 Jul 2014 10:16:01**

---

Vital Signs Position of Subject

Sitting ☐  
Standing ☐  
Supine ☒

---



**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: ECG (12-Lead Standard) screening**  
**Generated On: 14 Jul 2014 10:16:01**

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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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: ECG (12-Lead Standard) screening**  
**Generated On: 14 Jul 2014 10:16:01**

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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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: ECG (12-Lead Standard)**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: ECG (12-Lead Standard)**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Spirometry**  
**Generated On: 14 Jul 2014 10:16:01**

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Spirometry**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Chest X-Ray**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Chest X-Ray**  
**Generated On: 14 Jul 2014 10:16:01**

---

Interpretation

Normal ☐  
Abnormal ☐

---

Clinically significant

No ☐  
Yes ☐

---

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

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Haematology**  
**Generated On: 14 Jul 2014 10:16:01**

---

Category	Clinical Chemistry	<input type="checkbox"/>
	Drug Screen	<input type="checkbox"/>
	Haematology	<input checked="" type="checkbox"/>
	Serology	<input type="checkbox"/>
	Pregnancy Testing	<input type="checkbox"/>
	Urinalysis	<input type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

---

Were samples collected?	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

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

---

Was the subject fasting for at least 10 hours at time of sample collection?	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine analysis**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Clinical Chemistry**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Serology for HIV and Hepatitis B and C**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen screening**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Urine Drug Screen screening  
Generated On: 14 Jul 2014 10:16:01

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen**  
**Generated On: 14 Jul 2014 10:16:01**

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Alcohol Breath Test screening**  
**Generated On: 14 Jul 2014 10:16:01**

---

Category	Clinical Chemistry	<input type="checkbox"/>
	Drug Screen	<input type="checkbox"/>
	Haematology	<input type="checkbox"/>
	Serology	<input type="checkbox"/>
	Pregnancy Testing	<input type="checkbox"/>
	Urinalysis	<input type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input checked="" type="checkbox"/>

---

Was the alcohol breath test performed?	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

If No, please specify the reason:	<hr/>
-----------------------------------	-------

---

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

---

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

---

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

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Alcohol Breath Test**  
**Generated On: 14 Jul 2014 10:16:01**

---

Category	Clinical Chemistry	<input type="checkbox"/>
	Drug Screen	<input type="checkbox"/>
	Haematology	<input type="checkbox"/>
	Serology	<input type="checkbox"/>
	Pregnancy Testing	<input type="checkbox"/>
	Urinalysis	<input type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input checked="" type="checkbox"/>

---

Was the alcohol breath test performed?	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>

---

If No, please specify the reason:	<hr/>
-----------------------------------	-------

---

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

---

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

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Pregnancy Test screening**  
**Generated On: 14 Jul 2014 10:16:01**

---

Category	Clinical Chemistry	<input type="checkbox"/>
	Drug Screen	<input type="checkbox"/>
	Haematology	<input type="checkbox"/>
	Serology	<input type="checkbox"/>
	Pregnancy Testing	<input checked="" type="checkbox"/>
	Urinalysis	<input type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

---

Not Done	<hr/>
----------	-------

---

If Not Done, specify reason	<hr/>
-----------------------------	-------

---

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

---

Specify result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>
	Unclear	<input type="checkbox"/>

---

If unclear, please confirm with FSH test	<hr/>
--	-------

---

Specify result of FSH test	< 20 IU/L	<input type="checkbox"/>
	>= 20 IU/L	<input type="checkbox"/>

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Pregnancy Test**  
**Generated On: 14 Jul 2014 10:16:01**

---

Category	Clinical Chemistry	<input type="checkbox"/>
	Drug Screen	<input type="checkbox"/>
	Haematology	<input type="checkbox"/>
	Serology	<input type="checkbox"/>
	Pregnancy Testing	<input checked="" type="checkbox"/>
	Urinalysis	<input type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

---

Not Done ☐

---

If Not Done, specify reason ☐

---

Specify result

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

---

If unclear, please confirm with FSH test ☐

---

Specify result of FSH test

< 20 IU/L	<input type="checkbox"/>
>= 20 IU/L	<input type="checkbox"/>

---

Time of Test ☐

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Cotinine Test screening**  
**Generated On: 14 Jul 2014 10:16:01**

---

Category	Clinical Chemistry	<input type="checkbox"/>
	Drug Screen	<input type="checkbox"/>
	Haematology	<input type="checkbox"/>
	Serology	<input type="checkbox"/>
	Pregnancy Testing	<input type="checkbox"/>
	Urinalysis	<input type="checkbox"/>
	Cotinine Screening	<input checked="" type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

---

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 <input type="checkbox"/>
	Positive >=200 mg/ml <input type="checkbox"/>

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Cotinine Test**  
**Generated On: 14 Jul 2014 10:16:01**

---

Category	Clinical Chemistry	<input type="checkbox"/>
	Drug Screen	<input type="checkbox"/>
	Haematology	<input type="checkbox"/>
	Serology	<input type="checkbox"/>
	Pregnancy Testing	<input type="checkbox"/>
	Urinalysis	<input type="checkbox"/>
	Cotinine Screening	<input checked="" type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

---

Not Done	<hr/>
----------	-------

---

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

---

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

Result	Negative <200 ng/ml <input type="checkbox"/>
	Positive >=200 mg/ml <input type="checkbox"/>

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Plasma Nicotine Sample**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CoHb Blood Sample**  
**Generated On: 14 Jul 2014 10:16:01**

---

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CO Breath Test <NR/>**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CO Breath Test <Product/>**  
**Generated On: 14 Jul 2014 10:16:01**

---

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CO Breath Test <Wash-out/>**  
**Generated On: 14 Jul 2014 10:16:01**

---

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CYP2A6 activity samples**  
**Generated On: 14 Jul 2014 10:16:01**

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: CYP2A6 activity samples**  
**Generated On: 14 Jul 2014 10:16:01**

---

Parameter

trans-3'-hydroxycotinine ☐  
cotinine ☒

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication Y/N**  
**Generated On: 14 Jul 2014 10:16:01**

---

Has the subject taken previous or concomitant  
medication?

No ☐  
Yes ☐

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 14 Jul 2014 10:16:01**

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



**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 14 Jul 2014 10:16:01**

---

- 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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 14 Jul 2014 10:16:01**

---

- 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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Previous and Concomitant Medication**  
**Generated On: 14 Jul 2014 10:16:01**

---

- 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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Adverse Events Y/N**  
**Generated On: 14 Jul 2014 10:16:01**

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Was there any Adverse Event for this subject?

No ☐  
Yes ☐

---



**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Adverse Events**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Adverse Events**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Adverse Events**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: End of study**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Questionnaire on smoking urges (QSU)**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Questionnaire on smoking urges (QSU)**  
**Generated On: 14 Jul 2014 10:16:01**

---

Assessment Status Completed ☐  
Abandoned ☐

---

1. I have a desire for a cigarette right now Strongly disagree ☐  
Disagree ☐  
Somewhat disagree ☐  
Do not agree or disagree ☐  
Somewhat agree ☐  
Agree ☐  
Strongly agree ☐  
Abandoned ☐

---

2. Nothing would be better than smoking a cigarette right now Strongly disagree ☐  
Disagree ☐  
Somewhat disagree ☐  
Do not agree or disagree ☐  
Somewhat agree ☐  
Agree ☐  
Strongly agree ☐  
Abandoned ☐

---

3. If it were possible I would probably smoke now Strongly disagree ☐  
Disagree ☐  
Somewhat disagree ☐  
Do not agree or disagree ☐  
Somewhat agree ☐  
Agree ☐  
Strongly agree ☐  
Abandoned ☐

---

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

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

5. All I want right now is a cigarette

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

6. I have an urge for a cigarette

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

7. A cigarette would taste good now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

8. I would do almost anything for a cigarette now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

9. Smoking would make me less depressed

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---



**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Questionnaire on smoking urges (QSU)**  
**Generated On: 14 Jul 2014 10:16:01**

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10. I am going to smoke as soon as possible	Strongly disagree	<input type="radio"/>
	Disagree	<input type="radio"/>
	Somewhat disagree	<input type="radio"/>
	Do not agree or disagree	<input type="radio"/>
	Somewhat agree	<input type="radio"/>
	Agree	<input type="radio"/>
	Strongly agree	<input type="radio"/>
	Abandoned	<input type="radio"/>

---

**Final 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

---

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

---

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

---

---

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

---

---

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

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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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Cough Assessment**  
**Generated On: 14 Jul 2014 10:16:01**

---

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

---

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

---

---

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

---

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Cough Assessment**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

---

---

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 7.0 (Main CRF): Case Book**

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

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

**Generated On: 14 Jul 2014 10:16:01**

---

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Vital Signs <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: ECG (12-Lead Standard) <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

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 7.0 (Main CRF): Case Book**

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

**Form: ECG (12-Lead Standard) <Unscheduled />**

**Generated On: 14 Jul 2014 10:16:01**

---

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

---

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

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Spirometry <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

---

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  
L

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Spirometry <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Physical Examination <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: Physical Examination <Unscheduled />  
Generated On: 14 Jul 2014 10:16:01

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Weight <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

Date of assessment  
DD/MMM/YYYY

---

Time of assessment  
hour:min 24-hour clock

---

Weight

Fixed Unit:  
kg

Final 7.0 (Main CRF): Case Book  
Project Name: ZRHM-PK-05-JP  
Form: X-Ray <Unscheduled />  
Generated On: 14 Jul 2014 10:16:01

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: X-Ray <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

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

---



**Final 7.0 (Main CRF): Case Book**

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

**Form: Clinical Chemistry <Unscheduled />**

**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Haematology <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine analysis <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

Category	Clinical Chemistry	<input type="checkbox"/>
	Drug Screen	<input type="checkbox"/>
	Haematology	<input type="checkbox"/>
	Serology	<input type="checkbox"/>
	Pregnancy Testing	<input type="checkbox"/>
	Urinalysis	<input checked="" type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

---

Date of sample collection  
DD/MMM/YYYY

---

Time of sample collection

---

Urinalysis

---

Result

---

Unit

---

Lower limit

---

Upper limit

---

Flag

---

Clinically Significant?

No ☐

Yes ☐

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine analysis <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

Comment

---

Please document clinically relevant abnormalities in the AE form

---

**Final 7.0 (Main CRF): Case Book**

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

**Form: Serology for HIV and Hepatitis B and C <Unscheduled />**

**Generated On: 14 Jul 2014 10:16:01**

---

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 7.0 (Main CRF): Case Book

Project Name: ZRHM-PK-05-JP

Form: Serology for HIV and Hepatitis B and C <Unscheduled />

Generated On: 14 Jul 2014 10:16:01

---

	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 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Drug Screen <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

Category	Clinical Chemistry <input type="checkbox"/>
	Drug Screen <input checked="" type="checkbox"/>
	Haematology <input type="checkbox"/>
	Serology <input type="checkbox"/>
	Pregnancy Testing <input type="checkbox"/>
	Urinalysis <input type="checkbox"/>
	Cotinine Screening <input type="checkbox"/>
	Alcohol Breath Test <input type="checkbox"/>

---

Date of sample collection	Fixed Unit: DD/MMM/YYYY
---------------------------	----------------------------

---

Time of sample collection	Fixed Unit: hour:min 24-hour clock
---------------------------	---------------------------------------

---

---

Drug type	Amphetamines <input checked="" type="checkbox"/>
	Barbiturates <input 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"/>

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Alcohol Breath Test <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

---

Category	Clinical Chemistry	<input type="checkbox"/>
	Drug Screen	<input type="checkbox"/>
	Haematology	<input type="checkbox"/>
	Serology	<input type="checkbox"/>
	Pregnancy Testing	<input type="checkbox"/>
	Urinalysis	<input type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input checked="" type="checkbox"/>

---

Date of assessment	
DD/MMM/YYYY	<hr/>

---

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

---

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

---



**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Urine Pregnancy Test <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

---

Category	Clinical Chemistry	<input type="checkbox"/>
	Drug Screen	<input type="checkbox"/>
	Haematology	<input type="checkbox"/>
	Serology	<input type="checkbox"/>
	Pregnancy Testing	<input checked="" type="checkbox"/>
	Urinalysis	<input type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

---

Date of Test	
DD/MMM/YYYY	<hr/>

---

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

---

Specify result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>
	Unclear	<input type="checkbox"/>

---

Specify result of FSH test	< 20 IU/L	<input type="checkbox"/>
	>= 20 IU/L	<input type="checkbox"/>

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Blood Samples <Unscheduled />**  
**Generated On: 14 Jul 2014 10:16:01**

---

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 V3.0 (Site Level): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Subject (Site level)**  
**Generated On: 12 Sep 2014 11:14:45**

---

Subject (site level)

---

**Final V3.0 (Site Level): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Deviation Form**  
**Generated On: 12 Sep 2014 11:14:45**

---

Cohort \_\_\_\_\_

---

Subject \_\_\_\_\_

---

Assessment \_\_\_\_\_

---

Visit

Screen Failure ☐

Screening ☐

Admission ☐

Wash-out (Day 0) ☐

Single Use (Day 1) ☐

Wash-out (Day 2) ☐

Single Use (Day 3) ☐

Day 4 ☐

Discharge ☐

Other ☐

---

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

---

Timepoint \_\_\_\_\_

---

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

---

Date Deviation Occurred

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

---

Date Deviation Reported

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

---

**Final V3.0 (Site Level): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Deviation Form**  
**Generated On: 12 Sep 2014 11:14:45**

---

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 V3.0 (Site Level): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Site Accountability**  
**Generated On: 12 Sep 2014 11:14:45**

---

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 \_\_\_\_\_

---

Number of packs received \_\_\_\_\_

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Lab-BU**  
**Generated On: 14 Jul 2014 10:16:01**

Test Category \_\_\_\_\_

Date of Sample Collection \_\_\_\_\_

Time of Blood Sample Collection \_\_\_\_\_

Time of Urine Sample Collection \_\_\_\_\_

Test Name \_\_\_\_\_

Result \_\_\_\_\_

Text Result \_\_\_\_\_

Unit \_\_\_\_\_

Lower limit \_\_\_\_\_

Upper limit \_\_\_\_\_

Flag \_\_\_\_\_

Clinically Significant? No ☐  
Yes ☐

Comment \_\_\_\_\_

Result Category \_\_\_\_\_

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Lab-BU**  
**Generated On: 14 Jul 2014 10:16:01**

---

Text Result Code

---

Reference Value Category

---

Timepoint(COHB)

---

Material Code

---

Chyle Comment Code

---

Chyle Comment English

---

Hemolysis Comment Code

---

Hemolysis Comment English

---

Specimen Comment Code 1

---

Specimen English Comment 1

---

Specimen Comment Code 2

---

Specimen English Comment 2

---

Result Supplementary Comment Code 1

---

Result Supplementary English Comment Code 1

---



**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Lab-BU**  
**Generated On: 14 Jul 2014 10:16:01**

---

Result Supplementary Comment Code 2

---

Result Supplementary English Comment Code 2

---

Accession No.

---

Please document clinically relevant abnormalities in the AE form

---

Date (BU)

---

Blood Sample time(BU)

---

Urine Sample time(BU)

---

H\_NOW (Derived):

---

Derived Form name

---

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Biomarker(Blood)**  
**Generated On: 14 Jul 2014 10:16:01**

Sample type	
Sample Barcode	
Analyte	
Result	
Result Unit	
Lab Status	
Sample comment	
Detection method	
Planned time point (Hour)	
Day of Visit	
Celerion Study Number	
Date of Collection	
Timepoint-minutes	
Urine Start Day	

**Final 7.0 (Main CRF): Case Book**  
**Project Name: ZRHM-PK-05-JP**  
**Form: Biomarker(Blood)**  
**Generated On: 14 Jul 2014 10:16:01**

---

Urine End Day

---