



PMI RESEARCH & DEVELOPMENT

Study ZRHM-REXA-08-US **Clinical Study Report Appendix 16.1.2** **Sample Case Report Form, Subject Questionnaire, and** **Subject Smoking Diary**

Study Title: A randomized, controlled, open-label, 3-arm parallel group, multi-center study to demonstrate reductions in exposure to selected smoke constituents in apparently healthy smokers switching to the Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) or observing smoking abstinence, compared to continuing to use menthol conventional cigarettes, for 5 days in confinement and prolonged by 86 days in an ambulatory setting

Study Number: ZRHM-REXA-08-US

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

Study Initiated (first subject screened): 17 December 2013

Study Completed (last subject last visit): 12 October 2014

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Version: 1.0

Date: 25 May 2016

This study was conducted in accordance with Good Clinical Practice.

Confidentiality Statement

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 SAMPLE CASE REPORT FORM, SUBJECT QUESTIONNAIRE AND SUBJECT SMOKING DIARY

16.1.2.1 SAMPLE CASE REPORT FORM



Subject Case Report Forms

PROD 02.001 (MAIN) GMP 05AUG2014 - Case Book

Signature Prompt: I hereby confirm that all data is accurate to the best of my knowledge.



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Subject (Site level)

Generated On: 22 Sep 2014 07:54:21

Subject (site level)



**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Subject (Site level)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① SUBJ_DUM MY	\$4				SUBJ_DUM MY



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Subject

Generated On: 22 Sep 2014 07:54:21

Screening number

①

Site number

②

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Subject****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SUBJNUM	\$4				SUBJNUM
②	SITEID	\$3				SITEID



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Deviation Form

Generated On: 22 Sep 2014 07:54:21

Cohort ①Subject ②Assessment ③

Visit

Screen Failure ☐ ④

Screening ☐

Admission (Day -2) ☐

Baseline (Day -1) ☐

Baseline (Day 0) ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Discharge ☐

Day 30 ☐

Day 60 ☐

Day 90 ☐

Discharge (ambulatory) ☐

Other ☐

Other, Specify ⑤Timepoint ⑥Description of Deviation ⑦

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Deviation Form****Generated On: 22 Sep 2014 07:54:21**Date Deviation Occurred 8

DD/MMM/YYYY

Date Deviation Reported 9

DD/MMM/YYYY

Date Deviation Ended 10

DD/MMM/YYYY

Resolution of the Deviation 11Source of the Deviation 12

- CRA ☐
- Site personnel ☐
- Sponsor ☐
- CRO ☐
- Labs ☐
- IXRS ☐
- ePRO ☐

Deviation Category 13

- Violation ☐
- Mis-randomization ☐
- Mis-use of product ☐
- Concomitant medication ☐
- Time deviation ☐
- Time missing ☐
- Assessment missing ☐
- Other ☐

Other specify 14



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Deviation Form

Generated On: 22 Sep 2014 07:54:21

Deviation Type

Major ☒ 15

Minor ☐

If Major, Evaluation Category

Evaluable ☒ 16

Non Evaluable ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Deviation Form****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	COHORT	\$200				COHORT
②	SUBJ	\$4				SUBJ
③	ASSESS	\$200				ASSESS
④	PDVIS	2		1 = Screen Failure 2 = Screening 3 = Admission (Day -2) 4 = Baseline (Day -1) 5 = Baseline (Day 0) 6 = Day 1 7 = Day 2 8 = Day 3 9 = Day 4 10 = Day 5 11 = Day 6 12 = Discharge 13 = Day 30 14 = Day 60 15 = Day 90		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Deviation Form****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			16 = Discharge (ambulatory) 17 = Other		PDVIS
5 PDVISSPEC	\$200				PDVISSPEC
6 PDTPT	\$200				PDTPT
7 PDDESC	\$200				PDDESC
8 PDSTDT	dd MMM YYYY				PDSTDT
9 PDRPDT	dd MMM YYYY				PDRPDT
10 PDENDT	dd MMM YYYY				PDENDT
11 PDRES	\$200				PDRES
12 PDSOR	\$200		1 = CRA 2 = Site personnel		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Deviation Form

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Sponsor 4 = CRO 5 = Labs 6 = IXRS 7 = ePRO		PDSOR
13 PDCAT	2		1 = Violation 2 = Mis-random ization 3 = Mis-use of product 4 = Concomitan t medication 5 = Time deviation 6 = Time missing 7 = Assessment missing 8 = Other		PDCAT
14 PDOTHSPE C	\$200				PDOTHSPE C

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Deviation Form****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15	PDTYP	2		1 = Major 2 = Minor		PDTYP
16	PDEVAL	2		1 = Evaluable 2 = Non Evaluable		PDEVAL

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Subject Status****Generated On: 22 Sep 2014 07:54:21**

Date of 'Screen Failed' Event

Fixed Unit: ①
DD/MMM/YYYYDate of 'Discontinued From
Enrollment' EventFixed Unit: ②
DD/MMM/YYYY

Randomization Date

Fixed Unit: ③
DD/MMM/YYYY

Randomization Time

Fixed Unit: ④
hour:min 24-hour clock

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Subject Status****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SRNFDT	dd MMM YYYY				SRNFDT
②	DFEDT	dd MMM YYYY				DFEDT
③	RANDDAT	dd MMM YYYY				RANDDAT
④	RANDTIM	HH:nn				RANDTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Site Accountability****Generated On: 22 Sep 2014 07:54:21**

Date of batch dispensed	_____	①
Batch number	_____	②
Category	Received <input type="checkbox"/> ③ Returned <input type="checkbox"/>	
Batch Expiration Date (only for received event) DD/MMM/YYYY	_____	④
Number of unused packs returned	_____	⑤
Number of unused sticks returned (only for returned event)	_____	⑥
Number of packs received	_____	⑦

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Site Accountability****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	ACCDAT	dd MMM YYYY				ACCDAT
②	BATCHNO	\$10				BATCHNO
③	ACC_CAT	1		1 = Received 2 = Returned		ACC_CAT
④	BATCHDAT	dd MMM YYYY				BATCHDAT
⑤	ACCPACK	4				ACCPACK
⑥	ACCSTICK	6				ACCSTICK
⑦	PACREC	4				PACREC



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Screen Failure

Generated On: 22 Sep 2014 07:54:21

Reason for Screen Failure

Entry criteria not met ☐ ①

Withdrawal by subject ☐

Adverse Event ☐

Other ☐

If Other, Specify: _____ ②

Is there a pregnancy event?

No ☐ ③

Yes ☐

NA ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Screen Failure****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① SRNFRSN	1		1 = Entry criteria not met 2 = Withdrawal by subject 3 = Adverse Event 4 = Other		SRNFRSN
② RSNSPEC	\$200				RSNSPEC
③ PGNYN	\$2		N = No Y = Yes NA = NA		PGNYN



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Date of Visit<Ambulatory/>

Generated On: 22 Sep 2014 07:54:21

Visit Not Done

①

If Not Done, Specify Reason

②

Date of Visit

Fixed Unit:
DD/MMM/YYYY

③

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Date of Visit<Ambulatory/>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VISND	1				VISND
②	VISNDRSN	\$200				VISNDRSN
③	VISDAT	dd MMM YYYY				VISDAT



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Date of Visit

Generated On: 22 Sep 2014 07:54:21

Date of Visit

Fixed Unit: 
DD/MMM/YYYY

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Date of Visit****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VISDAT	dd MMM YYYY				VISDAT



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Date of Discharge

Generated On: 22 Sep 2014 07:54:21

Date of Visit

Fixed Unit: ①
DD/MMM/YYYY

Discharge Time

Fixed Unit: ②
hour:min 24-hour clock

Is the subject continuing in the ambulatory period?

No ☐ ③
Yes ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Date of Discharge****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VISDAT	dd MMM YYYY				VISDAT
②	DISTIM	HH:nn				DISTIM
③	CONTYN	\$1		N = No Y = Yes		CONTYN

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Additional Informed Consent****Generated On: 22 Sep 2014 07:54:21**

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

No ☐ ①
Yes ☐

Consent Date

Fixed Unit: ②
DD/MMM/YYYY

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

No ☐ ③
Yes ☐

Consent Date

Fixed Unit: ④
DD/MMM/YYYY

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Additional Informed Consent****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	ICUPB	1		0 = No 1 = Yes		ICUPB
②	ICUPBDAT	dd MMM YYYY				ICUPBDAT
③	ICTRS	1		0 = No 1 = Yes		ICTRS
④	ICTRSDAT	dd MMM YYYY				ICTRSDAT



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Inclusion Criteria

Generated On: 22 Sep 2014 07:54:21

Inclusion Criterion Number

①

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Inclusion Criterion

Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF. ☒ 2

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

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

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

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

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Inclusion Criteria

Generated On: 22 Sep 2014 07:54:21

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

Result

No ☐ 3
Yes ☐

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

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① IETESTCD	\$2		1 2 3 4 5 6 1: 	1: 2: 3: 4: 5: 6:	IETESTCD

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② IETEST_I	\$200		1 = Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Subject Is at a minimum 22 years of age(inclusiv e).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Smoking, apparently healthy subject as judged by the Investigator based on all available assessment s from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination , ECG, chest X-ray, and medical history).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Subject smokes at least 10 commercially available mCCs per day (no brand restrictions) , for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = The subject does not plan to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = The subject is ready to comply with study protocol (e.g. readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF. 2: Subject is at a minimum 22 years of age(inclusive). 3: Smoking, apparently healthy subject as judged by the Investigator based on all available assessments from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination, ECG, chest X-ray, and medical history). 4: Subject smokes at least 10 commercially available mCCs per	IETEST_I
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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3 IE_I_ORRE S	\$1		N = No Y = Yes		IE_I_ORRE S



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Inclusion Criteria<ScreenFailure/>
Generated On: 22 Sep 2014 07:54:21

Inclusion Criterion Number

①



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Inclusion Criteria<ScreenFailure/>

Generated On: 22 Sep 2014 07:54:21

Inclusion Criterion

Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF. ☒ 2

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

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

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

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

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Inclusion Criteria<ScreenFailure/>
Generated On: 22 Sep 2014 07:54:21

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

Result

No ☒ 3
Yes ☐
Not Done ☐

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

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① IETESTCD	\$2		1 2 3 4 5 6	1: 1 2: 2 3: 3 4: 4 5: 5 6: 6	IETESTCD

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② IETEST_I	\$200		1 = Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Subject is at a minimum 22 years of age(inclusive).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Smoking, apparently healthy subject as judged by the Investigator based on all available assessment s from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination , ECG, chest X-ray, and medical history).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Subject smokes at least 10 commercially available mCCs per day (no brand restrictions) , for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = The subject does not plan to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = The subject is ready to comply with study protocol (e.g. readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol).		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Inclusion Criteria<ScreenFailure/>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF. 2: Subject is at a minimum 22 years of age(inclusive). 3: Smoking, apparently healthy subject as judged by the Investigator based on all available assessments from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination, ECG, chest X-ray, and medical history). 4: Subject smokes at least 10 commercially available mCCs per	IETEST_I
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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
IE_I_ORRE S1	\$8		N = No Y = Yes ND = Not Done		IE_I_ORRE S1



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Inclusion Criteria<Admission/>

Generated On: 22 Sep 2014 07:54:21

Inclusion Criterion Number

1

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Inclusion Criterion

Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF. ☒ 2

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

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

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

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

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Inclusion Criteria<Admission/>

Generated On: 22 Sep 2014 07:54:21

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

Result

No ☐ 3
Yes ☐

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

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① IETESTCD	\$2		3 4 5 6	1: 3 2: 4 3: 5 4: 6	IETESTCD

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② IETEST_I	\$200		1 = Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Subject is at a minimum 22 years of age(inclusive).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Smoking, apparently healthy subject as judged by the Investigator based on all available assessment s from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination , ECG, chest X-ray, and medical history).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Subject smokes at least 10 commercially available mCCs per day (no brand restrictions) , for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = The subject does not plan to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = The subject is ready to comply with study protocol (e.g. readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol).		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Inclusion Criteria<Admission/>

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: Smoking, IETEST_I apparently healthy subject as judged by the Investigator based on all available assessment s from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination , ECG, chest X-ray, and medical history). 2: Subject smokes at least 10 commerciall y available mCCs per day (no brand restrictions) , for the last 4 weeks, based on self-reportin g. Furthermor e, the subject has been smoking for at least the last 3 consecutive years. The smoking ...	
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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Inclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
IE_I_ORRE S	\$1		N = No Y = Yes		IE_I_ORRE S



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Exclusion Criteria

Generated On: 22 Sep 2014 07:54:21

Exclusion Criterion Number

①

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Exclusion Criterion

- As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason). ☒ 2
- A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated). ☐
- The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject. ☐
- Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) <0.7 and FEV1 <80% predicted value at postbronchodilator spirometry (GOLD, 2013). ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

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

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

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

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

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

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Exclusion Criteria

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

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

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

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

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. ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

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

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

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

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

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

Result

No ☒ 3
Yes ☐
NA ☐

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

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① IETESTCD	\$2		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22		IETESTCD

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② IETEST	\$200		1 = As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematologic, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject.		
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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) <0.7 and FEV1 <80% predicted value at postbronchodilator spirometry (GOLD, 2013).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Subject with asthma condition (FEV1/FVC < 0.75 and reversibility in FEV1 > 12% (or > 200 mL) from pre to post-bronchodilator values).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Subjects with renal insufficiency as defined by serum creatinine levels of >1.3 mg/dL for females and >1.5 mg/dL for males.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m2.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = 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.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = Any subject with an history of adverse events linked to caffeine or caffeine containing drugs (e.g., Vivarin), such as but not limited to hypersensitivity or allergy.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or NRT), as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = The subject has received medication (prescription or over-the-counter) within 14 days or within five half-lives of the drug (whichever is longer) prior to the Admission Day (Day -2), which has an impact on CYP1A2 or CYP2A6 activity.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			12 = If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives or subject's safety.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			13 = Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with the subject's participation in the study.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = The subject has a positive urine drug test.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			16 = Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B or hepatitis C.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			17 = Donation or receipt of whole blood or blood products within 3 months prior to Admission.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			18 = The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			19 = The subject is an employee of the investigational site or any other parties involved in the study or of their first degree relatives (parent, sibling, and child).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			20 = The subject has participated in a clinical study within 3 months prior to the Screening Visit.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			21 = For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			22 = For women only : Subject does not agree to use an acceptable method of effective contraception		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason). 2: A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated).	IETEST
PROD 02.001 (MAIN) GMP 05AUG2014 (649)				3: The subject has clinically relevant diseases which required medications (including	90 of 896

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
IE_E_ORRE S	\$8		N = No Y = Yes NA = NA		IE_E_ORRE S



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Exclusion Criterion Number

①



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Exclusion Criteria<ScreenFailure/>
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Exclusion Criterion

As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason). ☒ 2

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

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

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Exclusion Criteria<ScreenFailure/>

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

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

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

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

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

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



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- The subject has received medication (prescription or over-the-counter) within 14 days or within five half-lives of the drug (whichever is longer) prior to the Admission Day (Day -2), which has an impact on CYP1A2 or CYP2A6 activity. ☐
- If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives or subject's safety. Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with the subject's participation in the study. ☐
- 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. ☐



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Form: Exclusion Criteria<ScreenFailure/>

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

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

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

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

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

Result

No ☒ 3

Yes ☐

Not Done ☐

NA ☐

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Exclusion Criteria<ScreenFailure/>

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① IETESTCD	\$2		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22		IETESTCD

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② IETEST	\$200		1 = As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematologic, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject.		
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) <0.7 and FEV1 <80% predicted value at postbronchodilator spirometry (GOLD, 2013).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Subject with asthma condition (FEV1/FVC < 0.75 and reversibility in FEV1 > 12% (or > 200 mL) from pre to post-bronchodilator values).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Subjects with renal insufficiency as defined by serum creatinine levels of >1.3 mg/dL for females and >1.5 mg/dL for males.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m ² .		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = 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.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = Any subject with an history of adverse events linked to caffeine or caffeine containing drugs (e.g., Vivarin), such as but not limited to hypersensitivity or allergy.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or NRT), as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = The subject has received medication (prescription or over-the-counter) within 14 days or within five half-lives of the drug (whichever is longer) prior to the Admission Day (Day -2), which has an impact on CYP1A2 or CYP2A6 activity.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			12 = If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives or subject's safety.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			13 = Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with the subject's participation in the study.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
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			15 = The subject has a positive urine drug test.		
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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			16 = Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B or hepatitis C.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			17 = Donation or receipt of whole blood or blood products within 3 months prior to Admission.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			18 = The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			19 = The subject is an employee of the investigational site or any other parties involved in the study or of their first degree relatives (parent, sibling, and child).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			20 = The subject has participated in a clinical study within 3 months prior to the Screening Visit.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			21 = For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			22 = For women only : Subject does not agree to use an acceptable method of effective contraception		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason). 2: A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated).	IETEST
PROD 02.001 (MAIN) GMP 05AUG2014 (649)				3: The subject has clinically relevant diseases which required medications (including	120 of 896

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<ScreenFailure/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
IE_E_ORRE S1	\$8		N = No Y = Yes ND = Not Done NA = NA		IE_E_ORRE S1



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Exclusion Criteria<Admission/>

Generated On: 22 Sep 2014 07:54:21

Exclusion Criterion Number

①



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Exclusion Criteria<Admission/>

Generated On: 22 Sep 2014 07:54:21

Exclusion Criterion

- As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason). ☒ 2
- A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated). ☐
- The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject. ☐
- Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) <0.7 and FEV1 <80% predicted value at postbronchodilator spirometry (GOLD, 2013). ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Exclusion Criteria<Admission/>

Generated On: 22 Sep 2014 07:54:21

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

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

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

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

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

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



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Form: Exclusion Criteria<Admission/>

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

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

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

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

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. ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Exclusion Criteria<Admission/>

Generated On: 22 Sep 2014 07:54:21

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

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

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

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

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

Result

No ☒ 3
Yes ☐
NA ☐

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

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① IETESTCD	\$2		1 3 7 8 9 11: 1 0 11 12 13 2: 3 14 15 17 3: 7 21 22 4: 8 5: 9 6: 10 7: 11 8: 12 9: 13 10: 14 11: 15 12: 17 13: 21 14: 22		IETESTCD

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② IETEST	\$200		1 = As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematologic, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject.		
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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) <0.7 and FEV1 <80% predicted value at postbronchodilator spirometry (GOLD, 2013).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Subject with asthma condition (FEV1/FVC < 0.75 and reversibility in FEV1 > 12% (or > 200 mL) from pre to post-bronchodilator values).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Subjects with renal insufficiency as defined by serum creatinine levels of >1.3 mg/dL for females and >1.5 mg/dL for males.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m2.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = 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.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = Any subject with an history of adverse events linked to caffeine or caffeine containing drugs (e.g., Vivarin), such as but not limited to hypersensitivity or allergy.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or NRT), as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = The subject has received medication (prescription or over-the-counter) within 14 days or within five half-lives of the drug (whichever is longer) prior to the Admission Day (Day -2), which has an impact on CYP1A2 or CYP2A6 activity.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			12 = If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives or subject's safety.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			13 = Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with the subject's participation in the study.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = The subject has a positive urine drug test.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			16 = Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B or hepatitis C.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			17 = Donation or receipt of whole blood or blood products within 3 months prior to Admission.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			18 = The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			19 = The subject is an employee of the investigational site or any other parties involved in the study or of their first degree relatives (parent, sibling, and child).		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			20 = The subject has participated in a clinical study within 3 months prior to the Screening Visit.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			21 = For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			22 = For women only : Subject does not agree to use an acceptable method of effective contraception		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: As per Investigator judgment, the subject cannot participate in the study for any reason (e.g., medical, psychiatric and/or social reason). 2: The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory	IETEST
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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Exclusion Criteria<Admission/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
IE_E_ORRE \$8 S			N = No Y = Yes NA = NA		IE_E_ORRE S

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Randomization****Generated On: 22 Sep 2014 07:54:21**

Randomization number (4 digits) _____

①

Allocation Arm

THS 2.2 menthol ☐

②

mCC ☐SA ☐

Cigarette Consumption

10 – 19 conventional
menthol cigarettes per day ☐

③

Greater than 19
conventional menthol
cigarettes per day ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Randomization****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	RANDNO	\$4				RANDNO
②	TRTGP	1		1 = THS 2.2 menthol 2 = mCC 3 = SA		TRTGP
③	CIGCON	1		1 = 10 – 19 conventiona l menthol cigarettespe r day 2 = Greater than 19 conventiona l menthol cigarettes per day		CIGCON



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Demographics

Generated On: 22 Sep 2014 07:54:21

Date of Birth

Fixed Unit: ①
DD/MMM/YYYY

Sex

Male ②
Female

Race

White ③
Black or African American
American Indian or Alaska
Native
Asian
Native Hawaiian or Other
Pacific Islander
Other

Other, specify ④

Ethnicity

Hispanic ⑤
Not Hispanic

Date the Subject signed the Informed Consent

Fixed Unit: ⑥
DD/MMM/YYYY

Time the Subject signed the Informed Consent

Fixed Unit: ⑦
hour:min 24-hour clock

Age(Derived) ⑧

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Demographics****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DOB	dd MMM YYYY				DOB
②	SEX	\$8		M = Male F = Female		SEX
③	RACE	\$50		WHITE = White BLACK OR AFRICAN AMERICAN = Black or African American AMERICAN INDIAN OR ALASKA NATIVE = American Indian or Alaska Native ASIAN = Asian NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER = Native Hawaiian or Other Pacific Islander		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Demographics

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			OTHER = Other		RACE
④ RACEOTH	\$200				RACEOTH
⑤ ETHNIC	\$20		1 = Hispanic 2 = Not Hispanic		ETHNIC
⑥ INFORMDT	dd MMM YYYY				INFORMDT
⑦ INFORMTM	HH:nn				INFORMTM
⑧ AGE	2				AGE



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Medical History/Concomitant Disease
Generated On: 22 Sep 2014 07:54:21

Date of collection

Fixed Unit: **1**
DD/MMM/YYYY

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

No **2**
Yes ☐

Category for Medical History

Medical History **3**

Number

4

Diagnosis Description

5

Onset Date
DD/MMM/YYYY

6

Stop Date
DD/MMM/YYYY

7

Ongoing?

8

H_NOW (Derived):

9

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Medical History/Concomitant Disease****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	MHDAT	dd MMM YYYY				MHDAT
②	MHYN	\$1		N = No Y = Yes		MHYN
③	MHCAT	\$20		Medical History		MHCAT
④	MHSPID	\$10				MHSPID
⑤	MHTERM	\$200				MHTERM
⑥	MHSTDAT	dd- MMM- YYYY				MHSTDAT
⑦	MHENDAT	dd- MMM- YYYY				MHENDAT
⑧	MHONGO	1				MHONGO
⑨	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Vital Signs<Screening/<****Generated On: 22 Sep 2014 07:54:21**

Were Vitals Signs assessed?

No ☐ ①
Yes ☐

If No, please specify the reason: _____ ②

Has the subject smoked within 15 minutes prior to assessment

No ☐ ③
Yes ☐

Date of assessment

Fixed Unit: ④
DD/MMM/YYYY

Time of assessment

Fixed Unit: ⑤
hour:min 24-hour clock

Pulse rate

Fixed Unit: ⑥
beats per minute

Respiratory rate

Fixed Unit: ⑦
breaths per minute

Blood Pressure (systolic)

Fixed Unit: ⑧
mmHg

Blood Pressure (diastolic)

Fixed Unit: ⑨
mmHgPROD 02.001 (MAIN) GMP
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PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Vital Signs<Screening/<

Generated On: 22 Sep 2014 07:54:21

Vital Signs Position of Subject

Sitting ☒ 10
Standing ☐
Supine ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Vital Signs<Screening/<

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSSTAT	\$1		N = No Y = Yes		VSSTAT
②	VSREASND	\$200				VSREASND
③	VSSMKYN	\$1		N = No Y = Yes		VSSMKYN
④	VSDAT	dd MMM YYYY				VSDAT
⑤	VSTIM	HH:nn				VSTIM
⑥	VSORRES_P3 ULSE					VSORRES_P ULSE
⑦	VSORRES_R3 ESP					VSORRES_R ESP
⑧	VSORRES_S3 YSBP					VSORRES_S YSBP
⑨	VSORRES_3 DIABP					VSORRES_ DIABP
⑩	VSPOS	\$10		SITTING = Sitting		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Vital Signs<Screening/<****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			STANDING = Standing SUPINE = Supine		VSPOS

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Vital Signs****Generated On: 22 Sep 2014 07:54:21**

Were Vitals Signs assessed?

No ☐ ①
Yes ☐

If No, please specify the reason: _____ ②

Has the subject smoked within 15 minutes prior to assessment

No ☐ ③
Yes ☐

Date of assessment

Fixed Unit: ④
DD/MMM/YYYY

Time of assessment

Fixed Unit: ⑤
hour:min 24-hour clock

Pulse rate

Fixed Unit: ⑥
beats per minute

Respiratory rate

Fixed Unit: ⑦
breaths per minute

Blood Pressure (systolic)

Fixed Unit: ⑧
mmHg

Blood Pressure (diastolic)

Fixed Unit: ⑨
mmHgPROD 02.001 (MAIN) GMP
05AUG2014 (649)

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PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Vital Signs

Generated On: 22 Sep 2014 07:54:21

Vital Signs Position of Subject

Sitting ☒ 10
Standing ☐
Supine ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Vital Signs

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSSTAT	\$1		N = No Y = Yes		VSSTAT
②	VSREASND	\$200				VSREASND
③	VSSMKYN	\$1		N = No Y = Yes		VSSMKYN
④	VSDAT	dd MMM YYYY				VSDAT
⑤	VSTIM	HH:nn				VSTIM
⑥	VSORRES_P3 ULSE					VSORRES_P ULSE
⑦	VSORRES_R3 ESP					VSORRES_R ESP
⑧	VSORRES_S3 YSBP					VSORRES_S YSBP
⑨	VSORRES_3 DIABP					VSORRES_ DIABP
⑩	VSPOS	\$10		SITTING = Sitting		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Vital Signs****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			STANDING = Standing SUPINE = Supine		VSPOS



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Screening/>

Generated On: 22 Sep 2014 07:54:21

Was the physical examination performed?

No ☐ 1
Yes ☐

If No, please specify the reason: _____ 2

Date of assessment

Fixed Unit: 3
DD/MMM/YYYY

System

General Appearance ☐ 4
HEENT ☐
(head, eyes, ears, nose,
throat)
Thyroid Gland ☐
Heart ☐
Chest ☐
Lungs ☐
Gastrointestinal ☐
Cardiovascular System ☐
Neurologic ☐
Skin ☐
Back ☐
Musculoskeletal ☐
Abdomen ☐
Dentition ☐
Other ☐

Other, Specify _____ 5

Outcome

Normal ☐ 6
Abnormal ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Screening/>

Generated On: 22 Sep 2014 07:54:21

Abnormal, please specify _____ 7

Clinically significant No ☒ 8
Yes ☐

Not Done _____ 9

Not Done; please specify the reason: _____ 10

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination<Screening/>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PESTAT	\$1		N = No Y = Yes		PESTAT
②	PEREASND1	\$200				PEREASND1
③	PEDAT	dd MMM YYYY				PEDAT

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination<Screening/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④ PETESTCD	\$200		GAPPEAR = General Appearance HEENT = HEENT (head, eyes, ears, nose, throat)		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Screening/>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			THYROID = Thyroid Gland		
			HEART = Heart		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Screening/>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			CHEST = Chest		
			LUNGS = Lungs		
			GASTRO = Gastrointest inal		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Screening/>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
CVS = Cardiovascu lar System					
NEURO = Neurologic					



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Screening/>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			SKIN = Skin BACK = Back MUSCULO = Musculoskel etal		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Screening/>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
ABDOMEN = Abdomen DENTN = Dentition OTHER = Other					

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination<Screening/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			1: General Appearance 2: HEENT (head, eyes, ears, nose, throat) 3: Thyroid Gland 4: Heart 5: Chest 6: Lungs 7: Gastrointestinal 8: Cardiovascular System 9: Neurologic 10: Skin 11: Back 12: Musculoskeletal 13: Abdomen 14: Dentition 15: Other 16: Other 17: Other 18: Other 19: Other		PETESTCD
5 PESPEC	\$200				PESPEC



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Screening/>

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	PEORRES	\$8		NORMAL = Normal ABNORMAL = Abnormal		PEORRES
7	PETERM	\$200				PETERM
8	PECLSIG	\$1		N = No Y = Yes		PECLSIG
9	PESTAT2	1				PESTAT2
10	PEREASND2	\$200				PEREASND2

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product preference****Generated On: 22 Sep 2014 07:54:21**

Which Product Arm would you prefer to be randomized to:

THS 2.2 menthol ☒ 1

mCC ☐

SA ☐

No preference ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product preference****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① PRODPREF	1		1 = THS 2.2 menthol 2 = mCC 3 = SA 4 = No preference		PRODPREF



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Advice on the risk of smoking and debriefing
Generated On: 22 Sep 2014 07:54:21

Date

Fixed Unit: **①**
DD/MMM/YYYY

Has the subject received advices on the risks of smoking?

No ☒ **②**
Yes ☐

Has a debriefing been performed about THS 2.2?

No ☒ **③**
Yes ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Advice on the risk of smoking and debriefing
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SRDAT	dd MMM YYYY				SRDAT
②	SRAYN	\$1		N = No Y = Yes		SRAYN
③	SRDYN	\$1		N = No Y = Yes		SRDYN

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination****Generated On: 22 Sep 2014 07:54:21**

Was the physical examination performed?

No ☐ ①
Yes ☐

If No, please specify the reason: _____ ②

Date of Assessment

Fixed Unit: ③
DD/MMM/YYYY

System

General Appearance ☐ ④HEENT ☐
(head, eyes, ears, nose,
throat)Thyroid Gland ☐Heart ☐Chest ☐Lungs ☐Gastrointestinal ☐Cardiovascular System ☐Neurologic ☐Skin ☐Back ☐Musculoskeletal ☐Abdomen ☐Dentition ☐Other ☐

Other, Specify _____ ⑤

Outcome

Normal ☐ ⑥
Abnormal ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Physical Examination
Generated On: 22 Sep 2014 07:54:21

Abnormal, please specify _____ 7

Clinically significant No ☒ 8
Yes ☐

Not Done _____ 9

Not Done; please specify the reason: _____ 10

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PESTAT	\$1		N = No Y = Yes		PESTAT
②	PEREASND1	\$200				PEREASND1
③	PEDAT	dd MMM YYYY				PEDAT

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④ PETESTCD	\$200		GAPPEAR = General Appearance HEENT = HEENT (head, eyes, ears, nose, throat)		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			THYROID = Thyroid Gland		
			HEART = Heart		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			CHEST = Chest		
			LUNGS = Lungs		
			GASTRO = Gastrointest inal		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
CVS = Cardiovascu lar System					
NEURO = Neurologic					

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
SKIN = Skin					
BACK =					
Back					
MUSCULO					
=					
Musculoskel					
etal					

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
ABDOMEN = Abdomen DENTN = Dentition OTHER = Other					



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: General Appearance 2: HEENT (head, eyes, ears, nose, throat) 3: Thyroid Gland 4: Heart 5: Chest 6: Lungs 7: Gastrointestinal 8: Cardiovascular System 9: Neurologic 10: Skin 11: Back 12: Musculoskeletal 13: Abdomen 14: Dentition 15: Other 16: Other 17: Other 18: Other 19: Other	PETESTCD
5 PESPEC	\$200				PESPEC



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	PEORRES	\$8		NORMAL = Normal ABNORMAL = Abnormal		PEORRES
7	PETERM	\$200				PETERM
8	PECLSIG	\$1		N = No Y = Yes		PECLSIG
9	PESTAT2	1				PESTAT2
10	PEREASND2	\$200				PEREASND2



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Identification of Current Cigarette Brand
Generated On: 22 Sep 2014 07:54:21

Date

Fixed Unit: ①
DD/MMM/YYYY

Brand name

②

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Identification of Current Cigarette Brand****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SCDAT	dd MMM YYYY				SCDAT
②	SCORRES_C\$200 BNAM					SCORRES_C BNAM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: THS 2.2 menthol product test

Generated On: 22 Sep 2014 07:54:21

Was the THS 2.2 menthol product trial performed?

No ☐ ①
Yes ☐

If the THS 2.2 menthol product trial was not performed,
please explain _____ ②

How many THS 2.2 menthol tobacco sticks did the
subject use on this day? _____ ③

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

No ☐ ④
Yes ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: THS 2.2 menthol product test****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	TSHPRFYN	1		0 = No 1 = Yes		TSHPRFYN
②	TSHNDRSN	\$200				TSHNDRSN
③	TSHNO	2				TSHNO
④	TSHWILYN	1		0 = No 1 = Yes		TSHWILYN



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: THS 2.2 menthol product demonstration
Generated On: 22 Sep 2014 07:54:21

Has the subject seen a THS 2.2 menthol product demonstration?

No ☐ ①
Yes ☐

If the subject did not see the demonstration please explain

②

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: THS 2.2 menthol product demonstration****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	THSDEMOY \$1 N			N = No Y = Yes		THSDEMOY N
②	THSNDRSN \$200					THSNDRSN

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product administration-mCC****Generated On: 22 Sep 2014 07:54:21**Date of product use
DD/MMM/YYYY

①

Visit

Day -2 ②

Day -1

Day 0

Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 30

Day 60

Day 90

Type of Product Use

mCC ③

THS 2.2 Menthol

If type of Product Use different from the randomization
please explain

④

Time of distribution

⑤

Time of butt return

⑥

CC with SODIM?

⑦

CC not compatible?

⑧

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product administration-mCC****Generated On: 22 Sep 2014 07:54:21**

SODIM device number	_____	9
SODIM sample holder number	_____	10
SODIM file number	_____	11
Comment	_____	12
H_NOW (Derived):	_____	13

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

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Product administration-mCC

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① EXSTDTC	dd MMM YYYY				EXSTDAT
② EXTPT_CC	2		1 = Day -2 2 = Day -1 3 = Day 0 4 = Day 1 5 = Day 2 6 = Day 3 7 = Day 4 8 = Day 5 9 = Day 6 10 = Day 30 11 = Day 60 12 = Day 90		EXTPT_CC
③ EXCAT	\$80		CONVENTI ONAL CIGARETTE S = mCC THS = THS 2.2 Menthol	1: mCC	EXCAT
④ EXSPEC	\$200				EXSPEC
⑤ EXDISTTIM	HH:nn				EXDISTTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product administration-mCC****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	EXRETTIM	HH:nn				EXRETTIM
7	EXSODIM	1				EXSODIM
8	EXCOMPAT	1				EXCOMPAT
9	EXSODIMN	\$4				EXSODIMN O
10	EXSAMPNO	\$4				EXSAMPNO
11	EXSODIMFN	\$20				EXSODIMFN O
12	EXCOM	\$200				EXCOM
13	H_NOW	dd MMM yyyy hh:nn:ss				H_NOW



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Product administration-THS menthol
Generated On: 22 Sep 2014 07:54:21

Date of product use
DD/MMM/YYYY

①

Visit

Day -2 ②

Day 0

Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 30

Day 60

Day 90

Type of Product Use

mCC ③

THS 2.2 Menthol

If type of Product Use different from the randomization
please explain

④

Time of distribution

⑤

Time of product return

⑥

SODIM device number

⑦

SODIM sample holder number

⑧

Tobacco plug kit number

⑨

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product administration-THS menthol****Generated On: 22 Sep 2014 07:54:21**

Tobacco plug vial number	_____	10
SODIM file number	_____	11
Comment	_____	12
Batch Number	_____	13
H_NOW (Derived):	_____	14

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

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

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product administration-THS menthol****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EXSTDTC	dd MMM YYYY				EXSTDAT
②	EXTPT_THS 2			1 = Day -2 2 = Day 0 3 = Day 1 4 = Day 2 5 = Day 3 6 = Day 4 7 = Day 5 8 = Day 6 9 = Day 30 10 = Day 60 11 = Day 90		EXTPT_THS
③	EXCAT	\$80		CONVENTI ONAL CIGARETTE S = mCC THS = THS 2.2 Menthol	1: THS 2.2 Menthol	EXCAT
④	EXSPEC	\$200				EXSPEC
⑤	EXDISTTIM	HH:nn				EXDISTTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Product administration-THS menthol
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	EXRETTIM	HH:nn				EXRETTIM
7	EXSODIMN O	\$4				EXSODIMN O
8	EXSAMPNO	\$4				EXSAMPNO
9	EXPKITNO	\$5				EXPKITNO
10	EXPVIALNO	2				EXPVIALNO
11	EXSODIMFN O	\$20				EXSODIMFN O
12	EXCOM	\$200				EXCOM
13	BATCHNO	\$10				BATCHNO
14	H_NOW	dd MMM yyyy hh:nn:ss				H_NOW

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Smoking History****Generated On: 22 Sep 2014 07:54:21**

Date of Assessment

Fixed Unit: **1**
DD/MMM/YYYY

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

No **2**
Yes

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

No **3**
Yes

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

<10 **4**
10 to 19
>19

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

No **5**
Yes

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

No **6**
Yes

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Smoking History****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SHDAT	dd MMM YYYY				SHDAT
②	SHORRES1	\$1		N = No Y = Yes		SHORRES1
③	SHORRES2	\$1		N = No Y = Yes		SHORRES2
④	SHORRES3	\$8		1 = <10 2 = 10 to 19 3 = >19		SHORRES3
⑤	SHORRES4	\$1		N = No Y = Yes		SHORRES4
⑥	SHORRES5	\$1		N = No Y = Yes		SHORRES5

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: HST 4 hours****Generated On: 22 Sep 2014 07:54:21**

Visit Day 30 ☐ ①
Day 60 ☐
Day 90 ☐

Not Done _____ ②

If Not Done, please specify _____ ③

Date DD/MMM/YYYY _____ ④

SODIM device distribution time hour:min 24-hour clock _____ ⑤

SODIM device collection time hour:min 24-hour clock _____ ⑥

Now (Derived): _____ ⑦

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: HST 4 hours****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	HSTVIS	1		1 = Day 30 2 = Day 60 3 = Day 90	1: Day 30 2: Day 60 3: Day 90	HSTVIS
②	HSTND	1				HSTND
③	HSTNDRSN	\$200				HSTNDRSN
④	HSTDAT	dd MMM YYYY				HSTDAT
⑤	HSTDISTIM	HH:nn				HSTDISTIM
⑥	HSTCOLTIM	HH:nn				HSTCOLTIM
⑦	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Topography files status for mCC****Generated On: 22 Sep 2014 07:54:21**SODIM file number ①File Status ②
Accepted ☐
Rejected ☐
Error ☐Rejection / Error reason ③Date of analysis ④
DD/MMM/YYYYOperator ⑤
Valerie Poux ☐
Thierry Bachmann ☐
Anthony Bruchet ☐Comment ⑥Modified File Number ⑦H_NOW (Derived): ⑧

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book**

Form: Topography files status for mCC

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EXSODIMFN\$20 O					EXSODIMFN O
②	HSTSTATUS1			1 = Accepted 2 = Rejected 3 = Error		HSTSTATUS
③	HSTREAS	\$50				HSTREAS
④	HSTDAT	dd MMM YYYY				HSTDAT
⑤	HSTOPERAT\$80 ER			1 = Valerie Poux 2 = Thierry Bachmann 3 = Anthony Bruchet		HSTOPERAT ER
⑥	EXCOM	\$200				EXCOM
⑦	MOD_FINE NUM	\$22				MOD_FINE NUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Topography files status for mCC****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Topography files status for THS menthol
Generated On: 22 Sep 2014 07:54:21

SODIM file number _____ ①

File Status _____ ②
Accepted ☐
Rejected ☐
Error ☐

Rejection / Error reason _____ ③

Date of analysis _____ ④
DD/MMM/YYYY

Operator _____ ⑤
Valerie Poux ☐
Thierry Bachmann ☐
Anthony Bruchet ☐

Comment _____ ⑥

Modified File Number _____ ⑦

H_NOW (Derived): _____ ⑧



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Topography files status for THS menthol
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EXSODIMFN\$20 O					EXSODIMFN O
②	HSTSTATUS1			1 = Accepted 2 = Rejected 3 = Error		HSTSTATUS
③	HSTREAS	\$50				HSTREAS
④	HSTDAT	dd MMM YYYY				HSTDAT
⑤	HSTOPERAT\$80 ER			1 = Valerie Poux 2 = Thierry Bachmann 3 = Anthony Bruchet		HSTOPERAT ER
⑥	EXCOM	\$200				EXCOM
⑦	MOD_FINE NUM	\$22				MOD_FINE NUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Topography files status for THS menthol****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Visual Inspection of the Tobacco Plugs Results for THS
Generated On: 22 Sep 2014 07:54:21

Tobacco plug kit number ①

Tobacco plug vial number ②

Level ☐ 0 ③
☐ 1
☐ 2
☐ NA

Observation ☐ Ashes not anymore visible when shooting picture ④
☐ No tobacco in plug
☐ Not enough tobacco in the plug to perform the analysis
☐ Tobacco plug destroyed, analysis impossible
☐ No tobacco plug in the vial
☐ Other error

Picture File Name ⑤

Date of analysis ⑥
DD/MM/YYYY

H_NOW (Derived): ⑦



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Visual Inspection of the Tobacco Plugs Results for THS
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EXPKITNO	\$5				EXPKITNO
②	EXPVIALNO	2				EXPVIALNO
③	HSTLEVEL	\$2		0 = 0 1 = 1 2 = 2 NA = NA		HSTLEVEL
④	HSTOBS	1		1 = Ashes not anymore visible when shooting picture 2 = No tobacco in plug 3 = Not enough tobacco in the plug to perform the analysis 4 = Tobacco plug destroyed, analysis impossible		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Visual Inspection of the Tobacco Plugs Results for THS
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = No tobacco plug in the vial 6 = Other error		HSTOBS
5 HSTFILE	\$200				HSTFILE
6 HSTADAT	dd MMM YYYY				HSTADAT
7 H_NOW	dd MMM YYYY hh:nn:ss				H_NOW

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Weight and Height****Generated On: 22 Sep 2014 07:54:21**

Measurement(s) assessed?

No ☐ ①
Yes ☐

If No, please specify the reason: _____ ②

Date of assessment

Fixed Unit: ③
DD/MMM/YYYY

Weight

Fixed Unit: ④
kg

Height

Fixed Unit: ⑤
cm

BMI (Derived)

Fixed Unit: ⑥
kg/m²

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Weight and Height****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSSTAT_W H	\$1		N = No Y = Yes		VSSTAT_W H
②	VSREASND _WH	\$200				VSREASND _WH
③	VSDAT	dd MMM YYYY				VSDAT
④	VSORRES_ WEIGHT	4.1				VSORRES_ WEIGHT
⑤	VSORRES_ HEIGHT	4.1				VSORRES_ HEIGHT
⑥	VSORRES_B3.1 MI					VSORRES_B MI

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Weight****Generated On: 22 Sep 2014 07:54:21**

Measurement(s) assessed?

No ☐ ①
Yes ☐

If No, please specify the reason: _____ ②

Date of Assessment

Fixed Unit: ③
DD/MMM/YYYY

Time of assessment

Fixed Unit: ④
hour:min 24-hour clock

Weight

Fixed Unit: ⑤
kg

Waist circumference

Fixed Unit: ⑥
cm

BMI

⑦

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Weight****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSSTAT_W H	\$1		N = No Y = Yes		VSSTAT_W H
②	VSREASND _WH	\$200				VSREASND _WH
③	VSDAT	dd MMM YYYY				VSDAT
④	VSTIM	HH:nn				VSTIM
⑤	VSORRES_ WEIGHT	4.1				VSORRES_ WEIGHT
⑥	VSORRES_ WC	3				VSORRES_ WC
⑦	VSORRES_B3.1 MI					VSORRES_B MI

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: ECG (12-Lead Standard) <Screening/>****Generated On: 22 Sep 2014 07:54:21**Method of ECG Test 12 Lead Placement Cabrera ☒ ①Was the ECG performed? No ☐ ②
Yes ☐

If No, please specify the reason: _____ ③

Date of assessment: _____ Fixed Unit: ④
DD/MMM/YYYYPosition Sitting ☐ ⑤
Standing ☐
Supine ☒Heart Rate _____ Fixed Unit: ⑥
beats per minute

Heart Rate unit _____ beats per minute ⑦

QRS Interval _____ Fixed Unit: ⑧
msec

QRS Interval unit _____ msec ⑨

QT Interval _____ Fixed Unit: ⑩
msec

PROD 02.001 (MAIN) GMP 05AUG2014 (649) 224 of 896

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: ECG (12-Lead Standard) <Screening/>****Generated On: 22 Sep 2014 07:54:21**QT Interval unit msec **11**QTcB Interval Fixed Unit: **12**
msecQTcB Interval unit msec **13**QTcF Interval Fixed Unit: **14**
msecQTcF Interval unit msec **15**PR Interval Fixed Unit: **16**
msecPR Interval unit msec **17**Interpretation Normal ☐ **18**
Abnormal ☐If Abnormal, Clinical Significance Not clinically significant ☐ **19**
Clinically significant ☐If Not Clinically significant or clinically Significant, Please specify the finding(s) **20**



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: ECG (12-Lead Standard) <Screening/>
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EGMETHOD	\$20		12 LEAD STANDARD = 12 Lead Placement Cabrera		EGMETHOD
②	EGSTAT	\$1		N = No Y = Yes		EGSTAT
③	EGREASND	\$200				EGREASND
④	EGDAT	dd MMM YYYY				EGDAT
⑤	EGPOS	\$10		SITTING = Sitting STANDING = Standing SUPINE = Supine		EGPOS
⑥	EGORRES_3 HR					EGORRES_ HR
⑦	EGORRESU_3 _HR	\$10		beats per minute		EGORRESU_ _HR
⑧	EGORRES_3 QRS					EGORRES_ QRS

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: ECG (12-Lead Standard) <Screening/>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	EGORRESU_QRS	\$10		msec		EGORRESU_QRS
10	EGORRES_QT	3				EGORRES_QT
11	EGORRESU_QT	\$10		msec		EGORRESU_QT
12	EGORRES_QTC	3				EGORRES_QTC
13	EGORRESU_QTC	\$10		msec		EGORRESU_QTC
14	EGORRES_QTCF	3				EGORRES_QTCF
15	EGORRESU_QTCF	\$10		msec		EGORRESU_QTCF
16	EGORRES_PR	P3				EGORRES_PR
17	EGORRESU_PR	\$10		msec		EGORRESU_PR
18	EGINTP	\$40		NORMAL = Normal		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: ECG (12-Lead Standard) <Screening/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			ABNORMAL = Abnormal		EGINTP
19 EGCLSIG	\$40		NCS = Not clinically significant CS = Clinically significant		EGCLSIG
20 EGTERM	\$200				EGTERM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: ECG (12-Lead Standard)****Generated On: 22 Sep 2014 07:54:21**Method of ECG Test 12 Lead Placement Cabrera ☒ ①Was the ECG performed? No ☒ ②
Yes ☐

If No, please specify the reason: _____ ③

Date of Assessment Fixed Unit: ④
DD/MMM/YYYYPosition Sitting ☒ ⑤
Standing ☐
Supine ☐Heart Rate Fixed Unit: ⑥
beats per minute

Heart Rate unit beats per minute ⑦

QRS Interval Fixed Unit: ⑧
msec

QRS Interval unit msec ⑨

QT Interval Fixed Unit: ⑩
msecPROD 02.001 (MAIN) GMP
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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: ECG (12-Lead Standard)****Generated On: 22 Sep 2014 07:54:21**QT Interval unit msec **11**QTcB Interval Fixed Unit: **12**
msecQTcB Interval unit msec **13**PR Interval Fixed Unit: **14**
msecPR Interval unit msec **15**QTcF Interval Fixed Unit: **16**
msecQTcF Interval unit msec **17**Interpretation Normal ☐ **18**
Abnormal ☐If Abnormal, Clinical Significance Not clinically significant ☐ **19**
Clinically significant ☐If Not Clinically significant or clinically Significant, Please specify the finding(s) **20**



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: ECG (12-Lead Standard)

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EGMETHOD	\$20		12 LEAD STANDARD = 12 Lead Placement Cabrera		EGMETHOD
②	EGSTAT	\$1		N = No Y = Yes		EGSTAT
③	EGREASND	\$200				EGREASND
④	EGDAT	dd MMM YYYY				EGDAT
⑤	EGPOS	\$10		SITTING = Sitting STANDING = Standing SUPINE = Supine		EGPOS
⑥	EGORRES_3 HR					EGORRES_ HR
⑦	EGORRESU_3 _HR	\$10		beats per minute		EGORRESU_ _HR
⑧	EGORRES_3 QRS					EGORRES_ QRS



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: ECG (12-Lead Standard)

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	EGORRESU_QRS	\$10		msec		EGORRESU_QRS
10	EGORRES_QT	3				EGORRES_QT
11	EGORRESU_QT	\$10		msec		EGORRESU_QT
12	EGORRES_QTC	3				EGORRES_QTC
13	EGORRESU_QTC	\$10		msec		EGORRESU_QTC
14	EGORRES_PR	P3				EGORRES_PR
15	EGORRESU_PR	\$10		msec		EGORRESU_PR
16	EGORRES_QTCF	3				EGORRES_QTCF
17	EGORRESU_QTCF	\$10		msec		EGORRESU_QTCF
18	EGINTP	\$40		NORMAL = Normal		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: ECG (12-Lead Standard)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			ABNORMAL = Abnormal		EGINTP
19 EGCLSIG	\$40		NCS = Not clinically significant CS = Clinically significant		EGCLSIG
20 EGTERM	\$200				EGTERM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Spirometry****Generated On: 22 Sep 2014 07:54:21**

Was the spirometry performed?

No ☐ 1
Yes ☐

If No, please specify the reason: _____ 2

Category

With short-acting
bronchodilator ☐ 3
Without short-acting
bronchodilator ☐

Position _____ 4

Has the subject smoked within 1 hour prior to
assessment?No ☐ 5
Yes ☐Date of assessment
DD/MMM/YYYY _____ 6

Time of assessment _____ 7

Name of bronchodilator _____ 8

Dose _____ 9

Predicted FVC value

Fixed Unit: 10
L

Best measured FVC value

Fixed Unit: 11
L

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Spirometry****Generated On: 22 Sep 2014 07:54:21**

Percent of predicted FVC value

Fixed Unit: **17**
%

Best measured FEV1 value

Fixed Unit: **15**
L

Predicted FEV1 value

Fixed Unit: **14**
L

Percent of predicted FEV1 value

Fixed Unit: **15**
%

Calculated ratio between FEV1/FVC

16

MEF 25/75 value

Fixed Unit: **17**
L/s

Interpretation

Normal **16**
Abnormal

If Abnormal, Clinical Significance

Not clinically significant **16**
Clinically significant



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Spirometry

Generated On: 22 Sep 2014 07:54:21

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

20

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Spirometry****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PTSTAT	\$1		N = No Y = Yes		PTSTAT
②	PTREASND	\$200				PTREASND
③	PTCAT	\$80		WITH = With short-acting bronchodila tor WITHOUT = Without short-acting bronchodila tor 1: Without short-acting bronchodila tor 2: With short-acting bronchodila tor		PTCAT
④	PTPOS	\$20		SITTING SI TTING	1: SITTING 2: SITTING	PTPOS
⑤	PTRESTYN	\$40		N = No Y = Yes		PTRESTYN
⑥	PTDAT	dd MMM YYYY				PTDAT



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Spirometry

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
7	PTTIM	HH:nn				PTTIM
8	PTBD	\$200				PTBD
9	PTDOSE	\$10				PTDOSE
10	PTORRES_F 4.2 VCPRED					PTORRES_F VCPRED
11	PTORRES_F 4.2 VCMEAS					PTORRES_F VCMEAS
12	PTORRES_F 3 VCMPR					PTORRES_F VCMPR
13	PTORRES_F 4.2 EV1MEAS					PTORRES_F EV1MEAS
14	PTORRES_F 4.2 EV1PRED					PTORRES_F EV1PRED
15	PTORRES_F 3 EV1MPR					PTORRES_F EV1MPR
16	PTRATIO	4.2				PTRATIO
17	PTORRES_ 4.2 MEF					PTORRES_ MEF

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Spirometry****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
18	PTORRES_I NTP	\$40		NORMAL = Normal ABNORMAL = Abnormal		PTORRES_I NTP
19	PTCLSIG	\$40		NCS = Not clinically significant CS = Clinically significant		PTCLSIG
20	PTTERM	\$40				PTTERM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Gas Transfer

Generated On: 22 Sep 2014 07:54:21

Was the Gas Transfer performed?

No ☐ ①
Yes ☐

If No, please specify the reason: _____ ②

Category

With short-acting
bronchodilator ☐ ③
Without short-acting
bronchodilator ☐

Position

SITTING ④

Date of assessment
DD/MMM/YYYY _____ ⑤

Time of assessment _____ ⑥

DLCO value

Fixed Unit: ⑦
ml/min/mmHg

KCO value

Fixed Unit: ⑧
mmol/min/kPa/L

DLCO/VA value

Fixed Unit: ⑨
mmol/min/kPa/L



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Gas Transfer
Generated On: 22 Sep 2014 07:54:21

Interpretation

Normal ☒ 10
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☒ 11
Clinically significant ☐

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

17

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Gas Transfer****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PTSTAT4	\$1		N = No Y = Yes		PTSTAT4
②	PTREASND	\$200				PTREASND
③	PTCAT	\$80		WITH = With short-acting bronchodila tor WITHOUT = Without short-acting bronchodila tor		PTCAT
④	PTPOS	\$20		SITTING		PTPOS
⑤	PTDAT	dd MMM YYYY				PTDAT
⑥	PTTIM	HH:nn				PTTIM
⑦	PTORRES_D4.2 LCO					PTORRES_D LCO

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Gas Transfer****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	PTORRES_K4.2 CO					PTORRES_K CO
9	PTORRES_D4.2 LCOVA					PTORRES_D LCOVA
10	PTORRES_I \$40 NTP			NORMAL = Normal ABNORMAL = Abnormal		PTORRES_I NTP
11	PTCLSIG	\$40		NCS = Not clinically significant CS = Clinically significant		PTCLSIG
12	PTTERM	\$40				PTTERM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Lung Volume Measurements
Generated On: 22 Sep 2014 07:54:21

Were the Lung Volume Measurements performed?

No ☐ ①
Yes ☐

If No, please specify the reason: _____ ②

Category

With short-acting
bronchodilator ☐ ③
Without short-acting
bronchodilator ☐

Position

SITTING ④

Date of assessment
DD/MMM/YYYY _____ ⑤

Time of assessment _____ ⑥

VC value

Fixed Unit: ⑦
L

TLC value

Fixed Unit: ⑧
L

IC value

Fixed Unit: ⑨
L

FRC value

Fixed Unit: ⑩
L

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PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Lung Volume Measurements
Generated On: 22 Sep 2014 07:54:21

Interpretation

Normal ☒ 11
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☒ 17
Clinically significant ☐

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

☒ 13



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Lung Volume Measurements

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PTSTAT5	\$1		N = No Y = Yes		PTSTAT5
②	PTREASND	\$200				PTREASND
③	PTCAT	\$80		WITH = With short-acting bronchodila tor WITHOUT = Without short-acting bronchodila tor		PTCAT
④	PTPOS	\$20		SITTING		PTPOS
⑤	PTDAT	dd MMM YYYY				PTDAT
⑥	PTTIM	HH:nn				PTTIM
⑦	PTORRES_V4.2 C					PTORRES_V C

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Lung Volume Measurements****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	PTORRES_T 4.2 LC					PTORRES_T LC
9	PTORRES_I 4.2 C					PTORRES_I C
10	PTORRES_F 4.2 RC					PTORRES_F RC
11	PTORRES_I \$40 NTP			NORMAL = Normal ABNORMAL = Abnormal		PTORRES_I NTP
12	PTCLSIG	\$40		NCS = Not clinically significant CS = Clinically significant		PTCLSIG
13	PTTERM	\$40				PTTERM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Spirometry with a short-acting bronchodilator
Generated On: 22 Sep 2014 07:54:21

Was the Spirometry with a short-acting bronchodilator performed?

No ☐ 1
Yes ☐

If No, please specify the reason: _____ 2

Category

With short-acting
bronchodilator ☒ 3
Without short-acting
bronchodilator ☐

Position

SITTING 4

Date of assessment
DD/MMM/YYYY _____ 5

Time of assessment _____ 6

Name of bronchodilator _____ 7

Dose _____ 8

Predicted FVC value

Fixed Unit: 9
L

Best measured FVC value

Fixed Unit: 10
L

Percent of predicted FVC value

Fixed Unit: 11
%

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PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Spirometry with a short-acting bronchodilator
Generated On: 22 Sep 2014 07:54:21

Best measured FEV1 value

Fixed Unit: **17**
L

Predicted FEV1 value

Fixed Unit: **18**
L

Percent of predicted FEV1 value

Fixed Unit: **14**
%

Calculated ratio between FEV1/FVC

15

MEF 25/75 value

Fixed Unit: **16**
L/s

Interpretation

Normal ☐ **17**
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐ **18**
Clinically significant ☐

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

19



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Spirometry with a short-acting bronchodilator
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PTSTAT3	\$1		N = No Y = Yes		PTSTAT3
②	PTREASND	\$200				PTREASND
③	PTCAT	\$80		WITH = With short-acting bronchodila tor WITHOUT = Without short-acting bronchodila tor		PTCAT
④	PTPOS	\$20		SITTING		PTPOS
⑤	PTDAT	dd MMM YYYY				PTDAT
⑥	PTTIM	HH:nn				PTTIM
⑦	PTBD	\$200				PTBD
⑧	PTDOSE	\$10				PTDOSE



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Spirometry with a short-acting bronchodilator
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	PTORRES_F 4.2 VCPRED					PTORRES_F VCPRED
10	PTORRES_F 4.2 VCMEAS					PTORRES_F VCMEAS
11	PTORRES_F 3 VCMPR					PTORRES_F VCMPR
12	PTORRES_F 4.2 EV1MEAS					PTORRES_F EV1MEAS
13	PTORRES_F 4.2 EV1PRED					PTORRES_F EV1PRED
14	PTORRES_F 3 EV1MPR					PTORRES_F EV1MPR
15	PTRATIO	4.2				PTRATIO
16	PTORRES_ 4.2 MEF					PTORRES_ MEF
17	PTORRES_I \$40 NTP			NORMAL = Normal ABNORMAL = Abnormal		PTORRES_I NTP



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Spirometry with a short-acting bronchodilator
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
18 PTCLSIG	\$40		NCS = Not clinically significant CS = Clinically significant		PTCLSIG
19 PTTERM	\$40				PTTERM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Chest X-Ray****Generated On: 22 Sep 2014 07:54:21**

Category for Examination

Chest X-Ray ☒ ①

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

No ☒ ②Yes ☐

If No, please specify the reason: _____

③

Date of assessment

Fixed Unit: ☒ ④
DD/MMM/YYYY

System

General Appearance ☒ ⑤HEENT ☐(head, eyes, ears, nose,
throat)Thyroid Gland ☐Heart ☐Chest ☒Lungs ☐Gastrointestinal ☐Cardiovascular System ☐Neurologic ☐Skin ☐Back ☐Musculoskeletal ☐Abdomen ☐Dentition ☐Other ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Chest X-Ray

Generated On: 22 Sep 2014 07:54:21

Interpretation

Normal ☒ 6
Abnormal ☐

Clinically significant

No ☒ 7
Yes ☐

Abnormal, please specify:

☒ 8

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Chest X-Ray****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PECAT	\$80		CHEST XRAY = Chest X-Ray		XRPECAT
②	XRPESTAT	\$1		N = No Y = Yes		XRPESTAT
③	XRPEREASN	\$200				XRPEREASN
	D					D
④	XRPEDAT	dd- MMM- YYYY				XRPEDAT
⑤	XRPESTC	\$200		GAPPEAR = General Appearance HEENT = HEENT (head, eyes, ears, nose, throat) THYROID = Thyroid Gland HEART = Heart CHEST = Chest		
	D					

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Chest X-Ray****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			LUNGS = Lungs GASTRO = Gastrointest inal CVS = Cardiovascu lar System NEURO = Neurologic SKIN = Skin BACK = Back MUSCULO = Musculoskel etal ABDOMEN = Abdomen DENTN = Dentition OTHER = Other		XRPETESTC D
⑥ XRPEORRES\$8			NORMAL = Normal ABNORMAL = Abnormal		XRPEORRES

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Chest X-Ray****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑦ XRPECLSIG	\$1		N = No Y = Yes		XRPECLSIG
⑧ XRPETERM1	\$200				XRPETERM1

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Socio-Economic Status****Generated On: 22 Sep 2014 07:54:21**

Was paper questionnaire used?

No ☐ ①
Yes ☐

Reason not done

②

Date

Fixed Unit: ③
DD/MMM/YYYY

Time

Fixed Unit: ④
hour:min 24-hour clock

Q1. What is the highest level of education you have completed?

Less than High School ☐ ⑤
High School Graduate ☐
Some College ☐
College Graduate ☐
Advanced Degree ☐

Q2. What is your current occupational status?

Working now ☐ ⑥
Only temporarily laid off, ☐
sick leave or maternity
leave
Looking for work, ☐
unemployed
Retired ☐
Disabled, permanently or ☐
temporarily
Keeping house ☐
Student ☐
Other ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Socio-Economic Status****Generated On: 22 Sep 2014 07:54:21**

SPECIFY

7

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

8

Q4. Of these people, how many are children?

9

Q5. Of these people, how many are adults?

10

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

11

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

Less than \$10,000

12

\$10,000 to \$29,999

\$30,000 through \$44,999

\$45,000 through \$59,999

\$60,000 through \$74,999

\$75,000 through \$99,999

\$100,000 through

\$149,999

\$150,000 and over

I do not know

No response

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Socio-Economic Status****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSSTAT	\$1		N = No Y = Yes		QSSTAT
②	QSREASND	\$200				QSREASND
③	SESDAT	dd MMM YYYY				SESDAT
④	SESTIM	HH:nn				SESTIM
⑤	SES_Q1	1		1 = Less than High School 2 = High School Graduate 3 = Some College 4 = College Graduate 5 = Advanced Degree		SES_Q1
⑥	SES_Q2	1		1 = Working now		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Socio-Economic Status****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Only temporarily laid off, sick leave or maternity leave 3 = Looking for work, unemployed 4 = Retired 5 = Disabled, permanently or temporarily 6 = Keeping house 7 = Student 8 = Other		SES_Q2
7 SES_Q2SPE \$200 C					SES_Q2SPE C
8 SES_Q3	2				SES_Q3
9 SES_Q4	2				SES_Q4
10 SES_Q5	2				SES_Q5

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Socio-Economic Status****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
SES_Q6	2				SES_Q6
SES_Q7	2		1 = Less than \$10,000 2 = \$10,000 to \$29,999 3 = \$30,000 through \$44,999 4 = \$45,000 through \$59,999 5 = \$60,000 through \$74,999 6 = \$75,000 through \$99,999 7 = \$100,000 through \$149,999 8 = \$150,000 and over 9 = I do not know 10 = No response		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Socio-Economic Status

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					SES_Q7

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Haematology****Generated On: 22 Sep 2014 07:54:21**

Category

Clinical Chemistry ☐ ①Drug Screen ☐Haematology ☒Serology ☐Pregnancy Testing ☐Urinalysis ☐Cotinine Screening ☐Alcohol Test ☐

Were samples collected?

No ☐ ②Yes ☐

If No, please specify the reason: _____

③

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

No ☐ ④Yes ☐

Please document clinically relevant abnormalities in the AE form



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Haematology

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② LBSTAT	\$1		N = No Y = Yes		LBSTAT

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book**

Form: Haematology

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	LBREASND	\$200				LBREASND
4	LBFSTYN	\$1		N = No Y = Yes		LBFSTYN

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Clinical Chemistry****Generated On: 22 Sep 2014 07:54:21**

Category

Clinical Chemistry ☒ ①Drug Screen ☐Haematology ☐Serology ☐Pregnancy Testing ☐Urinalysis ☐Cotinine Screening ☐Alcohol Test ☐

Were samples collected?

No ☒ ②Yes ☐

If No, please specify the reason: _____ ③

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

No ☒ ④Yes ☐

Please document clinically relevant abnormalities in the AE form



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Clinical Chemistry

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② LBSTAT	\$1		N = No Y = Yes		LBSTAT

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Clinical Chemistry****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	LBREASND	\$200				LBREASND
4	LBFSTYN	\$1		N = No Y = Yes		LBFSTYN



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine analysis

Generated On: 22 Sep 2014 07:54:21

Category

Clinical Chemistry ☒ ①
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☐
Urinalysis ☒
Cotinine Screening ☐
Alcohol Test ☐

Were samples collected?

No ☒ ②
Yes ☐

If No, please specify the reason: _____

③

Please document clinically relevant abnormalities in the AE form

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine analysis****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② LBSTAT	\$1		N = No Y = Yes		LBSTAT

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine analysis****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
LBREASND	\$200				LBREASND



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Serology for HIV and Hepatitis B and C
Generated On: 22 Sep 2014 07:54:21

Category	Clinical Chemistry <input type="radio"/> ①
	Drug Screen <input type="radio"/>
	Haematology <input type="radio"/>
	Serology <input checked="" type="radio"/>
	Pregnancy Testing <input type="radio"/>
	Urinalysis <input type="radio"/>
	Cotinine Screening <input type="radio"/>
	Alcohol Test <input type="radio"/>

Not Done	_____ ②
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If Not Done, please specify the reason:	_____ ③
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PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Serology for HIV and Hepatitis B and C
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② LBBSTAT	1				LBBSTAT
③ LBREASND	\$200				LBREASND

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Drug Screen<Screening/>****Generated On: 22 Sep 2014 07:54:21**

Category

Clinical Chemistry ☒ ①Drug Screen ☒Haematology ☐Serology ☐Pregnancy Testing ☐Urinalysis ☐Cotinine Screening ☐Alcohol Test ☐

Not Done? _____ ②

If Not Done, please specify the reason: _____ ③

Date of sample collection

Fixed Unit: ☒ ④
DD/MMM/YYYY

Time of sample collection

Fixed Unit: ☒ ⑤
hour:min 24-hour clock

Drug type

Amphetamines ☒ ⑥Barbiturates ☐Benzodiazepines ☐Cannabinoids ☐Cocaine ☐Opiates ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine Drug Screen<Screening/>

Generated On: 22 Sep 2014 07:54:21

Result

Negative ☒ 7
Positive ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Drug Screen<Screening/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② DRUGSTAT 1					DRUGSTAT
③ ALCREASN D	\$200				DRUGREAS ND

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Drug Screen<Screening/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④ DRUGDAT	dd MMM YYYY				DRUGDAT
⑤ DRUGTIM	HH:nn				DRUGTIM
⑥ DRUGTEST	\$20		AMPHETAM INES = Amphetami nes BARBITURA TES = Barbiturates BENZODIAZ EPINES = Benzodiaze pines CANNABIN OIDS = Cannabinoi ds COCAINE = Cocaine OPIATES = Opiates	1: Amphetami nes 2: Barbiturates 3: Benzodiaze pines 4: Cannabinoi ds 5: Cocaine 6: Opiates	DRUGTEST

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Drug Screen<Screening/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑦ DRUGORRE \$8 S			NEGATIVE = Negative POSITIVE = Positive		DRUGORRE S

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Drug Screen****Generated On: 22 Sep 2014 07:54:21**

Category

Clinical Chemistry ☒ ①Drug Screen ☒Haematology ☐Serology ☐Pregnancy Testing ☐Urinalysis ☐Cotinine Screening ☐Alcohol Test ☐

Not Done? _____ ②

If Not Done, please specify the reason: _____ ③

Time of sample collection

Fixed Unit: ④
hour:min 24-hour clock

Drug type

Amphetamines ☒ ⑤Barbiturates ☐Benzodiazepines ☐Cannabinoids ☐Cocaine ☐Opiates ☐

Result

Negative ☒ ⑥Positive ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine Drug Screen

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② DRUGSTAT 1					DRUGSTAT
③ ALCREASN D	\$200				DRUGREAS ND



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine Drug Screen

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
4 DRUGTIM	HH:nn				DRUGTIM
5 DRUGTEST	\$20		AMPHETAM INES = Amphetami nes BARBITURA TES = Barbiturates BENZODIAZ EPINES = Benzodiaze pines CANNABIN OIDS = Cannabinoi ds COCAINE = Cocaine OPIATES = Opiates	1: Amphetami nes 2: Barbiturates 3: Benzodiaze pines 4: Cannabinoi ds 5: Cocaine 6: Opiates	DRUGTEST
6 DRUGORRE	\$8 S		NEGATIVE = Negative		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine Drug Screen

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			POSITIVE = Positive		DRUGORRES

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Alcohol Test<Screening/>****Generated On: 22 Sep 2014 07:54:21**

Category

Clinical Chemistry ☒ ①

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☒

Was the alcohol test performed? No ☒ ②
Yes ☐

If No, please specify the reason: _____ ③

Method used

Urine sample ☒ ④

Breath test ☐

Date of assessment

Fixed Unit: ⑤
DD/MMM/YYYY

Time of assessment

Fixed Unit: ⑥
hour:min 24-hour clock

Result

Negative ☒ ⑦

Positive ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Alcohol Test<Screening/>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② ALCSTAT	\$1		N = No Y = Yes		ALCSTAT

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Alcohol Test<Screening/>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③	ALCREASN D	\$200				ALCREASN D
④	ALCMETHO D	1		1 = Urine sample 2 = Breath test		ALCMETHO D
⑤	ALCDAT	dd MMM YYYY				ALCDAT
⑥	ALCTIM	HH:nn				ALCTIM
⑦	ALCORRES	\$30		NEGATIVE = Negative POSITIVE = Positive		ALCORRES

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Alcohol Test****Generated On: 22 Sep 2014 07:54:21**

Category

Clinical Chemistry ☒ 1
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☐
Urinalysis ☐
Cotinine Screening ☐
Alcohol Test ☒

Was the alcohol test performed?

No ☒ 2
Yes ☐

If No, please specify the reason:

☐ 3

Method used

Urine sample ☒ 4
Breath test ☐

Time of assessment

Fixed Unit: ☒ 5
hour:min 24-hour clock

Result

Negative ☒ 6
Positive ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Alcohol Test

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② ALCSTAT	\$1		N = No Y = Yes		ALCSTAT

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Alcohol Test****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③	ALCREASN D	\$200				ALCREASN D
④	ALCMETHO D	1		1 = Urine sample 2 = Breath test		ALCMETHO D
⑤	ALCTIM	HH:nn				ALCTIM
⑥	ALCORRES	\$30		NEGATIVE = Negative POSITIVE = Positive		ALCORRES



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine Pregnancy Test<Screening/>

Generated On: 22 Sep 2014 07:54:21

Category _____ Clinical Chemistry ☒ ①
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☒
Urinalysis ☐
Cotinine Screening ☐
Alcohol Test ☐

Not Done _____ ②

If Not Done, specify reason _____ ③

Date of Test _____ Fixed Unit: ☒ ④
DD/MMM/YYYY

Time of Test _____ Fixed Unit: ☒ ⑤
hour:min 24-hour clock

Specify result _____ Negative ☒ ⑥
Positive ☐
Unclear ☐

If unclear, please confirm with FSH test _____

Specify result of FSH test _____ < 20 IU/L ☒ ⑧
>= 20 IU/L ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine Pregnancy Test<Screening/>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② PGNSTAT	1				PGNSTAT
③ PGNREASN D	\$200				PGNREASN D

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Pregnancy Test<Screening/>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④	PGNDAT	dd MMM YYYY				PGNDAT
⑤	PGNTIM	HH:nn				PGNTIM
⑥	PGNORRES	\$8		NEGATIVE = Negative POSITIVE = Positive UNCLEAR = Unclear		PGNORRES
⑧	PGNORRES	\$8 N		1 = < 20 IU/L 2 = >= 20 IU/L		PGNORRES N



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine Pregnancy Test

Generated On: 22 Sep 2014 07:54:21

Category _____ Clinical Chemistry ☒ ①
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☒
Urinalysis ☐
Cotinine Screening ☐
Alcohol Test ☐

Not Done _____ ②

If Not Done, specify reason _____ ③

Date of Test _____ Fixed Unit: ☒ ④
DD/MMM/YYYY

Time of Test _____ Fixed Unit: ☒ ⑤
hour:min 24-hour clock

Specify result _____ Negative ☒ ⑥
Positive ☐
Unclear ☐

If unclear, please confirm with FSH test _____

Specify result of FSH test _____ < 20 IU/L ☒ ⑧
>= 20 IU/L ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine Pregnancy Test

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② PGNSTAT	1				PGNSTAT
③ PGNREASN D	\$200				PGNREASN D

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Pregnancy Test****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④	PGNDAT	dd MMM YYYY				PGNDAT
⑤	PGNTIM	HH:nn				PGNTIM
⑥	PGNORRES	\$8		NEGATIVE = Negative POSITIVE = Positive UNCLEAR = Unclear		PGNORRES
⑧	PGNORRES	\$8 N		1 = < 20 IU/L 2 = >= 20 IU/L		PGNORRES N

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Cotinine Test<Screening/>****Generated On: 22 Sep 2014 07:54:21**

Category	Clinical Chemistry <input type="radio"/> ①
	Drug Screen <input type="radio"/>
	Haematology <input type="radio"/>
	Serology <input type="radio"/>
	Pregnancy Testing <input type="radio"/>
	Urinalysis <input type="radio"/>
	Cotinine Screening <input checked="" type="radio"/>
	Alcohol Test <input type="radio"/>
Not Done	_____ ②
If Not Done, please specify the reason:	_____ ③
Date of Sample Collection	Fixed Unit: _____ ④ DD/MMM/YYYY
Time of Sample Collection	Fixed Unit: _____ ⑤ hour:min 24-hour clock
Result	Negative <200 ng/ml <input type="radio"/> ⑥ Positive >=200 ng/ml <input type="radio"/>

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Cotinine Test<Screening/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② LBBSTAT	1				LBBSTAT
③ LBREASND	\$200				LBREASND

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Cotinine Test<Screening/>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④	COTDAT	dd MMM YYYY				COTDAT
⑤	COTTIM	HH:nn				COTTIM
⑥	COTORRES	\$8		1 = Negative <200 ng/ml 2 = Positive ≥200 ng/ml		COTORRES

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Plasma Nicotine Sample****Generated On: 22 Sep 2014 07:54:21**

Not Done

 ①

If Not Done, please specify the reason:

 ②

Date

 DD/MM/YYYY ③

Time

 hour:min 24-hour clock ④

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Plasma Nicotine Sample****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Plasma Nicotine Samples <Day 5>****Generated On: 22 Sep 2014 07:54:21**Not Done ☐ ①If Not Done, please specify the reason: ☐ ②Date ☐
DD/MM/YYYY ☐ ③

Scheduled Time	T0 -15 min	<input type="checkbox"/> ④
	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"/>
	T0 + 20H	<input type="checkbox"/>
	T0 + 24H	<input type="checkbox"/>

Time ☐
hour:min 24-hour clock ☐ ⑤Now (Derived): ☐ ⑥



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Plasma Nicotine Samples <Day 5>

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTPT	\$40		1 = T0 -15 min 2 = T1 3 = T2 4 = T3 5 = T4 6 = T5 7 = T6 8 = T7 9 = T8 10 = T0 + 20H 11 = T0 + 24H	1: T0 -15 min 2: T1 3: T2 4: T3 5: T4 6: T5 7: T6 8: T7 9: T8	PCBTPT
⑤	PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Plasma Nicotine Samples <Day 5>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Plasma Nicotine Samples <Day 6>****Generated On: 22 Sep 2014 07:54:21**Not Done ☐ ①If Not Done, please specify the reason: ☐ ②Date ☐
DD/MM/YYYY ☐ ③

Scheduled Time	T0 -15 min	<input type="checkbox"/>	④
	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"/>	
	T0 + 20H	<input type="checkbox"/>	
T0 + 24H	<input type="checkbox"/>		

Time ☐
hour:min 24-hour clock ☐ ⑤



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Plasma Nicotine Samples <Day 6>

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTPT	\$40		1 = T0 -15 min 2 = T1 3 = T2 4 = T3 5 = T4 6 = T5 7 = T6 8 = T7 9 = T8 10 = T0 + 20H 11 = T0 + 24H	1: T0 + 20H 2: T0 + 24H	PCBTPT
⑤	PCBTIM	HH:nn				PCBTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Plasma Cotinine Sample

Generated On: 22 Sep 2014 07:54:21

Not Done _____ ①

If Not Done, please specify the reason: _____ ②

Date
DD/MM/YYYY _____ ③

Time
hour:min 24-hour clock _____ ④

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Plasma Cotinine Sample****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Plasma Cotinine Samples <Day 5>****Generated On: 22 Sep 2014 07:54:21**

Not Done

①

If Not Done, please specify the reason:

②

Date

DD/MM/YYYY

③

Scheduled Time

T0 -15 min

④

T1

T2

T3

T4

T5

T6

T7

T8

T0 + 20H

T0 + 24H

Time

hour:min 24-hour clock

⑤

Now (Derived):

⑥



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Plasma Cotinine Samples <Day 5>

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTPT	\$40		1 = T0 -15 min 2 = T1 3 = T2 4 = T3 5 = T4 6 = T5 7 = T6 8 = T7 9 = T8 10 = T0 + 20H 11 = T0 + 24H	1: T0 -15 min 2: T1 3: T2 4: T3 5: T4 6: T5 7: T6 8: T7 9: T8	PCBTPT
⑤	PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Plasma Cotinine Samples <Day 5>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Plasma Cotinine Samples <Day 6>****Generated On: 22 Sep 2014 07:54:21**

Not Done

①

If Not Done, please specify the reason:

②

Date

DD/MM/YYYY

③

Scheduled Time

T0 -15 min

④

T1

T2

T3

T4

T5

T6

T7

T8

T0 + 20H

T0 + 24H

Time

hour:min 24-hour clock

⑤



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Plasma Cotinine Samples <Day 6>

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTPT	\$40		1 = T0 -15 min 2 = T1 3 = T2 4 = T3 5 = T4 6 = T5 7 = T6 8 = T7 9 = T8 10 = T0 + 20H 11 = T0 + 24H	1: T0 + 20H 2: T0 + 24H	PCBTPT
⑤	PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample(SA)****Generated On: 22 Sep 2014 07:54:21**

Not Done ☐ ①

If Not Done, please specify the reason: ☐ ②

Date ☐ ③
DD/MMM/YYYY

Scheduled Time ☐ ④

Within 15 min prior to smoking ☐

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

Prior to gas transfer assessment ☐

Prior to gas transfer assessment and prior to product use ☐

10:00 - 11:30 ☐

10:00 - 12:30 ☐

Time ☐ ⑤
hour:min 24-hour clock

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample(SA)****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBCTPT	\$40		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30 6 = Prior to gas transfer assessment 7 = Prior to gas transfer assessment and prior to product use 8 = 10:00 - 11:30		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample(SA)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = 10:00 - 12:30	1: 08:00 - 09:30 2: 12:00 - 13:30 3: 16:00 - 17:30 4: 20:00 - 21:30	PCBCTPT
5 PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample(CC/THS)****Generated On: 22 Sep 2014 07:54:21**

Not Done ①

If Not Done, please specify the reason: ②

Date ③
DD/MMM/YYYY

Scheduled Time ④

Within 15 min prior to smoking ☐

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

Prior to gas transfer assessment ☐

Prior to gas transfer assessment and prior to product use ☐

10:00 - 11:30 ☐

10:00 - 12:30 ☐

Time ⑤
hour:min 24-hour clock

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample(CC/THS)****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBCTPT	\$40		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30 6 = Prior to gas transfer assessment 7 = Prior to gas transfer assessment and prior to product use		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample(CC/THS)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = 10:00 - 11:30 9 = 10:00 - 12:30	1: Within 15 min prior to smoking 2: 12:00 - 13:30 3: 16:00 - 17:30 4: 20:00 - 21:30	PCBCTPT
5 PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample****Generated On: 22 Sep 2014 07:54:21**Not Done ☐ ①If Not Done, please specify the reason: ☐ ②Date ☐ ③
DD/MM/YYYY

Timepoint ☐ ④

Within 15 min prior to smoking ☐

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☒

08:00 - 09:30 ☐

Prior to gas transfer assessment ☐

Prior to gas transfer assessment and prior to product use ☐

10:00 - 11:30 ☐

10:00 - 12:30 ☐

Time ☐ ⑤
hour:min 24-hour clock

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBCTPT	\$40		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30 6 = Prior to gas transfer assessment 7 = Prior to gas transfer assessment and prior to product use 8 = 10:00 - 11:30 9 = 10:00 - 12:30		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					PCBCTPT
5 PCBTIM	HH:nn				PCBTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: CoHb Blood Sample <prior to gas transfer>
Generated On: 22 Sep 2014 07:54:21

Not Done ☐ ①

If Not Done, please specify the reason: ☐ ②

Date ☐ ③
DD/MM/YYYY

Timepoint ☐ ④

Within 15 min prior to smoking ☐

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

Prior to gas transfer assessment ☒

Prior to gas transfer assessment and prior to product use ☐

10:00 - 11:30 ☐

10:00 - 12:30 ☐

Time ☐ ⑤
hour:min 24-hour clock

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample <prior to gas transfer>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBCTPT	\$40		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30 6 = Prior to gas transfer assessment 7 = Prior to gas transfer assessment and prior to product use 8 = 10:00 - 11:30 9 = 10:00 - 12:30		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: CoHb Blood Sample <prior to gas transfer>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					PCBCTPT
5 PCBTIM	HH:nn				PCBTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: CoHb Blood Sample <prior to gas transfer and product>
Generated On: 22 Sep 2014 07:54:21

Not Done ☐ ①

If Not Done, please specify the reason: ☐ ②

Date ☐ ③
DD/MM/YYYY

Timepoint ☐ ④

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

Time ☐ ⑤
hour:min 24-hour clock



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: CoHb Blood Sample <prior to gas transfer and product>
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBCTPT	\$40		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30 6 = Prior to gas transfer assessment 7 = Prior to gas transfer assessment and prior to product use 8 = 10:00 - 11:30 9 = 10:00 - 12:30		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: CoHb Blood Sample <prior to gas transfer and product>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					PCBCTPT
5 PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample <D30_D60>****Generated On: 22 Sep 2014 07:54:21**

Not Done

①

If Not Done, please specify the reason:

②

Date

DD/MMM/YYYY

③

Timepoint

Within 15 min prior to smoking

④

12:00 - 13:30

16:00 - 17:30

20:00 - 21:30

08:00 - 09:30

Prior to gas transfer

assessment

Prior to gas transfer
assessment and prior to
product use

10:00 - 11:30

10:00 - 12:30

Time

hour:min 24-hour clock

⑤

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample <D30_D60>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBCTPT	\$40		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30 6 = Prior to gas transfer assessment 7 = Prior to gas transfer assessment and prior to product use 8 = 10:00 - 11:30 9 = 10:00 - 12:30		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: CoHb Blood Sample <D30_D60>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					PCBCTPT
5 PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample <D0>****Generated On: 22 Sep 2014 07:54:21**

Not Done

①

If Not Done, please specify the reason:

②

Date

DD/MMM/YYYY

③

Timepoint

Within 15 min prior to smoking

④

12:00 - 13:30

16:00 - 17:30

20:00 - 21:30

08:00 - 09:30

Prior to gas transfer

assessment

Prior to gas transfer

assessment and prior to

product use

10:00 - 11:30

10:00 - 12:30

Time

hour:min 24-hour clock

⑤

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample <D0>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBCTPT	\$40		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30 6 = Prior to gas transfer assessment 7 = Prior to gas transfer assessment and prior to product use 8 = 10:00 - 11:30		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample <D0>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = 10:00 - 12:30	1: Prior to gas transfer assessment and prior to product use 2: 20:00 - 21:30	PCBCTPT
5 PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample <D90>****Generated On: 22 Sep 2014 07:54:21**Not Done ☐ ①If Not Done, please specify the reason: ☐ ②Date ☐ ③
DD/MMM/YYYY

Timepoint ☐ ④

Within 15 min prior to smoking ☐

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

Prior to gas transfer assessment ☐

Prior to gas transfer assessment and prior to product use ☐

10:00 - 11:30 ☐

10:00 - 12:30 ☒

Time ☐ ⑤
hour:min 24-hour clock

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample <D90>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBCTPT	\$40		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30 6 = Prior to gas transfer assessment 7 = Prior to gas transfer assessment and prior to product use 8 = 10:00 - 11:30 9 = 10:00 - 12:30		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CoHb Blood Sample <D90>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					PCBCTPT
5 PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Oxysterols****Generated On: 22 Sep 2014 07:54:21**

Not Done _____ ①

If Not Done, please specify the reason: _____ ②

Was the subject fasting for at least 10 hours at time of
sample collection? No ☒ ③
Yes ☐

Date
DD/MMM/YYYY _____ ④

Time
hour:min 24-hour clock _____ ⑤

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Oxysterols****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	LBFSTYN	\$1		N = No Y = Yes		LBFSTYN
④	PCBDAT	dd MMM YYYY				PCBDAT
⑤	PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CO Breath Test****Generated On: 22 Sep 2014 07:54:21**

Assessment not done

①

If Not Done, please specify the reason:

②

Actual Date of Assessment

Fixed Unit:
DD/MMM/YYYY

③

Actual Time of Assessment

Fixed Unit:
hour:min 24-hour clock

④

Result

Fixed Unit:
ppm

⑤

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CO Breath Test****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	COSTAT	1				COSTAT
②	COREASND	\$200				COREASND
③	CPDAT	dd MMM YYYY				CPDAT
④	CPTIM	HH:nn				CPTIM
⑤	COORRES	3				COORRES

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CO Breath Test <Repeat/>****Generated On: 22 Sep 2014 07:54:21**

Assessment not done ①

If Not Done, please specify the reason: ②

Scheduled Time ③

Within 15 min prior to smoking ☐

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

Prior to gas transfer assessment ☐

Prior to gas transfer assessment and prior to product use ☐

10:00 - 11:30 ☐

10:00 - 12:30 ☐

Actual Time of Assessment ④
hour:min 24-hour clock

Result(ppm) ⑤

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CO Breath Test <Repeat/>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	COSTAT	1				COSTAT
②	COREASND	\$200				COREASND
③	COTPT	\$200		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30 6 = Prior to gas transfer assessment 7 = Prior to gas transfer assessment and prior to product use 8 = 10:00 - 11:30 9 = 10:00 - 12:30		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CO Breath Test <Repeat/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: Within 15 min prior to smoking 2: 12:00 - 13:30 3: 16:00 - 17:30 4: 20:00 - 21:30	COTPT
④ CPTIM	HH:nn				CPTIM
⑤ COORRES	3				COORRES

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CO Breath Test <SA arm/>****Generated On: 22 Sep 2014 07:54:21**

Assessment not done ①

If Not Done, please specify the reason: ②

Scheduled Time ③

Within 15 min prior to smoking ☐

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

Prior to gas transfer assessment ☐

Prior to gas transfer assessment and prior to product use ☐

10:00 - 11:30 ☐

10:00 - 12:30 ☐

Actual Time of Assessment ④
hour:min 24-hour clock

Result(ppm) ⑤

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CO Breath Test <SA arm/>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① COSTAT	1				COSTAT
② COREASND	\$200				COREASND
③ COTPT	\$200		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30 6 = Prior to gas transfer assessment 7 = Prior to gas transfer assessment and prior to product use 8 = 10:00 - 11:30 9 = 10:00 - 12:30	1: 08:00 - 09:30 2: 12:00 - 13:30 3: 16:00 - 17:30 4: 20:00 - 21:30	COTPT



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: CO Breath Test <SA arm/>

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④	CPTIM	HH:nn				CPTIM
⑤	COORRES	3				COORRES

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CYP2A6 activity Sample****Generated On: 22 Sep 2014 07:54:21**

Not Done ①

If Not Done, please specify the reason: ②

Date of sample collection ③
DD/MMM/YYYY

Time of sample collection ④
hour:min 24-hour clock

Parameter ⑤
trans-3'-hydroxycotinine ☐
cotinine ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: CYP2A6 activity Sample

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM
⑤	PCBCAT	1		1 = trans-3'-hy droxycotin ine 2 = cotinine	1: trans-3'-hy droxycotin ine 2: cotinine	PCBCAT

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CYP1A2 activity Sample****Generated On: 22 Sep 2014 07:54:21**

Time of caffeine tablet intake

Fixed Unit: ①
hour:min 24-hour clock

Sample collection Not Done ②

If Not Done, please specify the reason: ③

Date of sample collection
DD/MMM/YYYY ④Time of sample collection
hour:min 24-hour clock ⑤

Parameter

Caffeine ⑥
Paraxanthine

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CYP1A2 activity Sample****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCB_MEATI M	HH:nn				PCB_MEATI M
②	PCBSTAT	1				PCBSTAT
③	PCBREASN D	\$200				PCBREASN D
④	PCBDAT	dd MMM YYYY				PCBDAT
⑤	PCBTIM	HH:nn				PCBTIM
⑥	PCBCAT1	1		1 = Caffeine 2 = Paraxanthin e	1: Caffeine 2: Paraxanthin e	PCBCAT1



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Not Done	<input type="checkbox"/>	①
If Not Done, please specify the reason:	<input type="checkbox"/>	②
Date DD/MMM/YYYY	<input type="checkbox"/>	③
Risk Marker	<input checked="" type="checkbox"/> hs-CRP, fibrinogen, homocysteine, LDL, HDL <input type="checkbox"/> sICAM-1 <input type="checkbox"/> HbA1c, Apo A1, and Apo B	④
Time hour:min 24-hour clock	<input type="checkbox"/>	⑤

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN	\$200				PCBREASN
	D					D
③	PCBDAT	dd MMM				PCBDAT
		YYYY				
④	PCBCAT_R	1		1 = hs-CRP, fibrinogen, homocysteine, LDL, HDL 2 = sICAM-1 3 = HbA1c, Apo A1, and Apo B		PCBCAT_R
	M					M
⑤	PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Risk Marker: sICAM-1****Generated On: 22 Sep 2014 07:54:21**

Not Done	<input type="checkbox"/>	①
If Not Done, please specify the reason:	<input type="checkbox"/>	②
Date DD/MMM/YYYY	<input type="checkbox"/>	③
Risk Marker	<input type="checkbox"/>	④
	hs-CRP, fibrinogen, homocysteine, LDL, HDL sICAM-1 HbA1c, Apo A1, and Apo B	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
Time hour:min 24-hour clock	<input type="checkbox"/>	⑤

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Risk Marker: sICAM-1****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200 D				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBCAT_R M	1 M		1 = hs-CRP, fibrinogen, homocysteine, LDL, HDL 2 = sICAM-1 3 = HbA1c, Apo A1, and Apo B		PCBCAT_R M
⑤	PCBTIM	HH:nn				PCBTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Not Done

①

If Not Done, please specify the reason:

②

Date
DD/MMM/YYYY

③

Risk Marker

hs-CRP, fibrinogen, ☐ ④
homocysteine, LDL, HDL
sICAM-1 ☐
HbA1c, Apo A1, and Apo B ☐

Time
hour:min 24-hour clock

⑤

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1, HbA1c, Apo A1, Apo B****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN	\$200 D				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBCAT_R	1 M		1 = hs-CRP, fibrinogen, homocysteine, LDL, HDL 2 = sICAM-1 3 = HbA1c, Apo A1, and Apo B		PCBCAT_R M
⑤	PCBTIM	HH:nn				PCBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Type	Product Use	①
Date of Birth		②
Date of completion DD/MMM/YYYY		③
Time of completion hh:mm		④
Date the questionnaire was completed for DD/MMM/YYYY		⑤
Assessment Status	Completed <input type="checkbox"/> Abandoned <input type="checkbox"/>	⑥

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

What tobacco/nicotine product did you use today?

- Abandoned ☒ 7
- THS 2.2 ☐
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Product use diary

Generated On: 22 Sep 2014 07:54:21

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

How many THS 2.2 tobacco sticks did you use today? 8

How many CC/ roll-your-own did you smoke today? 9

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

What NRT product did you used today?

- Nicotine Inhaler ☒ 10
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Product use diary

Generated On: 22 Sep 2014 07:54:21

Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch ☐

Nicotine Gum and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Gum and Nicotine Patch ☐

Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐

Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler and Other NRT Product ☐

Nicotine Nasal Spray and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Product use diary

Generated On: 22 Sep 2014 07:54:21

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

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

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

How many times did you use an inhaler today? _____ 11

How many times did you use a nasal spray today? _____ 12

How many gums did you use today? _____ 13

How many lozenges did you use today? _____ 14

How many patches did you use today? _____ 15

How many times did you use other NRT products today
not listed previously? _____ 16

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☒ 17
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

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

16

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

How many cigars/cigarillos did you smoke today?

19

How many times did you smoke a pipe today?

20

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

21

How many times did you use an electronic cigarette
today?

22

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Product Use		QSCAT
②	QSDOB	yyyy MMM dd				QSDOB
③	EXDATE_E	yyyy MMM dd				EXDATE_E
④	EXTIME	HH:nn				EXTIME
⑤	EXDATE_1_E	yyyy MMM dd				EXDATE_1_E
⑥	ASSESSME NTSTATUS	8		1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑦	EXPROD	8		-1 = Abandoned 1 = THS 2.2 2 = CC 4 = NRT 8 = Other tobacco product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			16 = Electronic cigarette 32 = None of the above 3 = THS 2.2 and CC 5 = THS 2.2 and NRT 6 = CC and NRT 7 = THS 2.2, CC and NRT 9 = THS 2.2 and Other tobacco product 10 = CC and Other tobacco product 12 = NRT and Other tobacco product 13 = THS 2.2, NRT and Other tobacco product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = CC, NRT and Other tobacco product 15 = THS 2.2, CC, NRT and Other tobacco product 17 = THS 2.2 and Electronic cigarette 18 = CC and Electronic cigarette 20 = NRT and Electronic cigarette 21 = THS 2.2, NRT and Electronic cigarette 22 = CC, NRT and Electronic cigarette		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			23 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette		
			24 = Other tobacco product and Electronic cigarette		
			25 = THS 2.2, Other tobacco product and Electronic cigarette		
			26 = CC, Other tobacco product and Electronic cigarette		
			27 = THS 2.2, CC, Other tobacco product and Electronic cigarette		
			28 = NRT, Other tobacco product and Electronic cigarette		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			29 = THS 2.2, NRT, Other tobacco product and Electronic cigarette 30 = CC, NRT, Other tobacco product and Electronic cigarette 31 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette		EXPROD
⑧ THSNUM	8				THSNUM
⑨ CCNUM	8				CCNUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10 NRTPROD	8		1 = Nicotine Inhaler 2 = Nicotine Nasal Spray 4 = Nicotine Gum 8 = Nicotine Lozenge 16 = Nicotine Patch 32 = Other NRT Product -1 = Abandoned -9 = Not Applicable 3 = Nicotine Inhaler and Nicotine Nasal Spray		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Nicotine Inhaler and Nicotine Gum		
			6 = Nicotine Nasal Spray and Nicotine Gum		
			7 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Gum		
			9 = Nicotine Inhaler and Nicotine Lozenge		
			10 = Nicotine Nasal Spray and Nicotine Lozenge		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Lozenge		
			12 = Nicotine Gum and Nicotine Lozenge		
			13 = Nicotine Inhaler, Nicotine Gum and Nicotine Lozenge		
			14 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		
			17 = Nicotine Inhaler and Nicotine Patch		
			18 = Nicotine Nasal Spray and Nicotine Patch		
			19 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			20 = Nicotine Gum and Nicotine Patch		
			21 = Nicotine Inhaler, Nicotine Gum and Nicotine Patch		
			22 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		
			23 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			24 = Nicotine Lozenge and Nicotine Patch		
			25 = Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch		
			26 = Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		
			27 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		

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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			28 = Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			29 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			30 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			31 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			33 = Nicotine Inhaler and Other NRT Product		
			34 = Nicotine Nasal Spray and Other NRT Product		
			35 = Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			36 = Nicotine Gum and Other NRT Product		
			37 = Nicotine Inhaler, Nicotine Gum and Other NRT Product		
			38 = Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		
			39 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			40 = Nicotine Lozenge and Other NRT Product		
			41 = Nicotine Inhaler, Nicotine Lozenge and Other NRT Product		
			42 = Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		
			43 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		

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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			44 = Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			45 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			46 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			47 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			48 = Nicotine Patch and Other NRT Product		
			49 = Nicotine Inhaler, Nicotine Patch and Other NRT Product		
			50 = Nicotine Nasal Spray, Nicotine Patch and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			51 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Patch and Other NRT Product		
			52 = Nicotine Gum,Nicotin e Patch and Other NRT Product		
			53 = Nicotine Inhaler, Nicotine Gum,Nicotin e Patch and Other NRT Product		NRTPROD

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
11	INHFREQ	8				INHFREQ
12	NASPFREQ	8				NASPFREQ
13	GUMFREQ	8				GUMFREQ
14	LOZFREQ	8				LOZFREQ
15	PATFREQ	8				PATFREQ
16	OTHNRTRF EQ	8				OTHNRTRF EQ
17	OTHPROD	8		1 = Chewable/S mokeless Tobacco 2 = Cigars/Cigar illos 4 = Pipe 8 = Other Tobacco Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		
			-9 = Not Applicable		
			3 = Chewable/S mokeless Tobacco and Cigars/Cigar illos		
			5 = Chewable/S mokeless Tobacco and Pipe		
			6 = Cigars/Cigar illos and Pipe		
			7 = Chewable/S mokeless Tobacco, Cigars/Cigar illos and Pipe		
			9 = Chewable/S mokeless Tobacco and Other Tobacco Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = Cigars/Cigar illos and Other Tobacco Product		
			11 = Chewable/S mokeless Tobacco and Cigars/Cigar illos and Other Tobacco Product		
			12 = Pipe and Other Tobacco Product		
			13 = Chewable/S mokeless Tobacco, Pipe and Other Tobacco Product		
			14 = Cigars/Cigar illos, Pipe and Other Tobacco Product		

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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Chewable/S mokeless Tobacco, Cigars/Cigar illos, Pipe and Other Tobacco Product		OTHPROD
18 TOBFREQ	8				TOBFREQ
19 CIGFREQ	8				CIGFREQ
20 PIPFREQ	8				PIPFREQ
21 TOBNFREQ	8				TOBNFREQ
22 ECNUM	8				ECNUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Adverse Events Y/N

Generated On: 22 Sep 2014 07:54:21

Was there any Adverse Event for this subject?

No ☒ 1
Yes ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Adverse Events Y/N****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① AEYN	\$1		N = No Y = Yes		AEYN

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Adverse Events****Generated On: 22 Sep 2014 07:54:21**AE Identifier ①Adverse Event ②Start Date ③DD/MMM/YYYY End Date ④DD/MMM/YYYY Ongoing at final contact No ☐ ⑤
Yes ☐Severity Mild Adverse Event ☐ ⑥
Moderate Adverse Event ☐
Severe Adverse Event ☐Serious AE No ☐ ⑦
Yes ☐Seriousness Criteria Fatal ☐ ⑧
Is life-threatening ☐
Requires hospitalization ☐
Results in ☐
disability/incapacity ☐
Congenital anomaly/birth ☐
defect ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Adverse Events****Generated On: 22 Sep 2014 07:54:21**

Treatment given No ☒ 9
Yes ☐

AE related to Study Procedure Related ☒ 10
Not Related ☐

Relationship to mCC/THS Related ☒ 11
Not Related ☐

AE expectedness No ☒ 17
Yes ☐

Action taken with study product Product use Interrupted ☒ 18
Product use Stopped ☐
Product use Reduced ☐
Not Applicable ☐
None ☐

Other action taken ☒ 14

Outcome Death Related to Adverse Event ☒ 15
Not Recovered or Not Resolved ☐
Recovered or Resolved ☐
Recovered or Resolved with Sequelae ☐
Recovering or Resolving ☐
Unknown ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Adverse Events****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	AESPID	\$10				AESPID
②	AETERM	\$200				AETERM
③	AESTDAT	dd MMM YYYY				AESTDAT
④	AEENDAT	dd MMM YYYY				AEENDAT
⑤	AEENRF	\$1		N = No Y = Yes		AEENRF
⑥	AESEV	\$8		MILD = Mild Adverse Event MODERATE = Moderate Adverse Event SEVERE = Severe Adverse Event		AESEV
⑦	AESER	\$1		N = No Y = Yes		AESER



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Adverse Events

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 AESERCRIT	1		1 = Fatal 2 = Is life-threatening 3 = Requires hospitalization 4 = Results in disability/in capacity 5 = Congenital anomaly/birth defect		AESERCRIT
9 AECONTRT	\$1		N = No Y = Yes		AECONTRT
10 AEREL_S	1		1 = Related 2 = Not Related		AEREL_S
11 AEREL_1	\$20		1 = Related 2 = Not Related		AEREL_1



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Adverse Events

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17	AEEXPD	\$1		N = No Y = Yes		AEEXPD
18	AEACN	\$40		PRODUCT USE INTERRUPT ED = Product use Interrupted PRODUCT USE STOPPED = Product use Stopped PRODUCT USE REDUCED = Product use Reduced NOT APPLICABL E = Not Applicable NONE = None		AEACN
19	AEACNOTH	\$200				AEACNOTH

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Adverse Events****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
AEOUT	\$40		FATAL = Death Related to Adverse Event NOT RECOVERE D/NOT RESOLVED = Not Recovered or Not Resolved RECOVERE D/RESOLVE D = Recovered or Resolved RECOVERE D/RESOLVE D WITH SEQUELAE = Recovered or Resolved with Sequelae RECOVERIN G/RESOLVI NG = Recovering or Resolving		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Adverse Events****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			UNKNOWN = Unknown		AEOU



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication Y/N
Generated On: 22 Sep 2014 07:54:21

Has the subject taken previous or concomitant
medication?

No ☒ 1
Yes ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Previous and Concomitant Medication Y/N****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① CMYN	\$1		N = No Y = Yes		CMYN



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
Generated On: 22 Sep 2014 07:54:21

Brand Name	<input type="text"/>	<input checked="" type="radio"/>
Start Date DD/MMM/YYYY	<input type="text"/>	<input checked="" type="radio"/>
Stop Date DD/MMM/YYYY	<input type="text"/>	<input checked="" type="radio"/>
Ongoing at final contact	<input type="text"/>	<input checked="" type="radio"/>
Total Daily dose - Dose	<input type="text"/>	<input checked="" type="radio"/>
Total Daily dose - Unit	<input type="text"/>	<input checked="" type="radio"/>
	Ampule Dosing Unit	<input type="radio"/>
	Bolus Dosing Unit	<input type="radio"/>
	Capsule Dosing Unit	<input type="radio"/>
	Gram	<input type="radio"/>
	Inhalation Dosing Unit	<input type="radio"/>
	International Unit	<input type="radio"/>
	Milligram	<input type="radio"/>
	Milliliter	<input type="radio"/>
	Nebule Dosing Unit	<input type="radio"/>
	Patch Dosing Unit	<input type="radio"/>
	Puff Dosing Unit	<input type="radio"/>
	Suppository Dosing Unit	<input type="radio"/>
	Tablet Dosing Unit	<input type="radio"/>
	Tablespoon Dosing Unit	<input type="radio"/>
	Teaspoon Dosing Unit	<input type="radio"/>
	Microgram per Day	<input type="radio"/>
	Not Applicable	<input type="radio"/>
	Other Dosing Unit	<input type="radio"/>
	Application	<input type="radio"/>



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
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Route	
	Auricular Route of Administration <input checked="" type="radio"/> 7
	Buccal Route of Administration <input type="radio"/>
	Conjunctival Route of Administration <input type="radio"/>
	Cutaneous Route of Administration <input type="radio"/>
	Dental Route of Administration <input type="radio"/>
	Electro-osmosis Route of Administration <input type="radio"/>
	Endocervical Route of Administration <input type="radio"/>
	Endosinusial Route of Administration <input type="radio"/>
	Endotracheal Route of Administration <input type="radio"/>
	Enteral Route of Administration <input type="radio"/>
	Epidural Route of Administration <input type="radio"/>
	Extraamniotic Route of Administration <input type="radio"/>
	Extracorporeal Circulation <input type="radio"/>
	Route of Administration Via Hemodialysis <input type="radio"/>
	Infiltration Route of Administration <input type="radio"/>
	Interstitial Route of Administration <input type="radio"/>
	Intraabdominal Route of Administration <input type="radio"/>
	Intraamniotic Route of Administration <input type="radio"/>
	Intraarterial Route of Administration <input type="radio"/>
	Intraarticular Route of Administration <input type="radio"/>
	Intrabiliary Route of Administration <input type="radio"/>



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- 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 Cavemosum 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 ☐



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-
- 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 ☐
 - Intratendinous Route of Administration ☐
 - Intratesticular Route of Administration ☐
 - Intrathecal Route of Administration ☐



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-
- 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 ☐
 - Occlusive Dressing Technique ☐
 - Ophthalmic Route of Administration ☐
 - Oral Route of Administration ☐
 - Oropharyngeal Route of Administration ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
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- 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 ☐
- Topical Route of Administration ☐
- Transdermal Route of Administration ☐
- Mucosal Route of Administration ☐
- Transplacental Route of Administration ☐
- Transtracheal Route of Administration ☐



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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 _____ 8

Concomitant Disease Number _____ 9

AE Number _____ 10

Other _____ 11



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
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	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	CMTRT	\$200				CMTRT
②	CMSTDAT	dd- MMM- YYYY				CMSTDAT
③	CMENDAT	dd- MMM- YYYY				CMENDAT
④	CMENRF	1				CMENRF
⑤	CMDOSTOT	8				CMDOSTOT
⑥	CMDOSU	\$40		AMPULE = Ampule Dosing Unit BOLUS = Bolus Dosing Unit CAPSULE = Capsule Dosing Unit G = Gram INHALATIO N = Inhalation Dosing Unit IU = Internation al Unit MG = Milligram		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			ML =		
			Milliliter		
			NEBULE =		
			Nebule		
			Dosing Unit		
			PATCH =		
			Patch		
			Dosing Unit		
			PUFF = Puff		
			Dosing Unit		
			SUPPOSITO		
			RY =		
			Suppository		
			Dosing Unit		
			TABLET =		
			Tablet		
			Dosing Unit		
			TBSP =		
			Tablespoon		
			Dosing Unit		
			TSP =		
			Teaspoon		
			Dosing Unit		
			UG =		
			Microgram		
			per Day		
			NOT		
			APPLICABL		
			E = Not		
			Applicable		
			OTHER =		
			Other		
			Dosing Unit		
			APPLICATIO		
			N =		
			Application		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Previous and Concomitant Medication****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
CMDOSU					

⑦ CMROUTE	\$30	AURICULAR (OTIC) = Auricular Route of Administrati on BUCCAL = Buccal Route of Administrati on CONJUNCTI VAL = Conjunctival Route of Administrati on CUTANEOU S = Cutaneous Route of Administrati on
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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Previous and Concomitant Medication****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			DENTAL = Dental Route of Administrati on ELECTROOS MOSIS = Electro-osm osis Route of Administrati on ENDOCERVI CAL = Endocervica l Route of Administrati on ENDOSINU SIAL = Endosinusia l Route of Administrati on ENDOTRAC HEAL = Endotrache al Route of Administrati on		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			ENTERAL = Enteral Route of Administration		
			EPIDURAL = Epidural Route of Administration		
			EXTRA-AMNIOTIC = Extraamniotic Route of Administration		
			EXTRACORPOREAL = Extracorporeal Circulation Route of Administration		
			HEMODIALYSIS = Administration Via Hemodialysis		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Previous and Concomitant Medication****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INFILTRATI ON = Infiltration Route of Administrati on		
			INTERSTITI AL = Interstitial Route of Administrati on		
			INTRAABDO MINAL = Intraabdomi nal Route of Administrati on		
			INTRA-AMN IOTIC = Intraamniot ic Route of Administrati on		
			INTRA-ART ERIAL = Intraarterial Route of Administrati on		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRA-ARTICULAR = Intraarticular Route of Administration		
			INTRABILIARY = Intrabiliary Route of Administration		
			INTRABRONCHIAL = Intrabronchial Route of Administration		
			INTRABURSAL = Intrabursal Route of Administration		
			INTRACARDIAC = Intracardiac Route of Administration		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRACART ILAGINOUS = Intracartilag inous Route of Administrati on INTRACAUD AL = Intracaudal Route of Administrati on INTRACAVE RNOUS = Intracavern ous Route of Administrati on INTRACAVI TARY = Intracavitar y Route of Administrati on INTRACERE BRAL = Intracerebr al Route of Administrati on		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRACIST ERNAL = Intracistern al Route of Administrati on INTRACORN EAL = Intracorneal Route of Administrati on INTRACOR ONAL DENTAL = Intracoronar Dental Route of Administrati on INTRACOR ONARY = Intracorona ry Route of Administrati on INTRACORP ORUS CAVERNOS UM = Intracorpor us Cavemosu m Route of Administrati on		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Previous and Concomitant Medication****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRADER MAL = Intradermal Route of Administrati on		
			INTRADISC AL = Intradiscal Route of Administrati on		
			INTRADUCT AL = Intraductal Route of Administrati on		
			INTRADUO DENAL = Intraduode nal Route of Administrati on		
			INTRADURA L = Intradural Route of Administrati on		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRAEPID ERMAL = Intraepider mal Route of Administrati on INTRAESOP HAGEAL = Intraesopha geal Route of Administrati on INTRAGAST RIC = Intragastric Route of Administrati on INTRAGING IVAL = Intragingiva l Route of Administrati on INTRAILEAL = Intraileal Route of Administrati on		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Previous and Concomitant Medication****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRALESIONAL = Intralesional Route of Administration		
			INTRALUMINAL = Intraluminal Route of Administration		
			INTRALYMPHATIC = Intralymphatic Route of Administration		
			INTRAMEDULLARY = Intramedullary Route of Administration		
			INTRAMENINGEAL = Intrameningeal Route of Administration		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Previous and Concomitant Medication****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRAMUSCULAR = Intramuscular Route of Administration		
			INTRAOCULAR = Intraocular Route of Administration		
			INTRAOVARIAN = Intraovarian Route of Administration		
			INTRAPERICARDIAL = Intrapericardial Route of Administration		
			INTRAPERITONEAL = Intraperitoneal Route of Administration		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRAPLEU RAL = Intrapleural Route of Administrati on INTRAPROS TATIC = Intraprostat ic Route of Administrati on INTRAPULM ONARY = Intrapulmo nary Route of Administrati on INTRASINA L = Intrasinal Route of Administrati on INTRASPIN AL = Intraspinal Route of Administrati on		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRASYNO VIAL = Intrasynovi al Route of Administrati on INTRATEND INOUS = Intratendin ous Route of Administrati on INTRATEST ICULAR = Intratesticul ar Route of Administrati on INTRATHEC AL = Intrathecal Route of Administrati on INTRATHOR ACIC = Endothoraci c Route of Administrati on		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRATUBU LAR = Intratubular Route of Administrati on INTRATUM OR = Intratuma l Route of Administrati on INTRATYMP ANIC = Intratym nic Route of Administrati on INTRAUTER INE = Intrauterine Route of Administrati on INTRAVASC ULAR = Intravascu lar Route of Administrati on		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRAVENO US = Intravenous Route of Administrati on INTRAVENO US BOLUS = Intravenous Bolus INTRAVENO US DRIP = Intravenous Drip INTRAVENT RICULAR = Intraventric ular Route of Administrati on INTRAVESI CAL = Intravesical Route of Administrati on INTRAVITR EAL = Intravitreal Route of Administrati on		

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05AUG2014 (649)

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PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			IONTOPHO RESIS = Iontophoresis is Route of Administration IRRIGATIO N = Irrigation-Route of Administration LARYNGEAL = Laryngeal Route of Administration NASAL = Nasal Route of Administration NASOGAST RIC = Nasogastric Route of Administration NOT APPLICABLE = Route of Administration Not Applicable		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			OCCLUSIVE DRESSING TECHNIQUE = Occlusive Dressing Technique OPHTHALMI C = Ophthalmic Route of Administrati on ORAL = Oral Route of Administrati on OROPHARY NGEAL = Oropharyng eal Route of Administrati on OTHER = Other Route of Administrati on PARENTERA L = Parenteral Route of Administrati on		

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PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			PERCUTANEOUS = Percutaneous Route of Administration		
			PERIARTICULAR = Periarticular Route of Administration		
			PERIDURAL = Peridural Route of Administration		
			PERINEURAL = Perineural Route of Administration		
			PERIODONTAL = Periodontal Route of Administration		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Previous and Concomitant Medication****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			RECTAL = Rectal Route of Administrati on RESPIRATO RY (INHALATI ON) = Inhalation Route of Administrati on RETROBUL BAR = Retrobulbar Route of Administrati on SOFT TISSUE = Soft Tissue Route Of Administrati on SUBARACH NOID = Subarachno id Route of Administrati on		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			SUBCONJUNCTIVAL = Subconjunctival Route of Administration		
			SUBCUTANEOUS = Subcutaneous Route of Administration		
			SUBLINGUAL = Sublingual Route of Administration		
			SUBMUCOSAL = Submucosal Route of Administration		
			TOPICAL = Topical Route of Administration		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Previous and Concomitant Medication****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			TRANSDER MAL = Transderma l Route of Administrati on TRANSMUC OSAL = Mucosal Route of Administrati on TRANSPLAC ENTAL = Transplacen tal Route of Administrati on TRANSTRA CHEAL = Transtrache al Route of Administrati on TRANSTYM PANIC = Transtympa nic Route of Administrati on		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Previous and Concomitant Medication****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			UNASSIGNE D = Unassigned Route of Administrati on UNKNOWN = Unknown Route of Administrati on URETERAL = Ureteral Route of Administrati on URETHRAL = Intraurethra l Route of Administrati on VAGINAL = Vaginal Route of Administrati on		CMROUTE



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Previous and Concomitant Medication
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	CMINDC	\$200				CMINDC
9	MHREFID	\$10				MHREFID
10	AEREFID	\$10				AEREFID
11	CMINDCAT	\$200				CMINDCAT

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: End of study****Generated On: 22 Sep 2014 07:54:21**

End of study date

Fixed Unit: ①
DD/MMM/YYYY

Has the subject completed the study ?

No ②
Yes

If No, please specify the reason:

Adverse Events ③
Protocol Violation
Withdrawal by Subject
Lost To Follow-up
Other

Details: ④

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: End of study****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DSDAT	dd MMM YYYY				DSDAT
②	DSTERM	\$1		N = No Y = Yes		DSTERM
③	EOSDSDEC OD	\$200		ADVERSE EVENT = Adverse Events PROTOCOL VIOLATION = Protocol Violation WITHDRAW AL BY SUBJECT = Withdrawal by Subject LOST TO FOLLOWUP = Lost To Follow-up OTHER = Other		EOSDSDEC OD
④	DSSPEC	\$200				DSSPEC

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Consent Withdrawal****Generated On: 22 Sep 2014 07:54:21**

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

No ☒ ①
Yes ☐

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

②

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

No ☒ ③
Yes ☐

Date of withdrawal of consent for transcriptomics
analysis _____

④

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Consent Withdrawal****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	WITHD_BIO\$1 B			N = No Y = Yes		WITHD_BIO B
②	WITHD_BD T	dd MMM YYYY				WITHD_BD T
③	WITHD_TR ANS	\$1		N = No Y = Yes		WITHD_TR ANS
④	WITHD_TD T	dd MMM YYYY				WITHD_TD T

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Withdrawal****Generated On: 22 Sep 2014 07:54:21**

Date of withdrawal

Fixed Unit: DD/MMM/YYYY **1**

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

No ☒ **2**
Yes ☐

If available, please provide details

3

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

No ☒ **4**
Yes ☐

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

No ☒ **5**
Yes ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Withdrawal****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	WTHD_DT	dd MMM YYYY				WTHD_DT
②	WITHDCON	\$1 S		N = No Y = Yes		WITHDCON S
③	WITHDSPE	\$200 C				WITHDSPE C
④	WITHDPHI	\$1		N = No Y = Yes		WITHDPHI
⑤	WITHDSAM	\$1 P		N = No Y = Yes		WITHDSAM P

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: 24 hour urine collections****Generated On: 22 Sep 2014 07:54:21**

Start Date Fixed Unit: ①
DD/MMM/YYYY

Start Time Fixed Unit: ②
hour:min 24-hour clock

End Date Fixed Unit: ③
DD/MMM/YYYY

End Time Fixed Unit: ④
hour:min 24-hour clock

Volume Fixed Unit: ⑤
mL

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: 24 hour urine collections****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	URIN_STDA	MMT	YYYY			URIN_STDA T
②	URIN_STTI	HH:nn M				URIN_STTI M
③	URIN_ENDA	MMT	YYYY			URIN_ENDA T
④	URIN_ENTI	HH:nn M				URIN_ENTI M
⑤	URIN_VOLU	4 ME				URIN_VOLU ME



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Sample Urine Collection

Generated On: 22 Sep 2014 07:54:21

Were samples for 24h collected?

No ☒ ①
Yes ☐

If No, please specify the reason: _____ ②

How many primary tubes were collected? _____ ③

How many back up tubes were collected? _____ ④

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Sample Urine Collection****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	LBSTAT	\$1		N = No Y = Yes		LBSTAT
②	LBREASND	\$200				LBREASND
③	LBTUBNO	2				LBTUBNO
④	LBBTUBNO	2				LBBTUBNO

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: 4 hour urine collection****Generated On: 22 Sep 2014 07:54:21**

Start Date

Fixed Unit: ①
DD/MMM/YYYY

Start Time

Fixed Unit: ②
hour:min 24-hour clock

End Time

Fixed Unit: ③
hour:min 24-hour clock

Volume

Fixed Unit: ④
mL

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: 4 hour urine collection****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	URIN_STDA	MMT	YYYY			URIN_STDA T
②	URIN_STTI	HH:nn	M			URIN_STTI M
③	URIN_ENTI	HH:nn	M			URIN_ENTI M
④	URIN_VOLU	4	ME			URIN_VOLU ME



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Sample Urine Collection (4 Hour collection)
Generated On: 22 Sep 2014 07:54:21

Were samples for 4h collected?

No ☐ ①
Yes ☐

If No, please specify the reason: _____ ②

How many primary tubes were collected? _____ ③

How many back up tubes were collected? _____ ④



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Sample Urine Collection (4 Hour collection)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	LBSTAT	\$1		N = No Y = Yes		LBSTAT
②	LBREASND	\$200				LBREASND
③	LBTUBNO	2				LBTUBNO
④	LBBTUBNO	2				LBBTUBNO



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 22 Sep 2014 07:54:21

Type MNWS **1**

Type Behaviour Rating Scale **2**
Self-Report

Date of Birth **3**

Date of assessment Fixed Unit: **4**
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment Fixed Unit: **5**
hour:min 24-hour clock

Assessment Status Completed **6**
Abandoned

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

How have you been feeling over the past 24 hours? **8**
None
Slight
Mild
Moderate
Severe
Abandoned



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 22 Sep 2014 07:54:21

How have you been feeling over the past 24 hours? None ☒ 9
Slight ☐
2. Anxious, nervous Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 10
Slight ☐
3. Depressed Mood, sad Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 11
Slight ☐
4. Desire or craving to smoke Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 12
Slight ☐
5. Difficulty concentrating Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 22 Sep 2014 07:54:21

How have you been feeling over the past 24 hours? None ☒ 13

6. Increased appetite, hungry, weight gain Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 14

7. Insomnia, sleep problems, awakening at night Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 15

8. Restless Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 16

9. Impatient Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 22 Sep 2014 07:54:21

How have you been feeling over the past 24 hours? None ☒ 17
Slight ☐
10. Constipation Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 16
Slight ☐
11. Dizziness Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 15
Slight ☐
12. Coughing Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 20
Slight ☐
13. Dreaming or nightmares Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 22 Sep 2014 07:54:21

How have you been feeling over the past 24 hours? None ☒ 21

14. Nausea Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 22

15. Sore Throat Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		MNWS		QSCAT
②	QSSCAT	\$40		Behaviour Rating Scale Self-Report		QSSCAT
③	QSDOB	yyyy MMM dd				QSDOB
④	QSDAT_E	yyyy MMM dd				QSDAT_E
⑤	QSTIM	HH:nn				QSTIM
⑥	ASSESSME 8 NTSTATUS			1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑧	QSORRES_ 8 MSWS1			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS1



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 QSORRES_ 8 MSWS2			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS2
10 QSORRES_ 8 MSWS3			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS3
11 QSORRES_ 8 MSWS4			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS4
12 QSORRES_ 8 MSWS5			1 = None 2 = Slight		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS5
13 QSORRES_ 8 MSWS6			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS6
14 QSORRES_ 8 MSWS7			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS7
15 QSORRES_ 8 MSWS8			1 = None 2 = Slight 3 = Mild 4 = Moderate		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Severe -1 = Abandoned		QSORRES_ MSWS8
16 QSORRES_ 8 MSWS9			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS9
17 QSORRES_ 8 MSWS10			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS10
18 QSORRES_ 8 MSWS11			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					QSORRES_ MSWS11
19 QSORRES_ 8 MSWS12			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS12
20 QSORRES_ 8 MSWS13			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS13
21 QSORRES_ 8 MSWS14			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS14



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
QSORRES_ 8 MSWS15			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS15

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Cough Assessment****Generated On: 22 Sep 2014 07:54:21**Type VAS for Cough **1**Date of Birth **2**Date of assessment Fixed Unit: **3**
DD/MMM/YYYY DD/MMM/YYYYTime of assessment Fixed Unit: **4**
hour:min 24-hour clockAssessment Status Completed **5**
Abandoned ☐Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs? Yes **6**
No ☐
Abandoned ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale **8**
How much is your cough bothering you?

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Cough Assessment****Generated On: 22 Sep 2014 07:54:21**

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☒ 9
Mild ☐
Moderate ☐
Severe ☐
Very severe ☐
Abandoned ☐
Not Applicable ☐

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day?

Rarely ☒ 10
Sometimes ☐
Fairly often ☐
Often ☐
Almost always ☐
Abandoned ☐
Not Applicable ☐

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

No sputum ☒ 11
A moderate amount of sputum ☐
A large amount of sputum ☐
A very large amount of sputum ☐
Abandoned ☐
Not Applicable ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Cough Assessment

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		VAS for Cough		QSCAT
②	QSDOB	yyyy MMM dd				QSDOB
③	QSDAT_E	yyyy MMM dd				QSDAT_E
④	QSTIM	HH:nn				QSTIM
⑤	ASSESSME 8 NTSTATUS			1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑥	QS_COUGH 8 _ORRES			1 = Yes 2 = No -1 = Abandoned		QS_COUGH _ORRES
⑧	QS_COUGH 8 _ORRES1					QS_COUGH _ORRES1
⑨	QS_COUGH 8 _ORRES2			1 = Very mild 2 = Mild		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Cough Assessment****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Moderate 4 = Severe 5 = Very severe -1 = Abandoned -9 = Not Applicable		QS_COUGH _ORRES2
10 QS_COUGH 8 _ORRES3			1 = Rarely 2 = Sometimes 3 = Fairly often 4 = Often 5 = Almost always -1 = Abandoned -9 = Not Applicable		QS_COUGH _ORRES3
11 QS_COUGH 8 _ORRES4			0 = No sputum 1 = A moderate amount of sputum 2 = A large amount of sputum		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Cough Assessment****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = A very large amount of sputum -1 = Abandoned -9 = Not Applicable		QS_COUGH_ORRES4



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device report - THS 2.2 menthol Cigarette Holder
Generated On: 22 Sep 2014 07:54:21

Were there any events with the device?

No ☐ 1
Yes ☐

Event Log Number

2

Date of Device Event
DD/MMM/YYYY

3

Time of
Device Event
hour:min 24-hour clock

4

Event Relates to Device Type:

5

Unique Device Identifier Serial Number

6

Event Description

CH stops heating before ☐ 7
end of smoking experience
CH does not charge when ☐
inserted into the Mobil unit
CH heater broken (LED ☐
blinking red)
Smoking experience does ☐
not start when pressing the
button
Electronic malfunction ☐
during
the smoking experience
Other ☐

Other Describe

8



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device report - THS 2.2 menthol Cigarette Holder
Generated On: 22 Sep 2014 07:54:21

Severity of Event	Minor (can be resolved easily) <input checked="" type="radio"/> 9
	Major (cannot be resolved. Device needs to be exchanged) <input type="radio"/>
Adverse Event Relationship	Is related to AE <input checked="" type="radio"/> 1r
	Is not related to AE <input type="radio"/>
If Related to AE, AE Number	<input type="text"/> 1r
Solution Proposed:	Device Replaced <input checked="" type="radio"/> 1r
	Device Recharged <input type="radio"/>
	Device Withdrawn <input type="radio"/>
If the device was replaced, New Device Serial Number:	<input type="text"/> 1e
Date of Device Event Closure DD/MMM/YYYY	<input type="text"/> 1e
Time of Device Event Closure hour:min 24-hour clock	<input type="text"/> 1e




PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device report - THS 2.2 menthol Cigarette Holder
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DE_YN	\$1		N = No Y = Yes		DE_YN
②	DESPID	3				DESPID
③	DEDAT	dd MMM YYYY				DEDAT
④	DETIM	HH:nn				DETIM
⑤	DETYP	\$25		THS 2.2 Cigarette Holder	1: THS 2.2 Cigarette Holder	DETYP
⑥	DEID	\$8				DEID
⑦	DEDESC	\$8		1 = CH stops heating before end of smoking experience 2 = CH does not charge when inserted into the Mobil unit		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device report - THS 2.2 menthol Cigarette Holder
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = CH heater broken (LED blinking red) 4 = Smoking experience does not start when pressing the button 5 = Electronic malfunction during the smoking experience 6 = Other		DEDESC
 DEDESC_SP\$200 EC					DEDESC_SP EC



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device report - THS 2.2 menthol Cigarette Holder
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 DESEV	\$8		1 = Minor (can be resolved easily) 2 = Major (cannot be resolved. Device needs to be exchanged)		DESEV
10 DEREL	\$8		1 = Is related to AE 2 = Is not related to AE		DEREL
11 DEANUM	2				DEANUM
12 DESOLUTIO N	\$8		1 = Device Replaced 2 = Device Recharged 3 = Device Withdrawn		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device report - THS 2.2 menthol Cigarette Holder
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					DESOLUTION
13 DEID_2	\$8				DEID_2
12 DECLOSDA T	dd MMM yyyy				DECLOSDA T
15 DECLOSTIM	HH:nn				DECLOSTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device report - THS 2.2 menthol Charging Unit
Generated On: 22 Sep 2014 07:54:21

Were there any events with the device?

No ☒ 1
Yes ☐

Event Log Number

2

Date of Device Event
DD/MMM/YYYY

3

Time of
Device Event
hour:min 24-hour clock

4

Event Relates to
Device Type:

5

Unique Device Identifier Serial Number

6

Event Description

Battery Malfunction ☒ 7
Device Discharged ☐
Other ☐

Other Describe

8

Severity of Event

Minor (can be resolved easily) ☒ 9
Major (cannot be resolved.
Device needs to be
exchanged) ☐

Adverse Event
Relationship

Is related to AE ☒ 10
Is not related to AE ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device report - THS 2.2 menthol Charging Unit
Generated On: 22 Sep 2014 07:54:21

Solution Proposed:

Device Replaced ☒ 11
Device Recharged ☐
Device Withdrawn ☐

If the device was replaced, New Device Serial Number: _____ 17

Date of Device Event Closure
DD/MMM/YYYY _____ 18

Time of Device Event Closure
hour:min 24-hour clock _____ 16



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device report - THS 2.2 menthol Charging Unit
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DE_YN	\$1		N = No Y = Yes		DE_YN
②	DESPID	3				DESPID
③	DEDAT	dd MMM YYYY				DEDAT
④	DETIM	HH:nn				DETIM
⑤	DETYP	\$25		THS 2.2 Charging Unit	1: THS 2.2 Charging Unit	DETYP
⑥	DEID	\$8				DEID
⑦	DECUDESC	\$8		1 = Battery Malfunction 2 = Device Discharged 3 = Other		DECUDESC
⑧	DEDESC_SP\$200 EC					DEDESC_SP EC



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device report - THS 2.2 menthol Charging Unit
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 DESEV	\$8		1 = Minor (can be resolved easily) 2 = Major (cannot be resolved. Device needs to be exchanged)		DESEV
10 DEREL	\$8		1 = Is related to AE 2 = Is not related to AE		DEREL
11 DESOLUTIO N	\$8		1 = Device Replaced 2 = Device Recharged 3 = Device Withdrawn		DESOLUTIO N



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device report - THS 2.2 menthol Charging Unit
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
🔍	DEID_2	\$8				DEID_2
🔍	DECLOSDA T	dd MMM YYYY				DECLOSDA T
🔍	DECLOSTIM	HH:nn				DECLOSTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device Inventory - THS 2.2 menthol Cigarette Holder
Generated On: 22 Sep 2014 07:54:21

Device Inventory Log Number	_____	①
Date of Device Distribution DD/MMM/YYYY	_____	②
Time of Device Distribution hour:min 24-hour clock	_____	③
Device Type	_____	④
Device Serial Number	_____	⑤
Date of Device Collection DD/MMM/YYYY	_____	⑥
Time of Device Collection hour:min 24-hour clock	_____	⑦



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device Inventory - THS 2.2 menthol Cigarette Holder
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DISPID	2				DISPID
②	DIDAT	dd MMM YYYY				DIDAT
③	DITIM	HH:nn				DITIM
④	DITYP	\$200		THS 2.2 Cigarette Holder	1: THS 2.2 Cigarette Holder	DITYP
⑤	DIID	\$8				DIID
⑥	DICOLDAT	dd MMM YYYY				DICOLDAT
⑦	DICOLTIM	HH:nn				DICOLTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device Inventory - THS 2.2 menthol Charging Unit
Generated On: 22 Sep 2014 07:54:21

Device Inventory Log Number	_____	①
Date of Device Distribution DD/MMM/YYYY	_____	②
Time of Device Distribution hour:min 24-hour clock	_____	③
Device Type	_____	④
Device Serial Number	_____	⑤
Date of Device Collection DD/MMM/YYYY	_____	⑥
Time of Device Collection hour:min 24-hour clock	_____	⑦



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Device Inventory - THS 2.2 menthol Charging Unit
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DISPID	2				DISPID
②	DIDAT	dd MMM YYYY				DIDAT
③	DITIM	HH:nn				DITIM
④	DITYP	\$200		THS 2.2 Charging Unit	1: THS 2.2 Charging Unit	DITYP
⑤	DIID	\$8				DIID
⑥	DICOLDAT	dd MMM YYYY				DICOLDAT
⑦	DICOLTIM	HH:nn				DICOLTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Bio-banking (Transcriptomics)
Generated On: 22 Sep 2014 07:54:21

Was a Bio-banking sample for transcriptomics taken?

No ☐ ①
Yes ☐

Date of Sample Collection

Fixed Unit: ②
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit: ③
hour:min 24-hour clock

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

No ☐ ④
Yes ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Bio-banking (Transcriptomics)****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	BIOBANKYN\$1			N = No Y = Yes		BIOBANKYN
②	BIODAT	dd MMM YYYY				BIODAT
③	BIOBTIM	HH:nn				BIOBTIM
④	BIOBFSTYN \$1			N = No Y = Yes		BIOBFSTYN



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Bio-banking (Biomarkers of exposure and risk markers)
Generated On: 22 Sep 2014 07:54:21

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

No ☐ ①
Yes ☐

Date of Sample Collection

Fixed Unit: ②
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit: ③
hour:min 24-hour clock

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

No ☐ ④
Yes ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Bio-banking (Biomarkers of exposure and risk markers)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	BIOBANKYN\$1 _1			N = No Y = Yes		BIOBANKYN _1
②	BIODAT	dd MMM YYYY				BIODAT
③	BIOBTIM	HH:nn				BIOBTIM
④	BIOBFSTYN \$1			N = No Y = Yes		BIOBFSTYN



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Bio-banking (nasal epithelial collection/buccal collection)
Generated On: 22 Sep 2014 07:54:21

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

No ☐ ①
Yes ☐

Date of Sample Collection

Fixed Unit: ②
DD/MMM/YYYY

Time of Buccal Collection

Fixed Unit: ③
hour:min 24-hour clock

Time of Nasal Epithelial Collection

Fixed Unit: ④
hour:min 24-hour clock

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

No ☐ ⑤
Yes ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Bio-banking (nasal epithelial collection/buccal collection)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	BIOBANKYN\$1 _2			N = No Y = Yes		BIOBANKYN _2
②	BIODAT	dd MMM YYYY				BIODAT
③	BIOBTIM1	HH:nn				BIOBTIM1
④	BIOBTIM2	HH:nn				BIOBTIM2
⑤	BIOBFSTYN \$1			N = No Y = Yes		BIOBFSTYN

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Vital Signs<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Date of assessment ①
DD/MMM/YYYY

Time of assessment ②
hour:min 24-hour clock

Has the subject smoked within 15 minutes prior to assessment ③
No ☐
Yes ☐

Pulse rate ④
beats per minute

Respiratory rate ⑤
breaths per minute

Blood Pressure (systolic) ⑥
mmHg

Blood Pressure (diastolic) ⑦
mmHg

Vital Signs Position of Subject ⑧
Sitting ☐
Standing ☐
Supine ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Vital Signs<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSDAT	dd MMM YYYY				VSDAT
②	VSTIM	HH:nn				VSTIM
③	VSSMKYN	\$1		N = No Y = Yes		VSSMKYN
④	VSORRES_P3 ULSE					VSORRES_P ULSE
⑤	VSORRES_R3 ESP					VSORRES_R ESP
⑥	VSORRES_S3 YSBP					VSORRES_S YSBP
⑦	VSORRES_ 3 DIABP					VSORRES_ DIABP
⑧	VSPOS	\$10		SITTING = Sitting STANDING = Standing SUPINE = Supine	1: Supine	VSPOS



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: ECG (12-Lead Standard)<Unscheduled />
Generated On: 22 Sep 2014 07:54:21

Date of assessment **1**
DD/MMM/YYYY

Position ☐ Sitting **2**
☐ Standing
☐ Supine

Heart Rate **3**
(beats per minute)

QRS Interval **4**
(msec)

QT Interval **5**
(msec)

QTcB Interval **6**
(msec)

QTcF Interval Fixed Unit: **7**
msec

PR Interval **8**
(msec)

Interpretation ☐ Normal **9**
☐ Abnormal

If Abnormal, Clinical Significance ☐ Not clinically significant **10**
☐ Clinically significant



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: ECG (12-Lead Standard)<Unscheduled />
Generated On: 22 Sep 2014 07:54:21

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



**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: ECG (12-Lead Standard)<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EGDAT	dd MMM YYYY				EGDAT
②	EGPOS	\$10		SITTING = Sitting STANDING = Standing SUPINE = Supine	1: Supine	EGPOS
③	EGORRES_ HR	3				EGORRES_ HR
④	EGORRES_ QRS	3				EGORRES_ QRS
⑤	EGORRES_ QT	3				EGORRES_ QT
⑥	EGORRES_ QTC	3				EGORRES_ QTC
⑦	EGORRES_ QTCF	3				EGORRES_ QTCF
⑧	EGORRES_P3 R					EGORRES_P R



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: ECG (12-Lead Standard)<Unscheduled />
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	EGINTP	\$40		NORMAL = Normal ABNORMAL = Abnormal		EGINTP
10	EGCLSIG	\$40		NCS = Not clinically significant CS = Clinically significant		EGCLSIG
11	EGTERM	\$200				EGTERM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Spirometry<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Category	With short-acting bronchodilator <input type="radio"/> ①
	Without short-acting bronchodilator <input type="radio"/>
Date of assessment: DD/MM/YYYY	_____ ②
Time of assessment: hour:min 24-hour clock	_____ ③
Position	_____ ④
Has the subject smoked within 1 hour prior to assessment?	No <input type="radio"/> ⑤ Yes <input type="radio"/>
Name of bronchodilator	_____ ⑥
Dose	_____ ⑦
Predicted FVC value	Fixed Unit: L ⑧

Best measured FVC value	Fixed Unit: L ⑨

Percent of predicted FVC value	Fixed Unit: % ⑩

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Spirometry<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Best measured FEV1 value

Fixed Unit: ☒ 11
L

Predicted FEV1 value

Fixed Unit: ☒ 12
L

Percent of predicted FEV1 value

Fixed Unit: ☒ 13
%

MEF 25-75

Fixed Unit: ☒ 14
L/s

MEF 25-75 unit

☒ 15
Liter
☐ Percentage
☐ Liters per second
☐ Milliliters per minute per
millimeter of mercury
☐ mmol/min/kPa/L
☐ mL/min/mmHg/L

Interpretation

Normal ☒ 16
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☒ 17
Clinically significant ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Spirometry<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

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





PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Spirometry<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PTCAT	\$80		WITH = With short-acting bronchodila tor WITHOUT = Without short-acting bronchodila tor		PTCAT
②	PTDAT	dd MMM YYYY				PTDAT
③	PTTIM	HH:nn				PTTIM
④	PTPOS	\$20		SITTING	1: SITTING	PTPOS
⑤	PTRESTYN	\$40		N = No Y = Yes		PTRESTYN
⑥	PTBD	\$200				PTBD
⑦	PTDOSE	\$10				PTDOSE

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Spirometry<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	PTORRES_F 4.2 VCPRED					PTORRES_F VCPRED
9	PTORRES_F 4.2 VCMEAS					PTORRES_F VCMEAS
10	PTORRES_F 3 VCMPR					PTORRES_F VCMPR
11	PTORRES_F 4.2 EV1MEAS					PTORRES_F EV1MEAS
12	PTORRES_F 4.2 EV1PRED					PTORRES_F EV1PRED
13	PTORRES_F 3 EV1MPR					PTORRES_F EV1MPR
14	PTORRES_ 4.2 MEF					PTORRES_ MEF
15	PTORRESU_ \$40 MEF			L = Liter % = Percentage L/s = Liters per second		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Spirometry<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			ml/min/mm Hg = Milliliters per minute per millimeter of mercury mmol/min/ kPa/L = mmol/min/ kPa/L mL/min/m mHg/L = mL/min/m mHg/L	1: Liters per second	PTORRESU_ MEF
16 PTORRES_I \$40 NTP			NORMAL = Normal ABNORMAL = Abnormal		PTORRES_I NTP
17 PTCLSIG \$40			NCS = Not clinically significant CS = Clinically significant		
PROD 02.001 (MAIN) GMP 05AUG2014 (649)					493 of 896

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Spirometry<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
PTCLSIG					
18 PTTERM	\$40				PTTERM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Date of assessment

Fixed Unit: ①
DD/MMM/YYYY

System

General Appearance ②

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

Other, Specify

③

Outcome

Normal ④

Abnormal ☐

Abnormal, please specify:

⑤

Clinically significant

No ⑥

Yes ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Physical Examination<Unscheduled />
Generated On: 22 Sep 2014 07:54:21

Not Done

7

Not Done; please specify the reason:

8

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PEDAT	dd MMM YYYY				PEDAT
②	PETESTCD	\$200		GAPPEAR = General Appearance		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			HEENT = HEENT (head, eyes, ears, nose, throat)		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			THYROID = Thyroid Gland		
			HEART = Heart		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			CHEST = Chest		
			LUNGS = Lungs		
			GASTRO = Gastrointest inal		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	----------------------	----------------------

CVS =
Cardiovascu
lar System
NEURO =
Neurologic



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	----------------------	----------------------

SKIN = Skin
BACK =
Back
MUSCULO
=
Musculoskel
etal



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Physical Examination<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			ABDOMEN = Abdomen DENTN = Dentition OTHER = Other		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: General Appearance 2: HEENT (head, eyes, ears, nose, throat) 3: Thyroid Gland 4: Heart 5: Chest 6: Lungs 7: Gastrointestinal 8: Cardiovascular System 9: Neurologic 10: Skin 11: Back 12: Musculoskeletal 13: Abdomen 14: Dentition 15: Other 16: Other 17: Other 18: Other 19: Other	PETESTCD
3 PESPEC	\$200				PEREASND1

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Physical Examination<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
4	PEORRES	\$8		NORMAL = Normal ABNORMAL = Abnormal		PEORRES
5	PETERM1	\$200				PETERM1
6	PECLSIG1	\$1		N = No Y = Yes		PECLSIG1
7	PESTAT2	1				PESTAT2
8	PEREASND2	\$200				PEREASND2

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Weight<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**Date of assessment
DD/MMM/YYYY

①

Time of assessment
hour:min 24-hour clock

②

Weight

Fixed Unit:
kg

③

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Weight<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSDAT	dd MMM YYYY				VSDAT
②	VSTIM	HH:nn				VSTIM
③	VSORRES_ WEIGHT	4.1				VSORRES_ WEIGHT

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: X-Ray<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Category for Examination

Chest X-Ray ☐ ①Date of assessment
DD/MM/YYYY☐ ②

System

General Appearance ☐ ③HEENT
(head, eyes, ears, nose,
throat)Thyroid Gland ☐Heart ☐Chest ☐Lungs ☐Gastrointestinal ☐Cardiovascular System ☐Neurologic ☐Skin ☐Back ☐Musculoskeletal ☐Abdomen ☐Dentition ☐Other ☐

Interpretation

Normal ☐ ④Abnormal ☐

Clinically significant

No ☐ ⑤Yes ☐

Abnormal, please specify:

☐ ⑥

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: X-Ray<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PECAT	\$80		CHEST XRAY = Chest X-Ray	1: CHESTXRAY	XRPECAT
②	XPEDAT1	dd MMM YYYY				XPEDAT1
③	XPETESTC	\$200 D		GAPPEAR = General Appearance HEENT = HEENT (head, eyes, ears, nose, throat) THYROID = Thyroid Gland HEART = Heart CHEST = Chest LUNGS = Lungs GASTRO = Gastrointestinal CVS = Cardiovascular System		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: X-Ray<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			NEURO = Neurologic SKIN = Skin BACK = Back MUSCULO = Musculoskel etal ABDOMEN = Abdomen DENTN = Dentition OTHER = Other	1: Chest	XPETESTC D
④ XRPEORRES\$8			NORMAL = Normal ABNORMAL = Abnormal		XRPEORRES
⑤ XRPECLSIG \$1			N = No Y = Yes		XRPECLSIG
⑥ XRPETERM1\$200					XRPETERM1

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Drug Screen<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Category	Clinical Chemistry <input type="radio"/> ①
	Drug Screen <input checked="" type="radio"/>
	Haematology <input type="radio"/>
	Serology <input type="radio"/>
	Pregnancy Testing <input type="radio"/>
	Urinalysis <input type="radio"/>
	Cotinine Screening <input type="radio"/>
	Alcohol Test <input type="radio"/>
Date of sample collection	Fixed Unit: ② DD/MMM/YYYY
Time of sample collection	Fixed Unit: ③ hour:min 24-hour clock
Drug type	Amphetamines <input type="radio"/> ④
	Barbiturates <input type="radio"/>
	Benzodiazepines <input type="radio"/>
	Cannabinoids <input type="radio"/>
	Cocaine <input type="radio"/>
	Opiates <input type="radio"/>
Result	Negative <input type="radio"/> ⑤
	Positive <input type="radio"/>

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Drug Screen<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② DRUGDAT	dd MMM YYYY				DRUGDAT
③ DRUGTIM	HH:nn				DRUGTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine Drug Screen<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④ DRUGTEST	\$20		AMPHETAM INES = Amphetami nes BARBITURA TES = Barbiturates BENZODIAZ EPINES = Benzodiaze pines CANNABIN OIDS = Cannabinoi ds COCAINE = Cocaine OPIATES = Opiates	1: Amphetami nes 2: Barbiturates 3: Benzodiaze pines 4: Cannabinoi ds 5: Cocaine 6: Opiates	DRUGTEST
⑤ DRUGORRE S	\$8		NEGATIVE = Negative POSITIVE = Positive		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine Drug Screen<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					DRUGORRES

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Alcohol Test<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Category	Clinical Chemistry <input type="radio"/> ①
	Drug Screen <input type="radio"/>
	Haematology <input type="radio"/>
	Serology <input type="radio"/>
	Pregnancy Testing <input type="radio"/>
	Urinalysis <input type="radio"/>
	Cotinine Screening <input type="radio"/>
	Alcohol Test <input type="radio"/>
Method used	Urine sample <input type="radio"/> ②
	Breath test <input type="radio"/>
Date of assessment DD/MMM/YYYY	_____ ③
Time of assessment hour:min 24-hour clock	_____ ④
Result	Negative <input type="radio"/> ⑤
	Positive <input type="radio"/>

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Alcohol Test<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test	1: Alcohol Test	LBCAT
② ALCMETHO 1 D			1 = Urine sample 2 = Breath test		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Alcohol Test<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					ALCMETHOD
③ ALCDAT	dd MMM YYYY				ALCDAT
④ ALCTIM	HH:nn				ALCTIM
⑤ ALCORRES	\$30		NEGATIVE = Negative POSITIVE = Positive		ALCORRES



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Urine Pregnancy Test<Unscheduled />
Generated On: 22 Sep 2014 07:54:21

Category	Clinical Chemistry <input type="checkbox"/> ①
	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 Test <input type="checkbox"/>
Date of Test DD/MM/YYYY	<input type="text"/> ②
Time of Test hour:min 24-hour clock	<input type="text"/> ③
Specify result	Negative <input type="checkbox"/> ④
	Positive <input type="checkbox"/>
	Unclear <input type="checkbox"/>
Specify result of FSH test	< 20 IU/L <input type="checkbox"/> ⑤
	>= 20 IU/L <input type="checkbox"/>

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Pregnancy Test<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test	1: Pregnancy Testing	LBCAT
② PGNDAT	dd MMM YYYY				PGNDAT
③ PGNTIM	HH:nn				PGNTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine Pregnancy Test<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④ PGNORRES	\$8		NEGATIVE = Negative POSITIVE = Positive UNCLEAR = Unclear		PGNORRES
⑤ PGNORRES	\$8		1 = < 20 IU/L 2 = >= 20 IU/L		PGNORRES
	N				N

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CO Breath Test<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Date of Assessment
DD/MMM/YYYY①

Actual Time of Assessment
hour:min 24-hour clock②

Result
ppm③

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: CO Breath Test<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	CODAT	dd MMM YYYY				CODAT
②	CPTIM	HH:nn				CPTIM
③	COORRES	3				COORRES

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Lab-BU-LabCorp****Generated On: 22 Sep 2014 07:54:21**

Experiment Type _____ ①

Date of Sample Collection _____ ②
YYYY/MM/DD

Subject Number _____ ③

Date of Birth _____ ④

Gender _____ ⑤
Male ☐
Female ☐

Time of Sample Collection _____ ⑥

Analyte Name _____ ⑦

Code _____ ⑧

Result _____ ⑨

Unit _____ ⑩

Lower limit _____ ⑪

Upper limit _____ ⑫

Flag _____ ⑬
Low ☐
High ☐
Abnormal ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Lab-BU-LabCorp****Generated On: 22 Sep 2014 07:54:21**

Clinically Significant?

No ☒ 14
Yes ☐Comment 15

Please document clinically relevant abnormalities in the AE form

Derived Form name(Lab Type-Date) 17Requisition or Accession number 16

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Lab-BU-LabCorp****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	LBCAT_1	\$40				LBCAT_1
②	LBDAT	dd MMM YYYY				LBDAT
③	SUBJECT_N O	\$40				SUBJECT_N O
④	LB_DOB	dd MMM YYYY				DOB
⑤	LBSEX	\$1		M = Male F = Female		LBSEX
⑥	LBTIM	HH:nn				LBTIM
⑦	LBSPEC	\$200				LBSPEC
⑧	TEST_CODE	\$40				TEST_CODE
⑨	LBORRES	7.2				LBORRES
⑩	LBSTRESU	\$40				LBSTRESU
⑪	LBORNRL0	\$20				LBORNRL0
⑫	LBORNRI	\$20				LBORNRI

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Lab-BU-LabCorp****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
16	LBFL	\$20		L = Low H = High A = Abnormal		LBFL
16	LBCLINSIG	\$1		N = No Y = Yes		LBCLINSIG
15	LBCOM	\$200				LBCOM
17	D_F_NAME	\$40				D_F_NAME
16	LBREFID	\$11				LBREFID

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Lab_BU_CCLS****Generated On: 22 Sep 2014 07:54:21**

Transmission Type	Cumulative <input type="checkbox"/> ①
	Incremental <input type="checkbox"/>
Subject ID or Number	_____ ②
Subject Sex	_____ ③
Subject Date of Birth	_____ ④
Visit Name	_____ ⑤
Visit Type	Scheduled <input type="checkbox"/> ⑥
	Unscheduled <input type="checkbox"/>
Accession ID	_____ ⑦
Actual Collection Date	_____ ⑧
Actual Collection Time	_____ ⑨
Specimen Condition	_____ ⑩
Battery ID	_____ ⑪
Battery Name	_____ ⑫
Lab Test ID	_____ ⑬
Lab Test Name	_____ ⑭

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Lab_BU_CCLS****Generated On: 22 Sep 2014 07:54:21**Test ID 15Test Status Done ☐ 16
Not Performed (Pending) ☐
Cancelled ☐Reported Text Result 17Reported Numeric Result 18Reference Range low 19Reference Range high 20Range Units 21Conventional Text Result 22Conventional Numeric Result 23Conventional Reference Range Low 24Conventional Reference Range High 25Conventional Units 26SI Text Result 27SI Numeric Result 28

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Lab_BU_CCLS****Generated On: 22 Sep 2014 07:54:21**SI Reference Range Low 29SI Reference Range High 30SI Units 31

Reported Result Type

Coded ☐ 37

Numeric ☐

Text ☐

Greater Than (quantifiable limit) ☐

Less Than (quantifiable limit) ☐

Range ☐

Alert Flag

Low Panic ☐ 33

Low Telephone ☐

Low ☐

High ☐

High Telephone ☐

High Panic ☐

Clinically Significant?

No ☐ 34

Yes ☐

Comment 35



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Lab_BU_CCLS

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	TRMTYP	\$1		C = Cumulative I = Incremental		TRMTYP
②	SUBJID	\$20				SUBJID
③	SEX_CCLS	\$1				SEX_CCLS
④	BRTHDTM	yyyy mm dd				BRTHDTM
⑤	VISITNUM	\$20				VISITNUM
⑥	VISITYP	\$1		S = Scheduled U = Unschedule d		VISITYP
⑦	ACCSNNUM	\$20				ACCSNNUM
⑧	LBDT	yyyy mm dd				LBDT
⑨	LBTM	HH:nn				LBTM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Lab_BU_CCLS

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10	SPECCND	\$200				SPECCND
11	BATTRID	\$20				BATTRID
12	BATTRNAM	\$40				BATTRNAM
13	LABTESTCD	\$20				LABTESTCD
14	LBTEST	\$100				LBTEST
15	TSTCD	\$20				TSTCD
16	TSTSTAT	\$1		D = Done N = Not Performed (Pending) X = Cancelled		TSTSTAT
17	RPTRESC	\$200				RPTRESC
18	RPTRESN	20.3				RPTRESN
19	RPTNRLO	\$40				RPTNRLO
20	RPTNRHI	\$20				RPTNRHI

PROD 02.001 (MAIN) GMP
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PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Lab_BU_CCLS

Generated On: 22 Sep 2014 07:54:21




	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
21	RPTU	\$20				RPTU
22	CNVRESC	\$200				CNVRESC
23	CNVRESN	20.3				CNVRESN
24	CNVNRLO	\$40				CNVNRLO
25	CNVNRHI	\$40				CNVNRHI
26	CNVU	\$20				CNVU
27	SIRESC	\$200				SIRESC
28	SIRESN	20.3				SIRESN
29	SINRLO	\$40				SINRLO
30	SINRHI	\$40				SINRHI
31	SIU	\$20				SIU
32	RPTRTYP	\$1		C = Coded N = Numeric		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Lab_BU_CCLS

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			T = Text G = Greater Than (quantifiable limit) L = Less Than (quantifiable limit) R = Range		RPTRTYP
 ALRTFL	\$2		LP = Low Panic LT = Low Telephone L = Low H = High HT = High Telephone HP = High Panic		ALRTFL
 LBCLINSIG	\$1		N = No Y = Yes		LBCLINSIG
 LBCOM	\$200				LBCOM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Oxysterol results****Generated On: 22 Sep 2014 07:54:21**

Sample Accession number	_____	①
Analyte	_____	②
Analyte code	_____	③
Result	_____	④
Result Unit	_____	⑤
Comment	_____	⑥
Lower limit of quantification	_____	⑦
Date of Collection DD MMM YYYY	_____	⑧
Collection time hh:mm 24 hour clock	_____	⑨

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Oxysterol results****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	LBREFID	\$11				LBREFID
②	LBTEST	\$100				LBTEST
③	LABTESTCD	\$20				LABTESTCD
④	LBORRES_O7.2 XY					LBORRES_O XY
⑤	LBORRESU	\$5				LBORRESU
⑥	COMMENT	\$200				COMMENT
⑦	LLOQ	\$10				LLOQ
⑧	LBDAT	dd MMM YYYY				LBDAT
⑨	LBTIM	HH:nn				LBTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Lab_BU_COHB****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Start Day (24 hour urine only)	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Lab_BU_COHB

Generated On: 22 Sep 2014 07:54:21

End Day (24 hour Urine Only)



**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book**

Form: Lab_BU_COHB

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book**

Form: Lab_BU_COHB

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1c PCTPMNUM	\$10				PCTPMNUM
1e PCTPSNUM	\$20				PCTPSNUM
1f PCTPENUM	\$20				PCTPENUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Clinical Chemistry<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Category

Clinical Chemistry ☒ ①

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Date of Sample Collection
DD/MM/YYYY

②

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

No ☒ ③

Yes ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Clinical Chemistry<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② LBDAT	dd MMM YYYY				LBDAT
③ LBFSTYN	\$1		N = No		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Clinical Chemistry<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			Y = Yes		LBFSTYN



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Haematology<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Category

Clinical Chemistry ☐ ①

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Test ☐

Date of Sample Collection
DD/MM/YYYY

②

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

No ☐ ③

Yes ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Haematology<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② LBDAT	dd MMM YYYY				LBDAT
③ LBFSTYN	\$1		N = No		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Haematology<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			Y = Yes		LBFSTYN

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Cough Assessment (Paper)****Generated On: 22 Sep 2014 07:54:21**Type Cough Assessment **1**

Was paper questionnaire used?

No **2**Yes ☐Reason not done **3**Date of assessment
DD/MMM/YYYYFixed Unit: **4**
DD/MMM/YYYY

Time of assessment

Fixed Unit: **5**
hour:min 24-hour clockHave you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?Yes **6**No ☐Abandoned ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you? **8**

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Cough Assessment (Paper)****Generated On: 22 Sep 2014 07:54:21**

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☒ 9
Mild ☐
Moderate ☐
Severe ☐
Very severe ☐
Abandoned ☐
Not Applicable ☐

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day?

Rarely ☒ 10
Sometimes ☐
Fairly often ☐
Often ☐
Almost always ☐
Abandoned ☐
Not Applicable ☐

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

No sputum ☒ 11
A moderate amount of sputum ☐
A large amount of sputum ☐
A very large amount of sputum ☐
Abandoned ☐
Not Applicable ☐

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

12

13



**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Cough Assessment (Paper)****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Cough Assessment		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑥	QS_COUGH 8 _ORRES			1 = Yes 2 = No -1 = Abandoned		QS_COUGH _ORRES
⑧	QS_COUGH 8 _ORRES1					QS_COUGH _ORRES1
⑨	QS_COUGH 8 _ORRES2			1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Cough Assessment (Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned -9 = Not Applicable		QS_COUGH_ORRES2
10 QS_COUGH 8_ORRES3			1 = Rarely 2 = Sometimes 3 = Fairly often 4 = Often 5 = Almost always -1 = Abandoned -9 = Not Applicable		QS_COUGH_ORRES3
11 QS_COUGH 8_ORRES4			0 = No sputum 1 = A moderate amount of sputum 2 = A large amount of sputum 3 = A very large amount of sputum		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Cough Assessment (Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned -9 = Not Applicable		QS_COUGH _ORRES4
 QS_COUGH \$200 _ORRES5					QS_COUGH _ORRES5
 D_F_NAME \$40 _QS					D_F_NAME _QS

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)****Generated On: 22 Sep 2014 07:54:21**

Type MNWS ①

Type Behaviour Rating Scale ②
Self-ReportWas paper questionnaire used? No ☐ ③
Yes ☐

Reason not done _____ ④

Date of assessment DD/MMM/YYYY Fixed Unit: ⑤
DD/MMM/YYYYTime of assessment _____ Fixed Unit: ⑥
hour:min 24-hour clock

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

-
1. Angry, irritable, frustrated ☒ 8
 2. Anxious, tense ☐
 3. Depressed Mood, sad ☐
 4. Desire or craving to smoke ☐
 5. Difficulty concentrating ☐
 6. Increased appetite, hungry, weight gain ☐
 7. Insomnia, sleep problems, awakening at night ☐
 8. Restless ☐
 9. Impatient ☐
 10. Constipation ☐
 11. Dizziness ☐
 12. Coughing ☐
 13. Dreaming or nightmares ☐
 14. Nausea ☐
 15. Sore throat ☐

Result

None ☒ 9

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

11



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		MNWS		QSCAT
②	QSSCAT	\$40		Behaviour Rating Scale Self-Report		QSSCAT
③	QSSTAT	\$1		N = No Y = Yes		QSSTAT
④	QSREASND	\$200				QSREASND
⑤	QSDAT	dd MMM YYYY				QSDAT
⑥	QSTIM	HH:nn				QSTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
QSTEST_M 2 SWS			1 = 1. Angry, irritable, frustrated		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	----------------------	----------------------

2 = 2.
Anxious,
tense



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			3 = 3. Depressed Mood, sad		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = 4, Desire or craving to smoke		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = 5. Difficulty concentrati ng		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = 6. Increased appetite, hungry, weight gain		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = 7. Insomnia, sleep problems, awakening at night		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			8 = 8. Restless		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			9 = 9. Impatient		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			10 = 10. Constipation		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			11 = 11. Dizziness		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			12 = 12. Coughing		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			13 = 13. Dreaming or nightmares		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	----------------------	----------------------

			14 = 14. Nausea		
--	--	--	--------------------	--	--



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			15 = 15. Sore throat		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: 1. Angry, irritable, frustrated	QSTEST_M SWS
				2: 2. Anxious, tense	
				3: 3. Depressed Mood, sad	
				4: 4. Desire or craving to smoke	
				5: 5. Difficulty concentrating	
				6: 6. Increased appetite, hungry, weight gain	
				7: 7. Insomnia, sleep problems, awakening at night	
				8: 8. Restless	
				9: 9. Impatient	
				10: 10. Constipation	
				11: 11. Dizziness	
				12: 12. Coughing	
				13: 13. Dreaming	
PROD 02.001 (MAIN) GMP 05AUG2014 (649)				or nightmares	569 of 896
				14: 14. Nausea	
				15: 15. Sore throat	



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 QSORRES_ 1 MSWS			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS
10 D_F_NAME \$40 _QS					D_F_NAME _QS

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Type	Product Use	1
Was paper questionnaire used?	No <input type="checkbox"/>	2
	Yes <input type="checkbox"/>	
Reason not done		3
Date of completion DD/MMM/YYYY		4
Time of completion hh:mm		5
Date the questionnaire was completed for DD/MMM/YYYY		6



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Product use diary(Paper)

Generated On: 22 Sep 2014 07:54:21

What tobacco/nicotine product did you use today?

- Abandoned ☒ 7
- THS 2.2 ☐
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Product use diary(Paper)

Generated On: 22 Sep 2014 07:54:21

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

How many THS 2.2 tobacco sticks did you use today? 8

How many CC/ roll-your-own did you smoke today? 9

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

What NRT product did you used today?

- Nicotine Inhaler ☒ 10
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐



Generated On: 22 Sep 2014 07:54:21

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Product use diary(Paper)

Generated On: 22 Sep 2014 07:54:21

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

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

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

How many times did you use an inhaler today? _____ 11

How many times did you use a nasal spray today? _____ 12

How many gums did you use today? _____ 13

How many lozenges did you use today? _____ 14

How many patches did you use today? _____ 15

How many times did you use other NRT products today
not listed previously? _____ 16

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☒ 17
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

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

16

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

How many cigars/cigarillos did you smoke today? _____ 19

How many times did you smoke a pipe today? _____ 20

How many times did you use a tobacco product today
not listed previously? _____ 21

How many times did you use an electronic cigarette
today? _____ 22

_____ 23

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Product Use		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	EXDATE	dd MMM YYYY				EXDATE
⑤	EXTIME	HH:nn				EXTIME
⑥	EXDATE_1	dd MMM YYYY				EXDATE_1
⑦	EXPROD	8		-1 = Abandoned 1 = THS 2.2 2 = CC 4 = NRT 8 = Other tobacco product 16 = Electronic cigarette		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			32 = None of the above		
			3 = THS		
			2.2 and CC		
			5 = THS		
			2.2 and NRT		
			6 = CC and NRT		
			7 = THS		
			2.2, CC and NRT		
			9 = THS		
			2.2 and Other tobacco product		
			10 = CC and Other tobacco product		
			12 = NRT and Other tobacco product		
			13 = THS		
			2.2, NRT and Other tobacco product		
			14 = CC, NRT and Other tobacco product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = THS 2.2, CC, NRT and Other tobacco product 17 = THS 2.2 and Electronic cigarette 18 = CC and Electronic cigarette 20 = NRT and Electronic cigarette 21 = THS 2.2, NRT and Electronic cigarette 22 = CC, NRT and Electronic cigarette 23 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			24 = Other tobacco product and Electronic cigarette		
			25 = THS		
			2.2, Other tobacco product and Electronic cigarette		
			26 = CC, Other tobacco product and Electronic cigarette		
			27 = THS		
			2.2, CC, Other tobacco product and Electronic cigarette		
			28 = NRT, Other tobacco product and Electronic cigarette		
			29 = THS		
			2.2, NRT, Other tobacco product and Electronic cigarette		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			30 = CC, NRT, Other tobacco product and Electronic cigarette 31 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette		EXPROD
8 THSNUM	8				THSNUM
9 CCNUM	8				CCNUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10 NRTPROD	8		1 = Nicotine Inhaler 2 = Nicotine Nasal Spray 4 = Nicotine Gum 8 = Nicotine Lozenge 16 = Nicotine Patch 32 = Other NRT Product -1 = Abandoned -9 = Not Applicable 3 = Nicotine Inhaler and Nicotine Nasal Spray		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Nicotine Inhaler and Nicotine Gum		
			6 = Nicotine Nasal Spray and Nicotine Gum		
			7 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Gum		
			9 = Nicotine Inhaler and Nicotine Lozenge		
			10 = Nicotine Nasal Spray and Nicotine Lozenge		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Lozenge		
			12 = Nicotine Gum and Nicotine Lozenge		
			13 = Nicotine Inhaler, Nicotine Gum and Nicotine Lozenge		
			14 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		
			17 = Nicotine Inhaler and Nicotine Patch		
			18 = Nicotine Nasal Spray and Nicotine Patch		
			19 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			20 = Nicotine Gum and Nicotine Patch		
			21 = Nicotine Inhaler, Nicotine Gum and Nicotine Patch		
			22 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		
			23 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			24 = Nicotine Lozenge and Nicotine Patch		
			25 = Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch		
			26 = Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		
			27 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			28 = Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			29 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			30 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			31 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			33 = Nicotine Inhaler and Other NRT Product		
			34 = Nicotine Nasal Spray and Other NRT Product		
			35 = Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			36 = Nicotine Gum and Other NRT Product		
			37 = Nicotine Inhaler, Nicotine Gum and Other NRT Product		
			38 = Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		
			39 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			40 = Nicotine Lozenge and Other NRT Product		
			41 = Nicotine Inhaler, Nicotine Lozenge and Other NRT Product		
			42 = Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		
			43 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			44 = Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			45 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			46 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			47 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			48 = Nicotine Patch and Other NRT Product		
			49 = Nicotine Inhaler, Nicotine Patch and Other NRT Product		
			50 = Nicotine Nasal Spray, Nicotine Patch and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			51 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Patch and Other NRT Product		
			52 = Nicotine Gum,Nicotin e Patch and Other NRT Product		
			53 = Nicotine Inhaler, Nicotine Gum,Nicotin e Patch and Other NRT Product		NRTPROD

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
11	INHFREQ	8				INHFREQ
12	NASPFREQ	8				NASPFREQ
13	GUMFREQ	8				GUMFREQ
14	LOZFREQ	8				LOZFREQ
15	PATFREQ	8				PATFREQ
16	OTHNRTRFREQ	8				OTHNRTRFREQ
17	OTHPROD	8		1 = Chewable/S mokeless Tobacco 2 = Cigars/Cigar illos 4 = Pipe 8 = Other Tobacco Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		
			-9 = Not Applicable		
			3 = Chewable/S mokeless Tobacco and Cigars/Cigar illos		
			5 = Chewable/S mokeless Tobacco and Pipe		
			6 = Cigars/Cigar illos and Pipe		
			7 = Chewable/S mokeless Tobacco, Cigars/Cigar illos and Pipe		
			9 = Chewable/S mokeless Tobacco and Other Tobacco Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = Cigars/Cigar illos and Other Tobacco Product		
			11 = Chewable/S mokeless Tobacco and Cigars/Cigar illos and Other Tobacco Product		
			12 = Pipe and Other Tobacco Product		
			13 = Chewable/S mokeless Tobacco, Pipe and Other Tobacco Product		
			14 = Cigars/Cigar illos, Pipe and Other Tobacco Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Chewable/S mokeless Tobacco, Cigars/Cigar illos, Pipe and Other Tobacco Product		OTHPROD
18 TOBFREQ	8				TOBFREQ
19 CIGFREQ	8				CIGFREQ
20 PIPFREQ	8				PIPFREQ
21 TOBNFREQ	8				TOBNFREQ
22 ECNUM	8				ECNUM
23 D_F_NAME_QS	\$40				D_F_NAME_QS



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: FTND Questionnaire

Generated On: 22 Sep 2014 07:54:21

Type FTND **1**Date of Birth **2**Date of assessment Fixed Unit: **3**
DD/MMM/YYYY DD/MMM/YYYYTime of assessment Fixed Unit: **4**
hour:min 24-hour clockAssessment Status Completed ☐ **5**
Abandoned ☐1. How soon after you wake up do you smoke your first cigarette? After 60 minutes ☐ **6**
31-60 minutes ☐
6-30 minutes ☐
Within 5 minutes ☐
Abandoned ☐2. Do you find it difficult to refrain from smoking in places where it is forbidden? No ☐ **7**
Yes ☐
Abandoned ☐3. Which cigarette would you hate most to give up? The first in the morning ☐ **8**
Any other ☐
Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book**Form: FTND Questionnaire****Generated On: 22 Sep 2014 07:54:21**

4. How many cigarettes per day do you smoke?

10 or less ☒ 9

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 ☒ 10

Yes ☐

Abandoned ☐

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

No ☒ 11

Yes ☐

Abandoned ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: FTND Questionnaire****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		FTND		QSCAT
②	QSDOB	yyyy MMM dd				QSDOB
③	QSDAT_E	yyyy MMM dd				QSDAT_E
④	QSTIM	HH:nn				QSTIM
⑤	ASSESSME NTSTATUS	8		1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑥	QS_FTND_ ORRES_1	8		0 = After 60 minutes 1 = 31-60 minutes 2 = 6-30 minutes 3 = Within 5 minutes -1 = Abandoned		QS_FTND_ ORRES_1
⑦	QS_FTND_ ORRES_2	8		0 = No 1 = Yes		




PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: FTND Questionnaire

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		QS_FTND_ ORRES_2
8 QS_FTND_ ORRES_3	8		1 = The first in the morning 0 = Any other -1 = Abandoned		QS_FTND_ ORRES_3
9 QS_FTND_ ORRES_4	8		0 = 10 or less 1 = 11-20 2 = 21-30 3 = 31 or more -1 = Abandoned		QS_FTND_ ORRES_4
10 QS_FTND_ ORRES_5	8		0 = No 1 = Yes -1 = Abandoned		QS_FTND_ ORRES_5

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: FTND Questionnaire****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 QS_FTND_ 8 ORRES_6			0 = No 1 = Yes -1 = Abandoned		QS_FTND_ ORRES_6



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 22 Sep 2014 07:54:21

Type MCEQ **1**

Date of Birth **2**

Date of assessment Fixed Unit: **3**
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment Fixed Unit: **4**
hour:min 24-hour clock

Assessment Status Completed **5**
Abandoned ☐

1. Was smoking satisfying? Not at all **6**
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 22 Sep 2014 07:54:21

2. Did cigarettes taste good? Not at all ☒ 7
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 ☒ 8
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

4. Did smoking calm you down? Not at all ☒ 9
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 22 Sep 2014 07:54:21

5. Did smoking make you feel more awake? Not at all ☒ 10
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

6. Did smoking make you feel less irritable? Not at all ☒ 11
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

7. Did smoking help you concentrate? Not at all ☒ 12
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 22 Sep 2014 07:54:21

8. Did smoking reduce your hunger for food? Not at all ☐ 13
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

9. Did smoking make you dizzy? Not at all ☐ 14
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

10. Did smoking make you nauseous? Not at all ☐ 15
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 22 Sep 2014 07:54:21

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

Not at all ☐ 16
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

12. Did you enjoy smoking?

Not at all ☐ 17
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		MCEQ		QSCAT
②	QSDOB	yyyy MMM dd				QSDOB
③	QSDAT_E	yyyy MMM dd				QSDAT_E
④	QSTIM	HH:nn				QSTIM
⑤	ASSESSME NTSTATUS	8		1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑥	MCEQ1	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ1



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
7 MCEQ2	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ2
8 MCEQ3	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ3
9 MCEQ4	8		1 = Not at all		





PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ4
10 MCEQ5	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ5
11 MCEQ6	8		1 = Not at all 2 = Very little		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ6
 MCEQ7	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ7
 MCEQ8	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ8
16 MCEQ9	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ9
15 MCEQ10	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Extremely -1 = Abandoned		MCEQ10
16 MCEQ11	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ11
17 MCEQ12	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		MCEQ12



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Behavioral Risk Factor Surveillance System Questionnaire
Generated On: 22 Sep 2014 07:54:21

Type Behavioral Risk Factor Surveillance System Questionnaire **1**

Was paper questionnaire used? No ☐ **2**
Yes ☐

Reason not done ☐ **3**

Date of assessment Fixed Unit: ☐ **4**
DD/MMM/YYYY

Time of assessment Fixed Unit: ☐ **5**
hour:min 24-hour clock

Have you ever smoked 100 cigarettes or more in your life? Yes ☐ **6**
No ☐
Don't know/Not sure ☐

Do you now smoke cigarettes every day, some days, or not at all? Every day ☐ **7**
Some days ☐
Not at all ☐
Don't know/Not sure ☐

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking? Yes ☐ **8**
No ☐
Don't know/Not sure ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Behavioral Risk Factor Surveillance System Questionnaire
Generated On: 22 Sep 2014 07:54:21

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

- Within the past month (less than 1 month ago) ☒ 9
- Within the past 3 months (1 month but less than 3 months ago) ☐
- Within the past 6 months (3 months but less than 6 months ago) ☐
- Within the past year (6 months but less than 1 year ago) ☐
- Within the past 5 years (1 year but less than 5 years ago) ☐
- Within the past 10 years (5 years but less than 10 years ago) ☐
- 10 years or more ☐
- Don't know/Not sure ☐

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

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

- Every day ☒ 10
- Some days ☐
- Not at all ☐
- Do not read. Not at all ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Behavioral Risk Factor Surveillance System Questionnaire
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Behavioral Risk Factor Surveillance System Questionnaire		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑥	QSORRES_ RFSS1	\$1		A = Yes B = No C = Don't know/Not sure		QSORRES_ RFSS1
⑦	QSORRES_ RFSS2	\$1		A = Every day B = Some days		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Behavioral Risk Factor Surveillance System Questionnaire
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			C = Not at all D = Don't know/Not sure		QSORRES_ RFSS2
8 QSORRES_ \$1 3			A = Yes B = No C = Don't know/Not sure		QSORRES_ 3
9 QSORRES_ \$2 4			A = Within the past month (less than 1 month ago) B = Within the past 3 months (1 month but less than 3 months ago) C = Within the past 6 months (3 months but less than 6 months ago)		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Behavioral Risk Factor Surveillance System Questionnaire
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			D = Within the past year (6 months but less than 1 year ago) E = Within the past 5 years (1 year but less than 5 years ago) F = Within the past 10 years (5 years but less than 10 years ago) G = 10 years or more H = Don't know/Not sure		QSORRES_4
QSORRES_5	\$1		A = Every day B = Some days		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Behavioral Risk Factor Surveillance System Questionnaire
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			C = Not at all D = Do not read. Not at all		QSORRES_5

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Smoking Questionnaire (SQ)****Generated On: 22 Sep 2014 07:54:21**Type Smoking Questionnaire **1**Was paper questionnaire used? No **2**
YesReason not done **3**Date of assessment Fixed Unit: **4**
DD/MMM/YYYYTime of assessment Fixed Unit: **5**
hour:min 24-hour clock1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)? Daily smoker (at least one cigarette per day, disregarding religious fasting) **6**
Occasional smoker (less than one cigarette per day)
Ex-smoker of cigarettes
Non-smoker of cigarettes2. Have you ever smoked 100 cigarettes or more in your life? Yes **7**
No3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day? Yes **8**
No

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Smoking Questionnaire (SQ)****Generated On: 22 Sep 2014 07:54:21**

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

Fixed Unit: Years **9**

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

Years

Fixed Unit: Years **11**

Months

Fixed Unit: Months **12**

Days

Fixed Unit: Days **13**

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

Years

Fixed Unit: Years **15**

Months

Fixed Unit: Months **16**

Days

Fixed Unit: Days **17**

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

18

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Smoking Questionnaire (SQ)****Generated On: 22 Sep 2014 07:54:21**

Time _____ Currently (last 3 months) ☒ 19
1 year ago ☐
5 years ago ☐
10 years ago ☐
15 years ago ☐
20 years ago ☐
More than 20 years ago ☐

8. On average, how many Manufactured cigarettes do/did you smoke per day? None ☒ 20
Less than 1 per day ☐

Manufactured Cigarettes per day _____ 21

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☒ 27
Less than 1 per day ☐

Hand-rolled Cigarettes per day _____ 28

8. On average, how many cigars do/did you smoke per day? None ☒ 24
Less than 1 per day ☐

Cigars per day _____ 25

8. On average, how many pipes do/did you smoke per day? None ☒ 26
Less than 1 per day ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Smoking Questionnaire (SQ)
Generated On: 22 Sep 2014 07:54:21

Pipes
per day

27

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Smoking Questionnaire (SQ)**

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Smoking Questionnaire		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑥	QS_SQORR ES_1	\$1		a = Daily smoker (at least one cigarette per day, disregarding religious fasting) b = Occasional smoker (less than one cigarette per day)		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Smoking Questionnaire (SQ)

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			c = Ex-smoker of cigarettes d = Non-smoker of cigarettes		QS_SQORR ES_1
7 QS_SQORR \$1 ES_2			a = Yes b = No		QS_SQORR ES_2
8 QS_SQORR \$1 ES_3			a = Yes b = No		QS_SQORR ES_3
9 QS_SQORR 2 ES_4					QS_SQORR ES_4
11 QS_SQORR 2 ES_5_YCAR					QS_SQORR ES_5_YCAR

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Smoking Questionnaire (SQ)****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17	QS_SQORR 2 ES_5_MON TH					QS_SQORR ES_5_MON TH
18	QS_SQORR 3 ES_5_DAY					QS_SQORR ES_5_DAY
19	QS_SQORR 2 ES_6_YEAR					QS_SQORR ES_6_YEAR
16	QS_SQORR 2 ES_6_MON TH					QS_SQORR ES_6_MON TH
17	QS_SQORR 3 ES_6_DAY					QS_SQORR ES_6_DAY
18	QS_SQORR \$200 ES_7					QS_SQORR ES_7



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Smoking Questionnaire (SQ)

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
16 QS_SQ_TIM\$200 E			1 = Currently (last 3 months) 2 = 1 year ago 3 = 5 years ago 4 = 10 years ago 5 = 15 years ago 6 = 20 years ago 7 = More than 20 years ago	1: Currently (last 3 months) 2: 1 year ago 3: 5 years ago 4: 10 years ago 5: 15 years ago 6: 20 years ago 7: More than 20 years ago	QS_SQ_TIM E
20 QS_SQORR 1 ES_8			1 = None		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Smoking Questionnaire (SQ)

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Less than 1 per day		QS_SQORR ES_8
21 QS_SQORR 3 ES_9					QS_SQORR ES_9
22 QS_SQORR 1 ES_10			1 = None 2 = Less than 1 per day		QS_SQORR ES_10
23 QS_SQORR 3 ES_11					QS_SQORR ES_11
24 QS_SQORR 1 ES_12			1 = None 2 = Less than 1 per day		QS_SQORR ES_12
25 QS_SQORR 3 ES_13					QS_SQORR ES_13

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Smoking Questionnaire (SQ)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
26 QS_SQORR 1 ES_14			1 = None 2 = Less than 1 per day		QS_SQORR ES_14
27 QS_SQORR 3 ES_15					QS_SQORR ES_15

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking****Generated On: 22 Sep 2014 07:54:21**

Was paper questionnaire used?

No ☐ ①
Yes ☐

Reason not done

②

Type

Prochaska Stage of Change ③
Questionnaire: Intention to
Quit Smoking

Date of assessment

Fixed Unit: ④
DD/MMM/YYYY

Time of assessment

Fixed Unit: ⑤
hour:min 24-hour clock

1. Are you currently a smoker?

Yes, I currently smoke ☐ ⑥
No, I quit within the last 6 ☐
months
No, I quit more than 6 ☐
months ago
No, I have never smoked ☐2. In the last year, how many times have you quit
smoking for at least 24 hours?

⑦

3. Are you seriously thinking of quitting smoking?

Yes, within the next 30 ☐ ⑧
days
Yes, within the next 6 ☐
months
No, not thinking of quitting ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSSTAT	\$1		N = No Y = Yes		QSSTAT
②	QSREASND	\$200				QSREASND
③	QSCAT	\$80		Prochaska Stage of Change Questionnai re: Intention to Quit Smoking		QSCAT
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑥	QS_PORRES\$1 _1			A = Yes, I currently smoke B = No, I quit within the last 6 months C = No, I quit more than 6 months ago		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			D = No, I have never smoked		QS_PORRES_1
7 QS_PORRES3_2					QS_PORRES_2
8 QS_PORRES\$1_3			A = Yes, within the next 30 days B = Yes, within the next 6 months C = No, not thinking of quitting		QS_PORRES_3

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions****Generated On: 22 Sep 2014 07:54:21**

Was paper questionnaire used?

Fixed Unit: ①
hour:min 24-hour clockNo ☐
Yes ☐

Reason not done

②

Date of Assessment

Fixed Unit: ③
DD/MMM/YYYY

Time of assessment

④

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

Fixed Unit: minutes ⑤

Question

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

Answer

Yes ☐ ⑦
No ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Supplemental Questions

Generated On: 22 Sep 2014 07:54:21

Comments (open-end)

8

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSSTAT	\$1		N = No Y = Yes		QSSTAT
②	QSREASND	\$200				QSREASND
③	QSDAT	dd MMM YYYY				QSDAT
④	QSTIM	HH:nn				QSTIM
⑤	QS_MQORR 2 ES1					QS_MQORR ES1

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6 QS_MQTES T	\$200		2 = 2. Did the SQ capture your smoking behavior completely?		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = 3. Did the SQ capture your smoking behavior correctly?		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = 4. Did the SQ capture your smoking history completely?		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			5 = 5. Did the SQ capture your smoking history correctly?		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			6 = 6. Was the SQ self-explaining?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Supplemental Questions

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = 7. Was the SQ easy to use?	1: 2. Did the SQ capture your smoking behavior completely? 2: 3. Did the SQ capture your smoking behavior correctly? 3: 4. Did the SQ capture your smoking history completely? 4: 5. Did the SQ capture your smoking history correctly? 5: 6. Was the SQ self-explaining? 6: 7. Was the SQ easy to use?	QS_MQTES T

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
7	QS_MQORR	\$1		a = Yes b = No		QS_MQORR ES2
8	QS_MQCOM	\$200				QS_MQCOM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Human Smoking Topography Questionnaire
Generated On: 22 Sep 2014 07:54:21

Type _____ Human Smoking Topography Questionnaire **1**

Was paper questionnaire used? No ☐ **2**
Yes ☐

Reason not done _____ **3**

Date of assessment _____ Fixed Unit: DD/MMM/YYYY **4**

Time of assessment _____ Fixed Unit: hour:min 24-hour clock **5**

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device. Strongly agree ☐ **7**
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you agree or strongly agree, please describe : _____ **8**



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Human Smoking Topography Questionnaire
Generated On: 22 Sep 2014 07:54:21

2. You enjoy smoking with the device as much as without it. Strongly agree ☒ 9
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you disagree or strongly disagree, please describe : _____ 10

3. The taste of the conventional cigarettes/products is different with the device. Strongly agree ☒ 11
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you agree or strongly agree, please describe : _____ 12

4. The device is easy to use. Strongly agree ☒ 13
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐

If you disagree or strongly disagree, please describe : _____ 14

5. Your smoking is disturbed by the device. Strongly agree ☒ 15
Agree ☐
Neither agree nor disagree ☐
Disagree ☐
Strongly disagree ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Human Smoking Topography Questionnaire
Generated On: 22 Sep 2014 07:54:21

If you agree or strongly agree, please describe : _____





PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Human Smoking Topography Questionnaire
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Human Smoking Topography Questionnaire		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑦	QSORRES_ 1	8		1 = Strongly agree 2 = Agree 3 = Neither agree nor disagree 4 = Disagree 5 = Strongly disagree		QSORRES_ 1







PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Human Smoking Topography Questionnaire
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 QSSPEC_1	\$200				QSSPEC_1
9 QSORRES_ 8 2			1 = Strongly agree 2 = Agree 3 = Neither agree nor disagree 4 = Disagree 5 = Strongly disagree		QSORRES_ 2
10 QSSPEC_2	\$200				QSSPEC_2
11 QSORRES_ 8 3			1 = Strongly agree 2 = Agree 3 = Neither agree nor disagree 4 = Disagree 5 = Strongly disagree		QSORRES_ 3




PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Human Smoking Topography Questionnaire
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 QSSPEC_3	\$200				QSSPEC_3
 QSORRES_ 8 4			1 = Strongly agree 2 = Agree 3 = Neither agree nor disagree 4 = Disagree 5 = Strongly disagree		QSORRES_ 4
 QSSPEC_4	\$200				QSSPEC_4
 QSORRES_ 8 5			1 = Strongly agree 2 = Agree 3 = Neither agree nor disagree 4 = Disagree 5 = Strongly disagree		QSORRES_ 5



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Human Smoking Topography Questionnaire
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 QSSPEC_5	\$200				QSSPEC_5



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

Type _____ Questionnaire on smoking urges **1**

Was paper questionnaire used? No ☐ **2**
Yes ☐

Reason not done _____ **3**

Date of assessment _____ **4**

DD/MMM/YYYY _____

Time of assessment _____ **5**

hour:min 24-hour clock _____

1. I have a desire for a cigarette right now

Strongly disagree	<input type="checkbox"/>	6
Disagree	<input type="checkbox"/>	
Somewhat disagree	<input type="checkbox"/>	
Do not agree or disagree	<input type="checkbox"/>	
Somewhat agree	<input type="checkbox"/>	
Agree	<input type="checkbox"/>	
Strongly agree	<input type="checkbox"/>	
Abandoned	<input type="checkbox"/>	



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

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

Strongly disagree ☒ 7

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 ☒ 8

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 ☒ 9

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

5. All I want right now is a cigarette

Strongly disagree ☐ 10

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

6. I have an urge for a cigarette

Strongly disagree ☐ 11

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

7. A cigarette would taste good now

Strongly disagree ☐ 12

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

8. I would do almost anything for a cigarette now

Strongly disagree ☐ 13

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

9. Smoking would make me less depressed

Strongly disagree ☐ 14

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

10. I am going to smoke as soon as possible

Strongly disagree ☐ 15

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

16



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Questionnaire on smoking urges		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑥	QSORES_ 8 1			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		QSORRES_ 1
7 QSORRES_ 8 2			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 2
8 QSORRES_ 8 3			1 = Strongly disagree 2 = Disagree		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 3
9 QSORRES_ 8 4			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree		




PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		QSORRES_ 4
10 QSORRES_ 8 5			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 5
11 QSORRES_ 8 6			1 = Strongly disagree 2 = Disagree		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 6
 QSORRES_ 8 7			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree		

PROD 02.001 (MAIN) GMP 05AUG2014 (649)




PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		QSORRES_ 7
13 QSORRES_ 8 8			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 8
14 QSORRES_ 8 9			1 = Strongly disagree 2 = Disagree		




PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 9
 QSORRES_ 8 10			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree / = Strongly agree		

PROD 02.001 (MAIN) GMP 05AUG2014 (649)



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		QSORRES_ 10
 D_F_NAME_QS	\$40				D_F_NAME_QS



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Generated On: 22 Sep 2014 07:54:21

Type _____ Modifier Cigarette Evaluation Questionnaire **1**

Was paper questionnaire used? No ☐ **2**
Yes ☐

Reason not done _____ **3**

Date of assessment _____ Fixed Unit: **4**
DD/MMM/YYYY

Time of assessment _____ Fixed Unit: **5**
hour:min 24-hour clock



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Generated On: 22 Sep 2014 07:54:21

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

- Was smoking satisfying? ☐ 6
- Did cigarettes taste good? ☐
- Did you enjoy the sensation in your throat and chest? ☐
- Did smoking calm you down? ☐
- Did smoking make you feel more awake? ☐
- Did smoking make you feel less irritable? ☐
- Did smoking help you concentrate? ☐
- Did smoking reduce your hunger for food? ☐
- Did smoking make you dizzy? ☐
- Did smoking make you nauseous? ☐
- Did smoking immediately relieve your craving for a cigarette? ☐
- Did you enjoy smoking? ☐

Response

- Not at all ☐ 7
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Modifier Cigarette Evaluation Questionnaire		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6 QSTEST	\$200		1 = Was smoking satisfying?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	----------------------	----------------------

| | | | 2 = Did cigarettes taste good? | | |



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	----------------------	----------------------

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	-------------------	-------------------

| | | | 4 = Did smoking calm you down? | | |



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Did smoking make you feel more awake?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	----------------------	----------------------

			6 = Did smoking make you feel less irritable?		
--	--	--	---	--	--



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Did smoking help you concentrate ?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = Did smoking reduce your hunger for food?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	-------------------	-------------------

| | | | 9 = Did smoking make you dizzy? | | |



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	----------------------	----------------------

| | | | 10 = Did smoking make you nauseous? | | |

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			11 = Did smoking immediately relieve your craving for a cigarette?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	----------------------	----------------------

12 = Did
you enjoy
smoking?

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: Was smoking satisfying? 2: Did cigarettes taste good? 3: Did you enjoy the sensation in your throat and chest? 4: Did smoking calm you down? 5: Did smoking make you feel more awake? 6: Did smoking make you feel less irritable? 7: Did smoking help you concentrate? 8: Did smoking reduce your hunger for food? 9: Did smoking make you dizzy? 10: Did smoking make you nauseous? 11: Did smoking immediately relieve your craving for a cigarette?	QSTEST
PROD 02.001 (MAIN) GMP 05AUG2014 (649)					682 of 896



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑦ QSORRES	1		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		QSORRES
⑧ D_F_NAME_QS	\$40				D_F_NAME_QS



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: FTND Questionnaire (FTND) (Paper)
Generated On: 22 Sep 2014 07:54:21

Type FTND **1**

Was paper questionnaire used? No ☐ **2**
Yes ☐

Reason not done **3**

Date of assessment Fixed Unit: **4**
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment Fixed Unit: **5**
hour:min 24-hour clock

1. How soon after you wake up do you smoke your first cigarette? After 60 minutes ☐ **6**
31-60 minutes ☐
6-30 minutes ☐
Within 5 minutes ☐
Abandoned ☐

2. Do you find it difficult to refrain from smoking in places where it is forbidden? No ☐ **7**
Yes ☐
Abandoned ☐

3. Which cigarette would you hate most to give up? The first in the morning ☐ **8**
Any other ☐
Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: FTND Questionnaire (FTND) (Paper)
Generated On: 22 Sep 2014 07:54:21

4. How many cigarettes per day do you smoke? 10 or less ☒ 9
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 ☒ 10
Yes ☐
Abandoned ☐

6. Do you smoke even if you are so ill that you are in bed most of the day? No ☒ 11
Yes ☐
Abandoned ☐

17

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: FTND Questionnaire (FTND) (Paper)****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		FTND		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑥	QS_FTND_ ORRES_1	8		0 = After 60 minutes 1 = 31-60 minutes 2 = 6-30 minutes 3 = Within 5 minutes -1 = Abandoned		QS_FTND_ ORRES_1
⑦	QS_FTND_ ORRES_2	8		0 = No 1 = Yes -1 = Abandoned		QS_FTND_ ORRES_2

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: FTND Questionnaire (FTND) (Paper)****Generated On: 22 Sep 2014 07:54:21**


Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 QS_FTND_8 ORRES_3			1 = The first in the morning 0 = Any other -1 = Abandoned		QS_FTND_8 ORRES_3
9 QS_FTND_8 ORRES_4			0 = 10 or less 1 = 11-20 2 = 21-30 3 = 31 or more -1 = Abandoned		QS_FTND_8 ORRES_4
10 QS_FTND_8 ORRES_5			0 = No 1 = Yes -1 = Abandoned		QS_FTND_8 ORRES_5
11 QS_FTND_8 ORRES_6			0 = No 1 = Yes -1 = Abandoned		QS_FTND_8 ORRES_6



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: FTND Questionnaire (FTND) (Paper)

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 D_F_NAME_QS	\$40				D_F_NAME_QS

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU)****Generated On: 22 Sep 2014 07:54:21**Type QSU **1**Date of Birth **2**Date of assessment **3**

DD/MMM/YYYY

Time of assessment **4**

hour:min 24-hour clock

Assessment Status Completed **5**
Abandoned

1. I have a desire for a cigarette right now **6**

Strongly disagree
Disagree
Somewhat disagree
Do not agree or disagree
Somewhat agree
Agree
Strongly agree
Abandoned



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU)
Generated On: 22 Sep 2014 07:54:21

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

Strongly disagree ☒ 7
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 ☒ 8
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 ☒ 9
Disagree ☐
Somewhat disagree ☐
Do not agree or disagree ☐
Somewhat agree ☐
Agree ☐
Strongly agree ☐
Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU)
Generated On: 22 Sep 2014 07:54:21

5. All I want right now is a cigarette

Strongly disagree ☐ 10

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

6. I have an urge for a cigarette

Strongly disagree ☐ 11

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

7. A cigarette would taste good now

Strongly disagree ☐ 12

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU)
Generated On: 22 Sep 2014 07:54:21

8. I would do almost anything for a cigarette now

Strongly disagree ☐ 13

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

9. Smoking would make me less depressed

Strongly disagree ☐ 14

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

10. I am going to smoke as soon as possible

Strongly disagree ☐ 15

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU)**

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		QSU		QSCAT
②	QSDOB	yyyy MMM dd				QSDOB
③	QSDAT_E	yyyy MMM dd				QSDAT_E
④	QSTIM	HH:nn				QSTIM
⑤	ASSESSME NTSTATUS	8		1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑥	QSORRES_ 1	8		1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Strongly agree -1 = Abandoned		QSORRES_ 1
7 QSORRES_ 8 2			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 2
8 QSORRES_ 8 3			1 = Strongly disagree		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 3
9 QSORRES_ 4	8		1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_4
QSORRES_ 8 5			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_5
QSORRES_ 8 6			1 = Strongly disagree		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_6
 QSORRES_7			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_7
QSORRES_8			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_8
QSORRES_9			1 = Strongly disagree		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 9
 QSORRES_ 8 10			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_10



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Cough Assessment (Paper) <Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Type Cough Assessment **1**

Date of assessment
DD/MM/YYYY

Fixed Unit: **2**
DD/MM/YYYY

Timepoint

Baseline (Day 0) **3**
Day 1 ☐
Day 2 ☐
Day 3 ☐
Day 4 ☐
Day 5 ☐
Day 6 ☐
Day 30 ☐
Day 60 ☐
Day 90 ☐

Time of assessment

Fixed Unit: **4**
hour:min 24-hour clock

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

Yes ☐ **5**
No ☐
Abandoned ☐

If YES, please answer the following questions:

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

7



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Cough Assessment (Paper) <Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☒ 8
Mild ☐
Moderate ☐
Severe ☐
Very severe ☐
Abandoned ☐
Not Applicable ☐

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day?

Rarely ☒ 9
Sometimes ☐
Fairly often ☐
Often ☐
Almost always ☐
Abandoned ☐
Not Applicable ☐

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

No sputum ☒ 10
A moderate amount of sputum ☐
A large amount of sputum ☐
A very large amount of sputum ☐
Abandoned ☐
Not Applicable ☐

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

11

12



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Cough Assessment (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Cough Assessment		QSCAT
②	QSDAT	dd MMM YYYY				QSDAT
③	QSTPT1	\$20		DAY0 = Baseline (Day 0) DAY1 = Day 1 DAY2 = Day 2 DAY3 = Day 3 DAY4 = Day 4 DAY5 = Day 5 DAY6 = Day 6 DAY30 = Day 30 DAY60 = Day 60 DAY90 = Day 90		QSTPT1
④	QSTIM	HH:nn				QSTIM
⑤	QS_COUGH 8 _ORRES			1 = Yes		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Cough Assessment (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = No -1 = Abandoned		QS_COUGH_ORRES
7 QS_COUGH 8_ORRES1					QS_COUGH_ORRES1
8 QS_COUGH 8_ORRES2			1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe -1 = Abandoned -9 = Not Applicable		QS_COUGH_ORRES2
9 QS_COUGH 8_ORRES3			1 = Rarely 2 = Sometimes 3 = Fairly often 4 = Often 5 = Almost always -1 = Abandoned -9 = Not Applicable		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Cough Assessment (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					QS_COUGH_ORRES3
QS_COUGH 8_ORRES4			0 = No sputum 1 = A moderate amount of sputum 2 = A large amount of sputum 3 = A very large amount of sputum -1 = Abandoned -9 = Not Applicable		QS_COUGH_ORRES4
QS_COUGH \$200_ORRES5					QS_COUGH_ORRES5
D_F_NAME \$40_QS					D_F_NAME_QS



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper) <Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Type MNWS ①

Type Behaviour Rating Scale Self-Report ②

Date of assessment DD/MM/YYYY Fixed Unit: DD/MM/YYYY ③

Timepoint Baseline (Day 0) ④
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 30
Day 60
Day 90

Time of assessment Fixed Unit: hour:min 24-hour clock ⑤

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper) <Unscheduled>
Generated On: 22 Sep 2014 07:54:21

-
1. Angry, irritable, frustrated ☒ 7
 2. Anxious, tense ☐
 3. Depressed Mood, sad ☐
 4. Desire or craving to smoke ☐
 5. Difficulty concentrating ☐
 6. Increased appetite, hungry, weight gain ☐
 7. Insomnia, sleep problems, awakening at night ☐
 8. Restless ☐
 9. Impatient ☐
 10. Constipation ☐
 11. Dizziness ☐
 12. Coughing ☐
 13. Dreaming or nightmares ☐
 14. Nausea ☐
 15. Sore throat ☐

Result

None ☒ 8

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		MNWS		QSCAT
②	QSSCAT	\$40		Behaviour Rating Scale Self-Report		QSSCAT
③	QSDAT	dd MMM YYYY				QSDAT
④	QSTPT2	\$20		DAY0 = Baseline (Day 0) DAY1 = Day 1 DAY2 = Day 2 DAY3 = Day 3 DAY4 = Day 4 DAY5 = Day 5 DAY6 = Day 6 DAY30 = Day 30 DAY60 = Day 60 DAY90 = Day 90		QSTPT2



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
5 QSTIM	HH:nn				QSTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑦ QSTEST_M 2 SWS			1 = 1. Angry, irritable, frustrated		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = 2. Anxious, tense		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = 3. Depressed Mood, sad		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = 4, Desire or craving to smoke		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = 5. Difficulty concentrati ng		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = 6. Increased appetite, hungry, weight gain		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = 7. Insomnia, sleep problems, awakening at night		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = 8. Restless		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = 9, Impatient		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = 10. Constipation		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = 11. Dizziness		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			12 = 12. Coughing		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
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(Paper)<Unscheduled>
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			13 = 13. Dreaming or nightmares		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = 14. Nausea		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = 15. Sore throat		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: 1. Angry, irritable, frustrated 2: 2. Anxious, tense 3: 3. Depressed Mood, sad 4: 4. Desire or craving to smoke 5: 5. Difficulty concentrating 6: 6. Increased appetite, hungry, weight gain 7: 7. Insomnia, sleep problems, awakening at night 8: 8. Restless 9: 9. Impatient 10: 10. Constipation 11: 11. Dizziness 12: 12. Coughing 13: 13. Dreaming or nightmares 14: 14. Nausea 15: 15. Sore throat	
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 QSORRES_ 1 MSWS			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS
9 D_F_NAME \$40 _QS					D_F_NAME _QS

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Type	Product Use	①
Date of completion DD/MMM/YYYY		②
Timepoint	Discharge	③
	Day 30	
	Day 60	
	Day 90	
Time of completion hh:mm		④
Date the questionnaire was completed for DD/MMM/YYYY		⑤



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Product use diary(Paper)<Unscheduled>
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What tobacco/nicotine product did you use today?

- Abandoned ☒ 6
- THS 2.2 ☐
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐



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Form: Product use diary(Paper)<Unscheduled>
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- THS 2.2, Other tobacco product and Electronic cigarette ☐
- CC, Other tobacco product and Electronic cigarette ☐
- THS 2.2, CC, Other tobacco product and Electronic cigarette ☐
- NRT, Other tobacco product and Electronic cigarette ☐
- THS 2.2, NRT, Other tobacco product and Electronic cigarette ☐
- CC, NRT, Other tobacco product and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐

How many THS 2.2 tobacco sticks did you use today? _____ ⑦

How many CC/ roll-your-own did you smoke today? _____ ⑧



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Product use diary(Paper)<Unscheduled>
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What NRT product did you used today?

- Nicotine Inhaler ☒ 9
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐



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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Product use diary(Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Product use diary(Paper)<Unscheduled>
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Nicotine Nasal Spray, ☐
Nicotine Patch and Other
NRT Product ☐
Nicotine Inhaler, Nicotine
Nasal Spray, Nicotine Patch
and Other NRT Product ☐
Nicotine Gum, Nicotine
Patch and Other NRT
Product ☐
Nicotine Inhaler, Nicotine
Gum, Nicotine Patch and
Other NRT Product ☐

How many times did you use an inhaler today? _____ 10

How many times did you use a nasal spray today? _____ 11

How many gums did you use today? _____ 12

How many lozenges did you use today? _____ 13

How many patches did you use today? _____ 14

How many times did you use other NRT products today
not listed previously? _____ 15



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Product use diary(Paper)<Unscheduled>
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What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☒ 16
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

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

17



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Product use diary(Paper)<Unscheduled>
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How many cigars/cigarillos did you smoke today? _____ 18

How many times did you smoke a pipe today? _____ 19

How many times did you use a tobacco product today
not listed previously? _____ 20

How many times did you use an electronic cigarette
today? _____ 21

_____ 22

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Product Use		QSCAT
②	EXDATE	dd MMM YYYY				EXDATE
③	QSTPT3	\$20		DISCHARGE = Discharge DAY30 = Day 30 DAY60 = Day 60 DAY90 = Day 90		QSTPT3
④	EXTIME	HH:nn				EXTIME
⑤	EXDATE_1	dd MMM YYYY				EXDATE_1
⑥	EXPROD	8		-1 = Abandoned 1 = THS 2.2 2 = CC 4 = NRT 8 = Other tobacco product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			16 = Electronic cigarette 32 = None of the above 3 = THS 2.2 and CC 5 = THS 2.2 and NRT 6 = CC and NRT 7 = THS 2.2, CC and NRT 9 = THS 2.2 and Other tobacco product 10 = CC and Other tobacco product 12 = NRT and Other tobacco product 13 = THS 2.2, NRT and Other tobacco product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = CC, NRT and Other tobacco product 15 = THS 2.2, CC, NRT and Other tobacco product 17 = THS 2.2 and Electronic cigarette 18 = CC and Electronic cigarette 20 = NRT and Electronic cigarette 21 = THS 2.2, NRT and Electronic cigarette 22 = CC, NRT and Electronic cigarette		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			23 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette 24 = Other tobacco product and Electronic cigarette 25 = THS 2.2, Other tobacco product and Electronic cigarette 26 = CC, Other tobacco product and Electronic cigarette 27 = THS 2.2, CC, Other tobacco product and Electronic cigarette 28 = NRT, Other tobacco product and Electronic cigarette		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			29 = THS 2.2, NRT, Other tobacco product and Electronic cigarette 30 = CC, NRT, Other tobacco product and Electronic cigarette 31 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette		EXPROD
7 THSNUM	8				THSNUM
8 CCNUM	8				CCNUM

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 NRTPROD	8		1 = Nicotine Inhaler 2 = Nicotine Nasal Spray 4 = Nicotine Gum 8 = Nicotine Lozenge 16 = Nicotine Patch 32 = Other NRT Product -1 = Abandoned -9 = Not Applicable 3 = Nicotine Inhaler and Nicotine Nasal Spray		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Nicotine Inhaler and Nicotine Gum		
			6 = Nicotine Nasal Spray and Nicotine Gum		
			7 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Gum		
			9 = Nicotine Inhaler and Nicotine Lozenge		
			10 = Nicotine Nasal Spray and Nicotine Lozenge		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Lozenge		
			12 = Nicotine Gum and Nicotine Lozenge		
			13 = Nicotine Inhaler, Nicotine Gum and Nicotine Lozenge		
			14 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		
			17 = Nicotine Inhaler and Nicotine Patch		
			18 = Nicotine Nasal Spray and Nicotine Patch		
			19 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			20 = Nicotine Gum and Nicotine Patch		
			21 = Nicotine Inhaler, Nicotine Gum and Nicotine Patch		
			22 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		
			23 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			24 = Nicotine Lozenge and Nicotine Patch		
			25 = Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch		
			26 = Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		
			27 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		

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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			28 = Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			29 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			30 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			31 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			33 = Nicotine Inhaler and Other NRT Product		
			34 = Nicotine Nasal Spray and Other NRT Product		
			35 = Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			36 = Nicotine Gum and Other NRT Product		
			37 = Nicotine Inhaler, Nicotine Gum and Other NRT Product		
			38 = Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		
			39 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			40 = Nicotine Lozenge and Other NRT Product		
			41 = Nicotine Inhaler, Nicotine Lozenge and Other NRT Product		
			42 = Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		
			43 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		

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**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			44 = Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			45 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			46 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			47 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			48 = Nicotine Patch and Other NRT Product		
			49 = Nicotine Inhaler, Nicotine Patch and Other NRT Product		
			50 = Nicotine Nasal Spray, Nicotine Patch and Other NRT Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			51 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Patch and Other NRT Product		
			52 = Nicotine Gum,Nicotin e Patch and Other NRT Product		
			53 = Nicotine Inhaler, Nicotine Gum,Nicotin e Patch and Other NRT Product		NRTPROD



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Form: Product use diary(Paper)<Unscheduled>
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	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10	INHFREQ	8				INHFREQ
11	NASPFREQ	8				NASPFREQ
12	GUMFREQ	8				GUMFREQ
13	LOZFREQ	8				LOZFREQ
14	PATFREQ	8				PATFREQ
15	OTHNRTRF EQ	8				OTHNRTRF EQ
16	OTHPROD	8		1 = Chewable/S mokeless Tobacco 2 = Cigars/Cigar illos 4 = Pipe 8 = Other Tobacco Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		
			-9 = Not Applicable		
			3 = Chewable/S mokeless Tobacco and Cigars/Cigar illos		
			5 = Chewable/S mokeless Tobacco and Pipe		
			6 = Cigars/Cigar illos and Pipe		
			7 = Chewable/S mokeless Tobacco, Cigars/Cigar illos and Pipe		
			9 = Chewable/S mokeless Tobacco and Other Tobacco Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = Cigars/Cigar illos and Other Tobacco Product		
			11 = Chewable/S mokeless Tobacco and Cigars/Cigar illos and Other Tobacco Product		
			12 = Pipe and Other Tobacco Product		
			13 = Chewable/S mokeless Tobacco, Pipe and Other Tobacco Product		
			14 = Cigars/Cigar illos, Pipe and Other Tobacco Product		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Product use diary(Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Chewable/S mokeless Tobacco, Cigars/Cigar illos, Pipe and Other Tobacco Product		OTHPROD
17 TOBFREQ	8				TOBFREQ
18 CIGFREQ	8				CIGFREQ
19 PIPFREQ	8				PIPFREQ
20 TOBNFREQ	8				TOBNFREQ
21 ECNUM	8				ECNUM
22 D_F_NAME_QS	\$40				D_F_NAME_QS

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Type Questionnaire on smoking urges **1**

Date of assessment **2**

DD/MM/YYYY

Timepoint Baseline (Day -1) **3**

Baseline (Day 0) ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 30 ☐

Day 60 ☐

Day 90 ☐

Time of assessment **4**

hour:min 24-hour clock

1. I have a desire for a cigarette right now Strongly disagree **5**

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

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

Strongly disagree ☒ 6

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 ☒ 7

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 ☒ 8

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

5. All I want right now is a cigarette

Strongly disagree ☐ 9

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

6. I have an urge for a cigarette

Strongly disagree ☐ 10

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

7. A cigarette would taste good now

Strongly disagree ☐ 11

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book**Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

8. I would do almost anything for a cigarette now

Strongly disagree ☐ 17

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

9. Smoking would make me less depressed

Strongly disagree ☐ 13

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

10. I am going to smoke as soon as possible

Strongly disagree ☐ 14

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

15

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Questionnaire on smoking urges		QSCAT
②	QSDAT	dd MMM YYYY				QSDAT
③	QSTPT4	\$20		BASELINE = Baseline (Day -1) DAY0 = Baseline (Day 0) DAY1 = Day 1 DAY2 = Day 2 DAY3 = Day 3 DAY4 = Day 4 DAY5 = Day 5 DAY30 = Day 30 DAY60 = Day 60 DAY90 = Day 90		QSTPT4
④	QSTIM	HH:nn				QSTIM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
5 QSORRES_ 8 1			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 1
6 QSORRES_ 8 2			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 2
⑦ QSORRES_ 8 3			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 3




PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21



Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 QSORRES_ 8 4			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 4
9 QSORRES_ 8 5			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 5
 QSORRES_ 8 6			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 6

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**


Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 QSORRES_ 8 7			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 7
 QSORRES_ 8 8			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree		

PROD 02.001 (MAIN) GMP 05AUG2014 (649)



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PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 8
 QSORRES_ 8 9			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 9

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 QSORRES_ 8 10			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 10
 D_F_NAME \$40 _QS					D_F_NAME _QS



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated on: 22 Sep 2014 07:54:21

Type Modifier Cigarette Evaluation Questionnaire ①

Date of assessment Fixed Unit: ②
DD/MMM/YYYY DD/MMM/YYYY

Timepoint Baseline (Day -1) ③
Baseline (Day 0)
Day 1
Day 2
Day 3
Day 4
Day 5
Day 30
Day 60
Day 90

Time of assessment Fixed Unit: ④
hour:min 24-hour clock



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated on 22 Sep 2014 07:54:21

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

- Was smoking satisfying? ☒ 5
- Did cigarettes taste good? ☐
- Did you enjoy the sensation in your throat and chest? ☐
- Did smoking calm you down? ☐
- Did smoking make you feel more awake? ☐
- Did smoking make you feel less irritable? ☐
- Did smoking help you concentrate? ☐
- Did smoking reduce your hunger for food? ☐
- Did smoking make you dizzy? ☐
- Did smoking make you nauseous? ☐
- Did smoking immediately relieve your craving for a cigarette? ☐
- Did you enjoy smoking? ☐

Response

- Not at all ☒ 6
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Modifier Cigarette Evaluation Questionnaire		QSCAT
②	QSDAT	dd MMM YYYY				QSDAT
③	QSTPT5	\$20		BASELINE = Baseline (Day -1) DAY0 = Baseline (Day 0) DAY1 = Day 1 DAY2 = Day 2 DAY3 = Day 3 DAY4 = Day 4 DAY5 = Day 5 DAY30 = Day 30 DAY60 = Day 60 DAY90 = Day 90		QSTPT5
④	QSTIM	HH:nn				QSTIM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
5 QSTEST	\$200		1 = Was smoking satisfying?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Did cigarettes taste good?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Did you enjoy the sensation in your throat and chest?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Did smoking calm you down?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Did smoking make you feel more awake?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Did smoking make you feel less irritable?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Did smoking help you concentrate?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = Did smoking reduce your hunger for food?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = Did smoking make you dizzy?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
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| | | | 10 = Did smoking make you nauseous? | | |



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = Did smoking immediately relieve your craving for a cigarette?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
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12 = Did
you enjoy
smoking?



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: Was smoking satisfying?	QSTEST
				2: Did cigarettes taste good?	
				3: Did you enjoy the sensation in your throat and chest?	
				4: Did smoking calm you down?	
				5: Did smoking make you feel more awake?	
				6: Did smoking make you feel less irritable?	
				7: Did smoking help you concentrate?	
				8: Did smoking reduce your hunger for food?	
				9: Did smoking make you dizzy?	
				10: Did smoking make you nauseous?	
PROD 02.001 (MAIN) GMP 05AUG2014 (649)				11: Did smoking immediately relieve your craving for a cigarette?	

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

Generated on 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑥ QSORRES	1		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		QSORRES
⑦ D_F_NAME_QS	\$40				D_F_NAME_QS



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Type FTND **1**

Date of assessment Fixed Unit: **2**
DD/MMM/YYYY DD/MMM/YYYY

Timepoint Screening **3**
Day 90

Time of assessment Fixed Unit: **4**
hour:min 24-hour clock

1. How soon after you wake up do you smoke your first cigarette? After 60 minutes **5**
31-60 minutes
6-30 minutes
Within 5 minutes
Abandoned

2. Do you find it difficult to refrain from smoking in places where it is forbidden? No **6**
Yes
Abandoned

3. Which cigarette would you hate most to give up? The first in the morning **7**
Any other
Abandoned



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

4. How many cigarettes per day do you smoke? 10 or less ☒ 8
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 ☒ 9
Yes ☐
Abandoned ☐

6. Do you smoke even if you are so ill that you are in bed most of the day? No ☒ 10
Yes ☐
Abandoned ☐

11



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		FTND		QSCAT
②	QSDAT	dd MMM YYYY				QSDAT
③	QSTPT6	\$20		SCREEN = Screening DAY90 = Day 90		QSTPT6
④	QSTIM	HH:nn				QSTIM
⑤	QS_FTND_ ORRES_1	8		0 = After 60 minutes 1 = 31-60 minutes 2 = 6-30 minutes 3 = Within 5 minutes -1 = Abandoned		QS_FTND_ ORRES_1
⑥	QS_FTND_ ORRES_2	8		0 = No 1 = Yes -1 = Abandoned		QS_FTND_ ORRES_2




PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
7 QS_FTND_ 8 ORRES_3			1 = The first in the morning 0 = Any other -1 = Abandoned		QS_FTND_ ORRES_3
8 QS_FTND_ 8 ORRES_4			0 = 10 or less 1 = 11-20 2 = 21-30 3 = 31 or more -1 = Abandoned		QS_FTND_ ORRES_4
9 QS_FTND_ 8 ORRES_5			0 = No 1 = Yes -1 = Abandoned		QS_FTND_ ORRES_5
10 QS_FTND_ 8 ORRES_6			0 = No 1 = Yes -1 = Abandoned		QS_FTND_ ORRES_6



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 D_F_NAME_QS	\$40				D_F_NAME_QS



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Urine analysis<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

Category

Clinical Chemistry ☒ ①
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☐
Urinalysis ☒
Cotinine Screening ☐
Alcohol Test ☐

Date of sample collection
DD/MM/YYYY

②

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Urine analysis<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL TEST = Alcohol Test		LBCAT
② LBDAT	dd MMM YYYY				LBDAT

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking****Post enrolment****Generated On: 22 Sep 2014 07:54:21**

Was paper questionnaire used?

No ☐ ①
Yes ☐

Reason not done

②

Type

Prochaska Stage of Change ③
Questionnaire: Intention to
Quit Smoking

Date of assessment

Fixed Unit: ④
DD/MMM/YYYY

Time of assessment

Fixed Unit: ⑤
hour:min 24-hour clock

1. Are you currently a smoker?

Yes, I currently smoke ☐ ⑥
No, I quit within the last 6 ☐
months
No, I quit more than 6 ☐
months ago
No, I have never smoked ☐2. In the last year, how many times have you quit
smoking for at least 24 hours?

⑦



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Post enrolment

Generated On: 22 Sep 2014 07:54:21

-
3. Are you seriously thinking of quitting smoking?
- Yes, within the next 30 days ☒ 8
- Yes, within the next 6 months ☐
- No, not thinking of quitting ☐
-

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking****Post enrolment****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSSTAT	\$1		N = No Y = Yes		QSSTAT
②	QSREASND	\$200				QSREASND
③	QSCAT	\$80		Prochaska Stage of Change Questionnai re: Intention to Quit Smoking		QSCAT
④	QSDAT	dd MMM yyyy				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑥	QS_PORRES\$1 _1			A = Yes, I currently smoke B = No, I quit within the last 6 months C = No, I quit more than 6 months ago		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking****Post enrolment****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			D = No, I have never smoked		QS_PORRES_1
7 QS_PORRES3_2					QS_PORRES_2
8 QS_PORRES\$1_3			A = Yes, within the next 30 days B = Yes, within the next 6 months C = No, not thinking of quitting		QS_PORRES_3

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Behavioral Risk Factor Surveillance System Questionnaire <unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Type Behavioral Risk Factor Surveillance System Questionnaire **1**

Date of assessment Fixed Unit: DD/MMM/YYYY **2**

Time of assessment Fixed Unit: hour:min 24-hour clock **3**

Have you ever smoked 100 cigarettes or more in your life? Yes **4**
No
Don't know/Not sure

Do you now smoke cigarettes every day, some days, or not at all? Every day **5**
Some days
Not at all
Don't know/Not sure

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking? Yes **6**
No
Don't know/Not sure

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Behavioral Risk Factor Surveillance System Questionnaire <unscheduled>****Generated On: 22 Sep 2014 07:54:21**

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

- Within the past month (less than 1 month ago) ☒ 7
- Within the past 3 months (1 month but less than 3 months ago) ☐
- Within the past 6 months (3 months but less than 6 months ago) ☐
- Within the past year (6 months but less than 1 year ago) ☐
- Within the past 5 years (1 year but less than 5 years ago) ☐
- Within the past 10 years (5 years but less than 10 years ago) ☐
- 10 years or more ☐
- Don't know/Not sure ☐

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

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

- Every day ☒ 8
- Some days ☐
- Not at all ☐
- Do not read. Not at all ☐


**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Behavioral Risk Factor Surveillance System Questionnaire <unscheduled>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Behavioral Risk Factor Surveillance System Questionnaire		QSCAT
②	QSDAT	dd MMM YYYY				QSDAT
③	QSTIM	HH:nn				QSTIM
④	QSORRES_ \$1 RFSS1			A = Yes B = No C = Don't know/Not sure		QSORRES_ RFSS1
⑤	QSORRES_ \$1 RFSS2			A = Every day B = Some days C = Not at all D = Don't know/Not sure		QSORRES_ RFSS2

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Behavioral Risk Factor Surveillance System Questionnaire <unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑥ QSORRES_ \$1 3			A = Yes B = No C = Don't know/Not sure		QSORRES_ 3
⑦ QSORRES_ \$2 4			A = Within the past month (less than 1 month ago) B = Within the past 3 months (1 month but less than 3 months ago) C = Within the past 6 months (3 months but less than 6 months ago) D = Within the past year (6 months but less than 1 year ago)		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Behavioral Risk Factor Surveillance System Questionnaire <unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			E = Within the past 5 years (1 year but less than 5 years ago) F = Within the past 10 years (5 years but less than 10 years ago) G = 10 years or more H = Don't know/Not sure		QSORRES_4
 QSORRES_ \$1 5			A = Every day B = Some days C = Not at all D = Do not read. Not at all		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Behavioral Risk Factor Surveillance System Questionnaire <unscheduled>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					QSORRES_ 5



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Smoking Questionnaire (SQ) <unscheduled>
Generated On: 22 Sep 2014 07:54:21

Type Smoking Questionnaire **1**

Date of assessment Fixed Unit: **2**
DD/MM/YYYY

Time of assessment Fixed Unit: **3**
hour:min 24-hour clock

1. What is your current cigarette smoking behavior
(including hand-rolled cigarettes)? Daily smoker (at least one
cigarette per day,
disregarding religious
fasting) **4**
Occasional smoker (less
than one cigarette per day) ☐
Ex-smoker of cigarettes ☐
Non-smoker of cigarettes ☐

2. Have you ever smoked 100 cigarettes or more in your
life? Yes **5**
No ☐

3. Did you ever smoke cigarettes regularly, i.e. at least 1
cigarette per day? Yes **6**
No ☐

4. If you ever smoked cigarettes regularly: At what age
did you start to smoke regularly? Fixed Unit: Years **7**

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



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Smoking Questionnaire (SQ) <unscheduled>
Generated On: 22 Sep 2014 07:54:21

Years Fixed Unit: Years **9**

Months Fixed Unit: Months **10**

Days Fixed Unit: Days **11**

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

Years Fixed Unit: Years **12**

Months Fixed Unit: Months **13**

Days Fixed Unit: Days **14**

7. What brand of cigarettes/hand-rolled tobacco did you
predominantly smoke in the last 12 months of smoking? **15**



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Smoking Questionnaire (SQ) <unscheduled>
Generated On: 22 Sep 2014 07:54:21

Time _____ Currently (last 3 months) ☒ 17
1 year ago ☐
5 years ago ☐
10 years ago ☐
15 years ago ☐
20 years ago ☐
More than 20 years ago ☐

8. On average, how many Manufactured cigarettes do/did you smoke per day? None ☒ 18
Less than 1 per day ☐

Manufactured Cigarettes per day _____ 19

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☒ 20
Less than 1 per day ☐

Hand-rolled Cigarettes per day _____ 21

8. On average, how many cigars do/did you smoke per day? None ☒ 22
Less than 1 per day ☐

Cigars per day _____ 23

8. On average, how many pipes do/did you smoke per day? None ☒ 24
Less than 1 per day ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Smoking Questionnaire (SQ) <unscheduled>
Generated On: 22 Sep 2014 07:54:21

Pipes
per day

25



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$80		Smoking Questionnaire		QSCAT
②	QSDAT	dd MMM YYYY				QSDAT
③	QSTIM	HH:nn				QSTIM
④	QS_SQORR ES_1	\$1		a = Daily smoker (at least one cigarette per day, disregarding religious fasting) b = Occasional smoker (less than one cigarette per day) c = Ex-smoker of cigarettes d = Non-smoker of cigarettes		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					QS_SQORR ES_1
5 QS_SQORR \$1 ES_2			a = Yes b = No		QS_SQORR ES_2
6 QS_SQORR \$1 ES_3			a = Yes b = No		QS_SQORR ES_3
7 QS_SQORR 2 ES_4					QS_SQORR ES_4
9 QS_SQORR 2 ES_5_YEAR					QS_SQORR ES_5_YEAR
10 QS_SQORR 2 ES_5_MON TH					QS_SQORR ES_5_MON TH
11 QS_SQORR 3 ES_5_DAY					QS_SQORR ES_5_DAY



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1f QS_SQORR 2 ES_6_YEAR					QS_SQORR ES_6_YEAR
1f QS_SQORR 2 ES_6_MON TH					QS_SQORR ES_6_MON TH
1f QS_SQORR 3 ES_6_DAY					QS_SQORR ES_6_DAY
1f QS_SQORR \$200 ES_7					QS_SQORR ES_7
1f QS_SQ_TIM \$200 E			1 = Currently (last 3 months) 2 = 1 year ago 3 = 5 years ago		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = 10 years ago 5 = 15 years ago 6 = 20 years ago 7 = More than 20 years ago	1: Currently (last 3 months) 2: 1 year ago 3: 5 years ago 4: 10 years ago 5: 15 years ago 6: 20 years ago 7: More than 20 years ago	QS_SQ_TIM E
18 QS_SQORR 1 ES_8			1 = None 2 = Less than 1 per day		QS_SQORR ES_8
19 QS_SQORR 3 ES_9					QS_SQORR ES_9



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Smoking Questionnaire (SQ)<unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
20 QS_SQORR 1 ES_10			1 = None 2 = Less than 1 per day		QS_SQORR ES_10
21 QS_SQORR 3 ES_11					QS_SQORR ES_11
22 QS_SQORR 1 ES_12			1 = None 2 = Less than 1 per day		QS_SQORR ES_12
23 QS_SQORR 3 ES_13					QS_SQORR ES_13
24 QS_SQORR 1 ES_14			1 = None 2 = Less than 1 per day		QS_SQORR ES_14
25 QS_SQORR 3 ES_15					QS_SQORR ES_15



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Supplemental Questions <Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Date of Assessment

Fixed Unit: **1**
DD/MMM/YYYY

Time of assessment

2

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

Fixed Unit: minutes **3**

Question

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

Answer

Yes **5** ☐
No ☐

Comments (open-end)

6

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions <Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSDAT	dd MMM YYYY				QSDAT
②	QSTIM	HH:nn				QSTIM
③	QS_MQORR 2 ES1					QS_MQORR ES1

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions <Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④ QS_MQTES T	\$200		2 = 2. Did the SQ capture your smoking behavior completely?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Supplemental Questions <Unscheduled>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = 3. Did the SQ capture your smoking behavior correctly?		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions <Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = 4. Did the SQ capture your smoking history completely?		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions <Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			5 = 5. Did the SQ capture your smoking history correctly?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Supplemental Questions <Unscheduled>

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = 6. Was the SQ self-explaining?		



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Supplemental Questions <Unscheduled>
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = 7. Was the SQ easy to use?	1: 2. Did the SQ capture your smoking behavior completely? 2: 3. Did the SQ capture your smoking behavior correctly? 3: 4. Did the SQ capture your smoking history completely? 4: 5. Did the SQ capture your smoking history correctly? 5: 6. Was the SQ self-explaining? 6: 7. Was the SQ easy to use?	QS_MQTES T

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Supplemental Questions <Unscheduled>****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
5 QS_MQORR \$1 ES2			a = Yes b = No		QS_MQORR ES2
6 QS_MQCOM \$200					QS_MQCOM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Gas Transfer<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

Category	With short-acting bronchodilator <input type="radio"/> ①
	Without short-acting bronchodilator <input type="radio"/>
Position	_____ ②
Date of assessment DD/MM/YY	_____ ③
Time of assessment	_____ ④
DLCO value	Fixed Unit: <input type="radio"/> ⑤ ml/min/mmHg

KCO value	Fixed Unit: <input type="radio"/> ⑥ mmol/min/kPa/L

DLCO/VA value	Fixed Unit: <input type="radio"/> ⑦ mmol/min/kPa/L

Interpretation	Normal <input type="radio"/> ⑧
	Abnormal <input type="radio"/>
If Abnormal, Clinical Significance	Not clinically significant <input type="radio"/> ⑨
	Clinically significant <input type="radio"/>



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Gas Transfer<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

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





PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Gas Transfer<Unscheduled />

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PTCAT	\$80		WITH = With short-acting bronchodila tor WITHOUT = Without short-acting bronchodila tor	1: GAS	PTCAT
②	PTPOS	\$20		SITTING	1: SITTING	PTPOS
③	PTDAT	dd MMM YYYY				PTDAT
④	PTTIM	HH:nn				PTTIM
⑤	PTORRES_D4.2 LCO					PTORRES_D LCO
⑥	PTORRES_K4.2 CO					PTORRES_K CO
⑦	PTORRES_D4.2 LCOVA					PTORRES_D LCOVA

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Gas Transfer<Unscheduled />****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	PTORRES_I NTP	\$40		NORMAL = Normal ABNORMAL = Abnormal		PTORRES_I NTP
9	PTCLSIG	\$40		NCS = Not clinically significant CS = Clinically significant		PTCLSIG
10	PTTERM	\$40				PTTERM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Lung Volume Measurements<Unscheduled />
Generated On: 22 Sep 2014 07:54:21

Category With short-acting
bronchodilator ☐ ①
Without short-acting
bronchodilator ☐

Position ②

Date of assessment
DD/MMM/YYYY ③

Time of assessment ④

VC value Fixed Unit: ⑤
L

TLC value Fixed Unit: ⑥
L

IC value Fixed Unit: ⑦
L

FRC value Fixed Unit: ⑧
L

Interpretation Normal ☐ ⑨
Abnormal ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Lung Volume Measurements<Unscheduled />
Generated On: 22 Sep 2014 07:54:21

If Abnormal, Clinical Significance

Not clinically significant ☒ 11
Clinically significant ☐

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

11



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Lung Volume Measurements<Unscheduled />
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① PTCAT	\$80		WITH = With short-acting bronchodila tor WITHOUT = Without short-acting bronchodila tor	1: LUNG	PTCAT
② PTPOS	\$20		SITTING	1: SITTING	PTPOS
③ PTDAT	dd MMM YYYY				PTDAT
④ PTTIM	HH:nn				PTTIM
⑤ PTORRES_V4.2 C					PTORRES_V C
⑥ PTORRES_T4.2 LC					PTORRES_T LC
⑦ PTORRES_I 4.2 C					PTORRES_I C



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Lung Volume Measurements<Unscheduled />
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
PTORRES_F 4.2 RC					PTORRES_F RC
PTORRES_I \$40 NTP			NORMAL = Normal ABNORMAL = Abnormal		PTORRES_I NTP
PTCLSIG \$40			NCS = Not clinically significant CS = Clinically significant		PTCLSIG
PTTERM \$40					PTTERM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Risk Markers(CCLS)****Generated On: 22 Sep 2014 07:54:21**

Transmission Type	Cumulative <input type="checkbox"/> ①
	Incremental <input type="checkbox"/>
Subject ID or Number	_____ ②
Subject Sex	_____ ③
Subject Date of Birth	_____ ④
Visit Name	_____ ⑤
Visit Type	Scheduled <input type="checkbox"/> ⑥
	Unscheduled <input type="checkbox"/>
Accession ID	_____ ⑦
Actual Collection Date	_____ ⑧
Actual Collection Time	_____ ⑨
Specimen Condition	_____ ⑩
Battery ID	_____ ⑪
Battery Name	_____ ⑫
Lab Test ID	_____ ⑬
Lab Test Name	_____ ⑭

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Risk Markers(CCLS)****Generated On: 22 Sep 2014 07:54:21**Test ID 15Test Status Done ☐ 16
Not Performed (Pending) ☐
Cancelled ☐Reported Text Result 17Reported Numeric Result 18Reference Range low 19Reference Range high 20Range Units 21Conventional Text Result 22Conventional Numeric Result 23Conventional Reference Range Low 24Conventional Reference Range High 25Conventional Units 26SI Text Result 27SI Numeric Result 28

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Risk Markers(CCLS)****Generated On: 22 Sep 2014 07:54:21**SI Reference Range Low 29SI Reference Range High 30SI Units 31

Reported Result Type

Coded ☐ 37

Numeric ☐

Text ☐

Greater Than (quantifiable limit) ☐

Less Than (quantifiable limit) ☐

Range ☐

Alert Flag

Low Panic ☐ 38

Low Telephone ☐

Low ☐

High ☐

High Telephone ☐

High Panic ☐



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Risk Markers(CCLS)

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	TRMTYP	\$1		C = Cumulative I = Incremental		TRMTYP
②	SUBJID	\$20				SUBJID
③	SEX_CCLS	\$1				SEX_CCLS
④	BRTHDTM	yyyy mm dd				BRTHDTM
⑤	VISITNUM	\$20				VISITNUM
⑥	VISITYP	\$1		S = Scheduled U = Unschedule d		VISITYP
⑦	ACCSNNUM	\$20				ACCSNNUM
⑧	LBDT	yyyy mm dd				LBDT
⑨	LBTM	HH:nn				LBTM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Risk Markers(CCLS)

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10	SPECCND	\$200				SPECCND
11	BATTRID	\$20				BATTRID
12	BATTRNAM	\$40				BATTRNAM
13	LABTESTCD	\$20				LABTESTCD
14	LBTEST	\$100				LBTEST
15	TSTCD	\$20				TSTCD
16	TSTSTAT	\$1		D = Done N = Not Performed (Pending) X = Cancelled		TSTSTAT
17	RPTRESC	\$200				RPTRESC
18	RPTRESN	20.3				RPTRESN
19	RPTNRLO	\$40				RPTNRLO
20	RPTNRHI	\$20				RPTNRHI




PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Risk Markers(CCLS)

Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
21	RPTU	\$20				RPTU
22	CNVRESC	\$200				CNVRESC
23	CNVRESN	20.3				CNVRESN
24	CNVNRLO	\$40				CNVNRLO
25	CNVNRHI	\$40				CNVNRHI
26	CNVU	\$20				CNVU
27	SIRESC	\$200				SIRESC
28	SIRESN	20.3				SIRESN
29	SINRLO	\$40				SINRLO
30	SINRHI	\$40				SINRHI
31	SIU	\$20				SIU
32	RPTRTYP	\$1		C = Coded N = Numeric		

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Risk Markers(CCLS)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			T = Text G = Greater Than (quantifiable limit) L = Less Than (quantifiable limit) R = Range		RPTRTYP
 ALRTFL	\$2		LP = Low Panic LT = Low Telephone L = Low H = High HT = High Telephone HP = High Panic		ALRTFL



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (CEMA, HPMA, HBMA)
Generated On: 22 Sep 2014 07:54:21

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (CEMA, HPMA, HBMA)
Generated On: 22 Sep 2014 07:54:21

Urine End Day








PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (CEMA, HPMA, HBMA)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (CEMA, HPMA, HBMA)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PCTPMNUM	\$10				PCTPMNUM
 PCTPSNUM	\$20				PCTPSNUM
 PCTPENUM	\$20				PCTPENUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (NNN, NNAL)****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (NNN, NNAL)

Generated On: 22 Sep 2014 07:54:21

Urine End Day








PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (NNN, NNAL)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (NNN, NNAL)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PCTPMNUM	\$10				PCTPMNUM
 PCTPSNUM	\$20				PCTPSNUM
 PCTPENUM	\$20				PCTPENUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (HEMA)****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (HEMA)

Generated On: 22 Sep 2014 07:54:21

Urine End Day








PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (HEMA)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (HEMA)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PCTPMNUM	\$10				PCTPMNUM
 PCTPSNUM	\$20				PCTPSNUM
 PCTPENUM	\$20				PCTPENUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

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

Generated On: 22 Sep 2014 07:54:21

Urine End Day








PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PCTPMNUM	\$10				PCTPMNUM
 PCTPSNUM	\$20				PCTPSNUM
 PCTPENUM	\$20				PCTPENUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (3-OH BaP)****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (3-OH BaP)

Generated On: 22 Sep 2014 07:54:21

Urine End Day








PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (3-OH BaP)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (3-OH BaP)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PCTPMNUM	\$10				PCTPMNUM
 PCTPSNUM	\$20				PCTPSNUM
 PCTPENUM	\$20				PCTPENUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Plasma (Caffeine, Paraxanthine)
Generated On: 22 Sep 2014 07:54:21

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Plasma (Caffeine, Paraxanthine)
Generated On: 22 Sep 2014 07:54:21

Urine End Day








PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Plasma (Caffeine, Paraxanthine)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Plasma (Caffeine, Paraxanthine)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PCTPMNUM	\$10				PCTPMNUM
 PCTPSNUM	\$20				PCTPSNUM
 PCTPENUM	\$20				PCTPENUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)
Generated On: 22 Sep 2014 07:54:21

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)
Generated On: 22 Sep 2014 07:54:21

Urine End Day








PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)
Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PCTPMNUM	\$10				PCTPMNUM
 PCTPSNUM	\$20				PCTPSNUM
 PCTPENUM	\$20				PCTPENUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (11-dTXb2)****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (11-dTXb2)

Generated On: 22 Sep 2014 07:54:21

Urine End Day





PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (11-dTXb2)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (11-dTXb2)

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1c PCTPMNUM	\$10				PCTPMNUM
1e PCTPSNUM	\$20				PCTPSNUM
1f PCTPENUM	\$20				PCTPENUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (iPF2a-III)****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (iPF2a-III)

Generated On: 22 Sep 2014 07:54:21

Urine End Day





PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (iPF2a-III)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (iPF2a-III)

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1c PCTPMNUM	\$10				PCTPMNUM
1e PCTPSNUM	\$20				PCTPSNUM
1f PCTPENUM	\$20				PCTPENUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (Ames)****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (Ames)

Generated On: 22 Sep 2014 07:54:21

Urine End Day








PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (Ames)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (Ames)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PCTPMNUM	\$10				PCTPMNUM
 PCTPSNUM	\$20				PCTPSNUM
 PCTPENUM	\$20				PCTPENUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (1-OHP)****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (1-OHP)

Generated On: 22 Sep 2014 07:54:21

Urine End Day





PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (1-OHP)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (1-OHP)****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1c	PCTPMNUM	\$10				PCTPMNUM
1e	PCTPSNUM	\$20				PCTPSNUM
1f	PCTPENUM	\$20				PCTPENUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (SPMA, SBMA)****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (SPMA, SBMA)

Generated On: 22 Sep 2014 07:54:21

Urine End Day





PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (SPMA, SBMA)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (SPMA, SBMA)

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1c PCTPMNUM	\$10				PCTPMNUM
1e PCTPSNUM	\$20				PCTPSNUM
1f PCTPENUM	\$20				PCTPENUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (MHBMA)****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (MHBMA)

Generated On: 22 Sep 2014 07:54:21

Urine End Day





PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (MHBMA)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (MHBMA)

Generated On: 22 Sep 2014 07:54:21

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1c PCTPMNUM	\$10				PCTPMNUM
1e PCTPSNUM	\$20				PCTPSNUM
1f PCTPENUM	\$20				PCTPENUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (Creatinine)****Generated On: 22 Sep 2014 07:54:21**

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book

Form: Biomarker-Urine (Creatinine)

Generated On: 22 Sep 2014 07:54:21

Urine End Day








PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Urine (Creatinine)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Urine (Creatinine)****Generated On: 22 Sep 2014 07:54:21**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PCTPMNUM	\$10				PCTPMNUM
 PCTPSNUM	\$20				PCTPSNUM
 PCTPENUM	\$20				PCTPENUM



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Plasma (Nic, Cot, tHCot)
Generated On: 22 Sep 2014 07:54:21

Sample Barcode	_____	①
Analyte	_____	②
Sample type	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Lower limit of quantification	_____	⑨
Planned time point (Hour)	_____	⑩
Day of Visit	_____	⑪
Celerion Study Number	_____	⑫
Date of Collection	_____	⑬
Timepoint-minutes	_____	⑭
Urine Start Day	_____	⑮



PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Plasma (Nic, Cot, tHCot)
Generated On: 22 Sep 2014 07:54:21

Urine End Day





PROD 02.001 (MAIN) GMP 05AUG2014: Case Book
Form: Biomarker-Plasma (Nic, Cot, tHCot)
Generated On: 22 Sep 2014 07:54:21

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCREFID	\$40				PCREFID
②	PCTEST	\$40				PCTEST
③	PCSPEC	\$40				PCSPEC
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCLOQ	\$20				PCLOQ
⑩	PCTPTNUM	\$20				PCTPTNUM
⑪	PCVSTNUM	\$10				PCVSTNUM
⑫	STUDYNM	\$40				STUDYNM
⑬	PCACTNUM	\$20				PCACTNUM

**PROD 02.001 (MAIN) GMP 05AUG2014: Case Book****Form: Biomarker-Plasma (Nic, Cot, tHCot)****Generated On: 22 Sep 2014 07:54:21**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
12	PCTPMNUM	\$10				PCTPMNUM
15	PCTPSNUM	\$20				PCTPSNUM
16	PCTPENUM	\$20				PCTPENUM



16.1.2.2 SUBJECT QUESTIONNAIRE ENGLISH

16.1.2.2.1 QUESTIONNAIRE ON SMOKING URGES

Questionnaire on smoking urges (QSU)

Date and time of assessment (24-hour clock)

/ /

:

hour min

☐ Tick if same as visit date

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

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

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

APPROVED BY
JUL 02 2013
MLIRB
Methods Independent Review Board



Questionnaire on smoking urges (QSU)						
4. I could control things better right now if I could smoke						
Strongly disagree						Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. All I want right now is a cigarette						
Strongly disagree						Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I have an urge for a cigarette						
Strongly disagree						Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. A cigarette would taste good now						
Strongly disagree						Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I would do almost anything for a cigarette now						
Strongly disagree						Strongly agree
<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)						
9. Smoking would make me less depressed						
Strongly disagree						Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I am going to smoke as soon as possible						
Strongly disagree						Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



16.1.2.2.2 MODIFIED CIGARETTE EVALUATION QUESTIONNAIRE

**Modifier Cigarette Evaluation Questionnaire (mCEQ)**

Date and time of assessment (24-hour clock) / / ☐ Tick if same as visit date
D D M M M Y Y Y Y

:
hour min

If you have smoked since you last completed this questionnaire, please mark 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?							
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"/>	
6. Did smoking make you feel less irritable?							
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"/>	
7. Did smoking help you concentrate?							
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"/>	
8. Did smoking reduce your hunger for food?							
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"/>	
9. Did smoking make you dizzy?							
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"/>	
10. Did smoking make you nauseous?							
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						
11. Did smoking immediately relieve your craving for a cigarette?						
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"/>
12. Did you enjoy smoking?						
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"/>



16.1.2.2.3 COUGH ASSESSMENT – VISUAL ANALOGUE SCALE



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

How much sputum do you produce when coughing?

0 = no sputum - 1 = a moderate amount of sputum - 2 = a larger 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 your coughing? (open question)

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JUL 02 2013
MLRB
Astellas Independent Review Board



16.1.2.2.4 FAGERSTRÖM-NICOTINE-DEPENDENCE TEST

**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 prohibited?
 - ◆ No (0)
 - ◆ Yes (1)
3. Which cigarette would you most hate to give up?
 - ◆ The first one in the morning (1)
 - ◆ Any other one (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 waking up than during the rest of the day?
 - ◆ No (0)
 - ◆ Yes (1)
6. Do you smoke even if you are so sick 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

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JUL 02 2013
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Medizinisches Versorgungszentrum



Fagerstrom Test for Nicotine Dependence (cont.)

Your score was: _____

Your level of dependence on nicotine is:

0-2 Very low dependence

6-7 High dependence

3-4 Low dependence

8-10 Very high dependence

5 Medium 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."



16.1.2.2.5 MINNESOTA NICOTINE WITHDRAWAL SCALE

**Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)****Behavior Rating Scale Self-Report**

Date and time of assessment (24-hour clock) / / ☐ Tick if same as visit date
D D M M M Y Y Y Y

:
hour min

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

	None	Slight	Mild	Moderate	Severe
1. Angry, irritable, frustrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Anxious, nervous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Depressed Mood, sad	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Desire or craving to smoke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Difficulty concentrating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Increased appetite, hungry, weight gain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Insomnia, sleep problems, awakening at night	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Restless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Impatient	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Constipation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Dizziness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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JUL 02 2013

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MAINTAINING SUBSTANCE DEPENDENCY



Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)					
Behavior Rating Scale Self-Report					
12. Coughing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Dreaming or nightmares	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Nausea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Sore throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heart Rate	_____				bpm
Weight	_____				Kg



16.1.2.2.6 HST QUESTIONNAIRE



Human Smoking Topography Questionnaire Protocol: ZRHM-REXA-08-US

Subject No.: Visit: ☐ Day 0 ☐ Day 4 ☐ Day 30 ☐ Day 60 ☐ Day 90Date filled out
(D D M M M Y Y Y Y)Time filled out (in 24-hour format)
(H H : M M)

To what extent do you agree with the following sentences/statements:

1. The smoking of conventional products/cigarettes is different with this device.

- ☐
- Totally agree
-
- ☐
- Agree
-
- ☐
- Neither agree nor disagree
-
- ☐
- Disagree
-
- ☐
- Totally disagree

If you agree or totally agree, explain:

2. You enjoy smoking with the device just as much as without it.

- ☐
- Totally agree
-
- ☐
- Agree
-
- ☐
- Neither agree nor disagree
-
- ☐
- Disagree
-
- ☐
- Totally disagree

If you disagree or totally disagree, explain:



Human Smoking Topography Questionnaire Protocol: ZRHM-REXA-08-US

Subject No.: Visit: ☐ Day 0 ☐ Day 4 ☐ Day 30 ☐ Day 60 ☐ Day 90Date filled out
(D D M M M Y Y Y Y)Time filled out (in 24-hour format)
(H H : M M)

3. The taste of conventional products/cigarettes is different with this device.

- ☐ Totally agree
☐ Agree
☐ Neither agree nor disagree
☐ Disagree
☐ Totally disagree

If you agree or totally agree, explain:

4. The device is easy to use.

- ☐ Totally agree
☐ Agree
☐ Neither agree nor disagree
☐ Disagree
☐ Totally disagree

If you disagree or totally disagree, explain:

5. The device changes the way you smoke.

- ☐ Totally agree
☐ Agree
☐ Neither agree nor disagree
☐ Disagree
☐ Totally disagree

If you agree or totally agree, explain:



16.1.2.2.7 SOCIO-ECONOMIC STATUS



SES Questionnaire

Protocol: ZRHM-REXA-08-US

Subject #: Visit: ☐ Day 4Date Completed
(D D M M M Y Y Y Y)Time Completed (24 hour clock)
(H H : M M)

Q1. What is the highest level of education you have completed?	
1 <input type="checkbox"/>	Less than High School
2 <input type="checkbox"/>	High School Graduate
3 <input type="checkbox"/>	Some College
4 <input type="checkbox"/>	College Graduate
5 <input type="checkbox"/>	Advanced Degree
Q2. What is your current occupational status?	
1 <input type="checkbox"/>	Working now
2 <input type="checkbox"/>	Only temporarily laid off, sick leave or maternity leave
3 <input type="checkbox"/>	Looking for work, unemployed
4 <input type="checkbox"/>	Retired
5 <input type="checkbox"/>	Disabled, permanently or temporarily
6 <input type="checkbox"/>	Keeping house
7 <input type="checkbox"/>	Student
8 <input type="checkbox"/>	Other (SPECIFY):
Q3. How many people are currently living in your household, including yourself?	
<input type="text"/> <input type="text"/>	
Q4. Of these people, how many are children?	
<input type="text"/> <input type="text"/>	
Q5. Of these people, how many are adults?	
<input type="text"/> <input type="text"/>	
Q6. Of the adults, how many bring income into the household?	
<input type="text"/> <input type="text"/>	

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NOV 26 2013



SES Questionnaire

Protocol: ZRHM-REXA-08-US

Subject #: Visit: ☐ Day 4Date Completed
(D D M M M Y Y Y Y)Time Completed (24 hour clock)
(H H : M M)

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

- | | | |
|----|--------------------------|-----------------------------|
| 1 | <input type="checkbox"/> | Less than \$10,000 |
| 2 | <input type="checkbox"/> | \$10,000 to \$29,999 |
| 3 | <input type="checkbox"/> | \$30,000 through \$44,999 |
| 4 | <input type="checkbox"/> | \$45,000 through \$59,999 |
| 5 | <input type="checkbox"/> | \$60,000 through \$74,999 |
| 6 | <input type="checkbox"/> | \$75,000 through \$99,999 |
| 7 | <input type="checkbox"/> | \$100,000 through \$149,999 |
| 8 | <input type="checkbox"/> | \$150,000 and over |
| 9 | <input type="checkbox"/> | I do not know |
| 10 | <input type="checkbox"/> | No response |



16.1.2.2.8 CURRENT AND PAST SMOKING BEHAVIOUR

Smoking questionnaire (SQ)

Protocol: ZRHM-REXA-08-US

Subject #:

Visit: ☐ Day -1 ☐ Day 5

[illegible]

Time Completed (24 hour clock)
(H H : M M)

Self-administrated to be answered by subjects

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?

A Daily smoker (at least one cigarette per day, disregarding religious fasting)..... ☐

B Occasional smoker (less than one cigarette per day)..... ☐

C Ex-smoker of cigarettes..... ☐

D Non-smoker of cigarettes..... ☐

2. Have you ever smoked 100 cigarettes or more in your life?

A Yes..... ☐

B No..... ☐

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?

A Yes..... ☐

B No..... ☐

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

_____ years

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

_____ years plus _____ months plus _____ days

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

_____ years plus _____ months plus _____ days

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MLIRB
Missouri Legislative Review Board



Smoking questionnaire (SQ)

Protocol: ZRHM-REXA-08-US

Subject #: Visit: ☐ Day -1 ☐ Day 5Date Completed
(D D M M M Y Y Y Y)Time Completed (24 hour clock)
(H H : M M)

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

Name of brand: _____

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

		Manufactured Cigarettes	Hand-rolled Cigarettes	Cigars	Pipes
A	Currently (last 3 months)	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day
B	1 year ago	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day
C	5 years ago	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day
D	10 years ago	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day
E	15 years ago	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day
F	20 years ago	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day
G	More than 20 years ago	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day	<input type="checkbox"/> none <input type="checkbox"/> less than 1 per day <input type="text"/> per day



Smoking questionnaire (SQ)

Protocol: ZRHM-REXA-08-US

Subject #: Visit: ☐ Day -1 ☐ Day 5Date Completed
(D D M M M Y Y Y Y)Time Completed (24 hour clock)
(H H : M M)

Age and sex of the respondent are required for a comprehensive assessment, but are not contained in the questionnaire. It is assumed that this information is obtained separately.



16.1.2.2.9 META-SMOKING QUESTIONNAIRE COMPARATOR



Meta-questionnaire (to be answered after SQ)

Protocol: ZRHM-REXA-08-US

Subject #: Visit: ☐ Day -1 ☐ Day 5Date Completed
(D D M M M Y Y Y Y)Time Completed (24 hour clock)
(H H : M M)

Question 1 to be answered by Investigator

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

 minutes

Questions 2-8 are self-administrated to be answered by subjects

2. Did the SQ capture your smoking behavior completely?

A Yes ☐B No ☐

3. Did the SQ capture your smoking behavior correctly?

A Yes ☐B No ☐

4. Did the SQ capture your smoking history completely?

A Yes ☐B No ☐

5. Did the SQ capture your smoking history correctly?

A Yes ☐B No ☐

6. Was the SQ self-explaining?

A Yes ☐B No ☐APPROVED BY
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MLIRE
Medical Information Research & Development



Meta-questionnaire (to be answered after SQ)

Protocol: ZRHM-REXA-08-US

Subject #: Visit: ☐ Day -1 ☐ Day 5Date Completed
(D D M M M Y Y Y Y)Time Completed (24 hour clock)
(H H : M M)

7. Was the SQ easy to use?

- A Yes ☐
- B No ☐

8. Comments (open-end)



16.1.2.2.10 PROCHASKA 'STAGE OF CHANGE' QUESTIONNAIRE



Prochaska 'Stage of Change' Questionnaire

Protocol: ZRHM-REXA-08-US

Subject #: Visit: ☐ Screening ☐ Day -2 ☐ Day 30 ☐ Day 60 ☐ Day 90Date Completed
(D D M M M Y Y Y Y)Time Completed (24 hour clock)
(H H : M M)Assessment

1. Are you currently a smoker?

- A) Yes, I currently smoke
- B) No, I quit within the last 6 months
- C) No, I quit more than 6 months ago
- D) No, I have never smoked

Smokers only

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

3. Are you seriously thinking of quitting smoking?

- A) Yes, within the next 30 days
- B) Yes, within the next 6 months
- C) No, not thinking of quitting

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NOV 26 2013
MLIRE
Mitsubishi Pharmaceutical Indus. Corp.



16.1.2.2.11 BEHAVIOURAL RISK FACTOR SURVEILLANCE SYSTEM
QUESTIONNAIRE



2011 Behavioral Risk Factor Surveillance System Questionnaire Protocol: ZRHM-REXA-08-US

Subject No.: Visit: ☐ Day -1 ☐ Day 5Date filled out
(D D M M M Y Y Y Y)Time filled out (in 24-hour format)
(H H : M M)

Section 7: Tobacco use

Self-administered for subjects to fill out

1. Have you ever smoked 100 cigarettes or more in your life? NOTE: 5 packs = 100 cigarettes
A Yes..... <input type="checkbox"/>
B No [go to question 5]..... <input type="checkbox"/>
C Don't know/am not sure [go to question 5]..... <input type="checkbox"/>
2. Do you currently smoke cigarettes every day, some days, or never?
A Every day..... <input type="checkbox"/>
B Some days..... <input type="checkbox"/>
B Never [go to question 4]..... <input type="checkbox"/>
C Don't know/am not sure [go to question 5]..... <input type="checkbox"/>
3. During the past 12 months, did you quit smoking for a day or more because you were trying to kick the habit?
A Yes..... <input type="checkbox"/>
B No [go to question 5]..... <input type="checkbox"/>
C Don't know/am not sure [go to question 5]..... <input type="checkbox"/>
4. How long has it been since you smoked a cigarette for the last time, including one or two puffs?
A In the past month (less than 1 month ago)..... <input type="checkbox"/>
B In the past 3 months (more than 1 month, but less than 1 months ago)..... <input type="checkbox"/>
C In the past 6 months (more than 3 months, but less than 6 months ago)..... <input type="checkbox"/>
D In the past year (more than 6 months, but less than 1 year ago)..... <input type="checkbox"/>
E In the past 5 years (more than 1 year, but less than 5 years ago)..... <input type="checkbox"/>
F In the past 10 years (more than 5 years, but less than 10 years ago)..... <input type="checkbox"/>



2011 Behavioral Risk Factor Surveillance System Questionnaire Protocol: ZRHM-REXA-08-US

Subject No.: Visit: ☐ Day -1 ☐ Day 5Date filled out
(D D M M M Y Y Y Y)Time filled out (in 24-hour format)
(H H : M M)

Section 7: Tobacco use

Self-administered for subjects to fill out

G	10 years ago or more	<input type="checkbox"/>
H	Don't know/am not sure [go to question 5].....	<input type="checkbox"/>
5. Do you currently use chewing tobacco, snuff or snus every day, some days, or never?		
NOTE: <i>Snus</i> (snuff in Swedish) is a moist smokeless tobacco usually sold in small bags that are placed between the lips and gums.		
A	Every day.....	<input type="checkbox"/>
B	Some days.....	<input type="checkbox"/>
C	Never	<input type="checkbox"/>
Don't read.		
D	Never	<input type="checkbox"/>



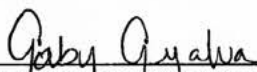
16.1.2.3 SUBJECT QUESTIONNAIRE LOCAL LANGUAGE

16.1.2.3.1 QUESTIONNAIRE ON SMOKING URGES

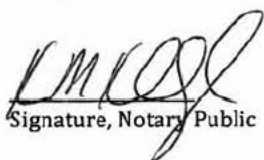


City of New York, State of New York, County of New York

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 United States (Spanish) following Covance's process of concept definition, Dual Forward Translation, Reconciliation, Back Translation, Resolution, Covance cognitive interviewing with 6 adult smokers, final proofreading, and formatting.


Gaby Grijalva, Project Coordinator

Sworn to before me this
Friday, May 24, 2013


Signature, Notary Public



Stamp, Notary Public



Cuestionario sobre la urgencia de fumar (Questionnaire on smoking urges, QSU)							
Fecha y hora de la evaluación (sistema horario de 24 horas)		_ _ / _ _ / _ _ D D M M M M A A A A		<input type="checkbox"/> Marque aquí si es la misma fecha de la visita			
		_ _ : _ _ hora min					
1. Deseo fumar un cigarrillo ahora mismo							
Completa- mente en desacuerdo						Completa- mente de acuerdo	
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Nada sería mejor que fumar un cigarrillo ahora mismo							
Completa- mente en desacuerdo						Completa- mente de acuerdo	
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Si fuera posible, probablemente fumaría ahora							
Completa- mente en desacuerdo						Completa- mente de acuerdo	
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

APPROVED BY
JUL 02 2013
MLRB



Cuestionario sobre la urgencia de fumar (Questionnaire on smoking urges, QSU)							
4. Podría controlar mejor las cosas ahora mismo si pudiera fumar							
Completa- mente en desacuerdo							Completa- mente de acuerdo
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Lo único que quiero ahora mismo es un cigarrillo							
Completa- mente en desacuerdo							Completa- mente de acuerdo
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Tengo la urgencia de fumar un cigarrillo							
Completa- mente en desacuerdo							Completa- mente de acuerdo
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Un cigarrillo sabría bien ahora							
Completa- mente en desacuerdo							Completa- mente de acuerdo
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Haría casi cualquier cosa por un cigarrillo ahora							
Completa- mente en desacuerdo							Completa- mente de acuerdo
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Cuestionario sobre la urgencia de fumar (Questionnaire on smoking urges, QSU)							
9. Fumar me haría sentir menos deprimido							
Completa- mente en desacuerdo							Completa- mente de acuerdo
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Voy a fumar tan pronto como sea posible							
Completa- mente en desacuerdo							Completa- mente de acuerdo
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



16.1.2.3.2 MODIFIED CIGARETTE EVALUATION QUESTIONNAIRE

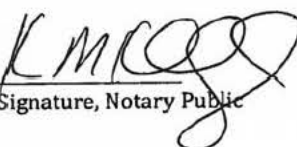


City of New York, State of New York, County of New York

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 United States (Spanish) following Covance's process of concept definition, Dual Forward Translation, Reconciliation, Back Translation, Resolution, Covance cognitive interviewing with 6 adult smokers, final proofreading, and formatting.


Gaby Grijalva, Project Coordinator

Sworn to before me this
Friday, May 24, 2013


Signature, Notary Public



Stamp, Notary Public



Cuestionario modificado de evaluación del cigarrillo (Modified Cigarette Evaluation Questionnaire, mCEQ)						
Fecha y hora de la evaluación (sistema horario de 24 horas)						<input type="checkbox"/> Marque aquí si es la misma fecha de la visita
D D / M M M / A A A A						
hora : min						
Si ha fumado desde que completó por última vez este cuestionario, seleccione la opción que mejor represente cómo se sintió al fumar						
1. ¿Fue placentero fumar?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ¿Los cigarrillos tenían buen sabor?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. ¿Disfrutó la sensación en la garganta y el pecho?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. ¿Fumar le calmó?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Cuestionario modificado de evaluación del cigarrillo						
5. ¿Fumar le hizo sentir más despierto?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. ¿Fumar le hizo sentir menos irritable?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. ¿Fumar le ayudó a concentrarse?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. ¿Fumar redujo su apetito?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. ¿Fumar le hizo sentirse mareado?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. ¿Fumar le hizo sentir náuseas?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Cuestionario modificado de evaluación del cigarrillo						
11. ¿Fumar alivió de inmediato su antojo de un cigarrillo?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. ¿Disfrutó fumar?						
No, para nada	Muy poco	Poco	Moderadamente	Mucho	Muchísimo	Extremadamente
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

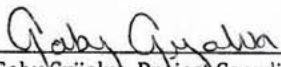


16.1.2.3.3 COUGH ASSESSMENT – VISUAL ANALOGUE SCALE

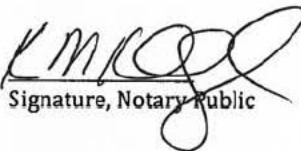


City of New York, State of New York, County of New York

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 United States (Spanish) following Covance's process of concept definition, Dual Forward Translation, Reconciliation, Back Translation, Resolution, Covance cognitive interviewing with 6 adult smokers, final proofreading, and formatting.


Gaby Grijalva, Project Coordinator

Sworn to before me this
Friday, May 24, 2013


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Evaluación de la tos

¿Ha experimentado una necesidad frecuente de toser, por ejemplo, ha tosido varias veces en las últimas 24 horas?

SÍ/NO

Si la respuesta es SÍ, responda las siguientes preguntas:

Primera pregunta: Escala de impacto de la tos

¿Cuánto le molesta su tos?

EVA: No me molesta en absoluto ----- Me resulta extremadamente molesto

Segunda pregunta: Escala de intensidad de la tos:

¿Qué tan intensa es su tos?

1 = muy leve 2 = leve 3 = moderada 4 = grave 5 = muy grave

Tercera pregunta: Escala de frecuencia de la tos:

¿Con qué frecuencia normalmente tiene que toser cada día?

1 = rara vez 2 = algunas veces 3 = con bastante frecuencia 4 = con frecuencia 5 = casi siempre

Cuarta pregunta: Producción de flema

¿Cuánta flema produce al toser?

0 = nada de flema 1 = una cantidad moderada de flema 2 = una cantidad grande de flema
3 = una cantidad muy grande de flema

Quinta pregunta:

¿Hay otras observaciones importantes que quisiera compartir con nosotros sobre su tos? (pregunta abierta)

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JUL 02 2013
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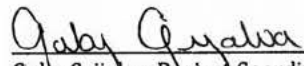


16.1.2.3.4 FAGERSTRÖM-NICOTINE-DEPENDENCE-TEST




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 "Fagerstrom-Nicotine-Dependence-Test" from English into United States (Spanish) following Covance's process of concept definition, Dual Forward Translation, Reconciliation, Back Translation, Resolution, Covance cognitive interviewing with 6 adult smokers, final proofreading, and formatting.


Gaby Grijalva, Project Coordinator

Sworn to before me this
Friday, May 24, 2013


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**Test de Dependencia a la Nicotina de Fagerstrom***

¿Fumar es "solo un hábito" o es usted adicto a esto? Haga esta prueba y conozca su nivel de dependencia a la nicotina.

1. ¿Qué tan pronto después de despertarse fuma su primer cigarrillo?
 - ◆ Después de 60 minutos (0)
 - ◆ 31-60 minutos (1)
 - ◆ 6-30 minutos (2)
 - ◆ Dentro de los 5 minutos (3)
2. ¿Le resulta difícil no fumar en lugares donde está prohibido hacerlo?
 - ◆ No (0)
 - ◆ Sí (1)
3. ¿Qué cigarrillo odiaría más dejar?
 - ◆ El primero de la mañana (1)
 - ◆ Cualquier otro (0)
4. ¿Cuántos cigarrillos fuma por día?
 - ◆ 10 o menos (0)
 - ◆ 11-20 (1)
 - ◆ 21-30 (2)
 - ◆ 31 o más (3)
5. ¿Fuma con mayor frecuencia durante las primeras horas después de despertarse que durante el resto del día?
 - ◆ No (0)
 - ◆ Sí (1)
6. ¿Fuma incluso cuando está tan enfermo que pasa la mayor parte del día en cama?
 - ◆ No (0)
 - ◆ Sí (1)

APPROVED BY
JUL 02 2013
MLIRB
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* Heatherton TF, Kozłowski 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

**Test de Dependencia a la Nicotina de Fagerstrom (cont.)**

Su puntaje fue: _____

Su nivel de dependencia a la nicotina es:

0-2 Dependencia muy baja	6-7 Dependencia alta
3-4 Dependencia baja	8-10 Dependencia muy alta
5 Dependencia media	

Puntajes de menos de 5: "Su nivel de dependencia a la nicotina todavía es bajo. Debe actuar ahora, antes de que su nivel de dependencia aumente".

Puntaje de 5: "Su nivel de dependencia a la nicotina es moderado. Si no deja pronto de fumar, su nivel de dependencia a la nicotina aumentará hasta convertirse posiblemente en una adicción grave. Actúe ahora para poner fin a su dependencia a la nicotina".

Puntaje de más de 7: "Su nivel de dependencia es alto. Usted no controla el hábito de fumar, ¡el hábito de fumar lo controla a usted! Cuando tome la decisión de dejar de fumar, es conveniente que hable con su médico sobre la terapia de reemplazo de nicotina u otros medicamentos que le ayuden a poner fin a su adicción".

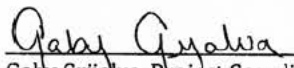


16.1.2.3.5 MINNESOTA NICOTINE WITHDRAWAL SCALE




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 "MNWS ENG SELF" from English into United States (Spanish) following Covance's process of concept definition, Dual Forward Translation, Reconciliation, Back Translation, Resolution, Covance cognitive interviewing with 6 adult smokers, final proofreading, and formatting.


Gaby Grijalva, Project Coordinator

Sworn to before me this
Friday, May 24, 2013


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Escala Minnesota de Dependencia/Abstinencia a la Nicotina (Minnesota Nicotine Dependence/Withdrawal Scale, MNWS)					
Autoinforme de la escala de calificación del comportamiento					
Fecha y hora de la evaluación (sistema horario de 24 horas)		<input type="text"/> / <input type="text"/> / <input type="text"/>		<input type="checkbox"/> Marque aquí si es la misma fecha de la visita	
		<input type="text"/> : <input type="text"/>			
		hora		min	
Indique para cada uno de los puntos a continuación cómo se ha sentido durante las últimas 24 horas.					
	Nada	Apenas	Leve-mente	Modera-damente	Intensa-mente
1. Enojado, irritable, frustrado	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Ansioso, nervioso	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Deprimido, triste	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Deseo o antojo de fumar	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Dificultad para concentrarse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Aumento del apetito, hambriento, aumento de peso	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Insomnio, problemas para dormir, se despierta de noche	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Intranquilo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Impaciente	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Estreñimiento	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

APPROVED BY

JUL 02 2013

MLRB
Medical Literature Review Board



Escala Minnesota de Dependencia/Abstinencia a la Nicotina (Minnesota Nicotine Dependence/Withdrawal Scale, MNWS)					
Autoinforme de la escala de calificación del comportamiento					
11. Mareos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Tos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Sueños o pesadillas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Náuseas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Dolor de garganta	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Frecuencia cardíaca	_____			ppm (pulsaciones por minuto)	
Peso	_____			kg	



16.1.2.3.6 HST QUESTIONNAIRE



I, Crystal Sotelo of Global Language Solutions, hereby certify that the foregoing document, to the best of our knowledge and belief, is a true, complete and accurate Spanish (US) language translation of the attached English language document,

Protocol No.: ZRHM-REXA-08-US

Source document:
HST questionnaire_19Nov2013

This document was translated by two or more professionals with adequate experience and qualifications in the medical field to properly interpret and translate such documents.

IRVINE, CALIFORNIA
December 13, 2013

Crystal Sotelo
Senior Project Manager
GLOBAL LANGUAGE SOLUTIONS



Cuestionario sobre topografía de fumar de los seres humanos

Protocolo: ZRHM-REXA-08-US

N.º de sujeto: Visita ☐ Día 0 ☐ Día 4 ☐ Día 30 ☐ Día 60 ☐ Día 90Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)

En qué medida está de acuerdo con las siguientes oraciones/afirmaciones:

1. El humo de los productos/cigarrillos convencionales es diferente con este dispositivo.
- ☐ Totalmente de acuerdo
 - ☐ De acuerdo
 - ☐ Ni de acuerdo ni en desacuerdo
 - ☐ En desacuerdo
 - ☐ Totalmente en desacuerdo

Si está de acuerdo o totalmente de acuerdo, explíquelo:

2. Disfruta fumar con el dispositivo tanto como sin él.
- ☐ Totalmente de acuerdo
 - ☐ De acuerdo
 - ☐ Ni de acuerdo ni en desacuerdo
 - ☐ En desacuerdo
 - ☐ Totalmente en desacuerdo

Si no está de acuerdo o está totalmente en desacuerdo, explíquelo:



Cuestionario sobre topografía de fumar de los seres humanos

Protocolo: ZRHM-REXA-08-US

N.º de sujeto: Visita ☐ Día 0 ☐ Día 4 ☐ Día 30 ☐ Día 60 ☐ Día 90Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)

3. El sabor de los productos/cigarrillos convencionales es diferente con este dispositivo.

- ☐ Totalmente de acuerdo
- ☐ De acuerdo
- ☐ Ni de acuerdo ni en desacuerdo
- ☐ En desacuerdo
- ☐ Totalmente en desacuerdo

Si está de acuerdo o totalmente de acuerdo, explíquelo:

4. El dispositivo es fácil de usar.

- ☐ Totalmente de acuerdo
- ☐ De acuerdo
- ☐ Ni de acuerdo ni en desacuerdo
- ☐ En desacuerdo
- ☐ Totalmente en desacuerdo

Si no está de acuerdo o está totalmente en desacuerdo, explíquelo:

5. El dispositivo altera su manera de fumar.

- ☐ Totalmente de acuerdo
- ☐ De acuerdo
- ☐ Ni de acuerdo ni en desacuerdo
- ☐ En desacuerdo
- ☐ Totalmente en desacuerdo

Si está de acuerdo o totalmente de acuerdo, explíquelo:



16.1.2.3.7 SOCIO-ECONOMIC STATUS



I, Crystal Sotelo of Global Language Solutions, hereby certify that the foregoing document, to the best of our knowledge and belief, is a true, complete and accurate Spanish (US) language translation of the attached English language document,

Protocol No.: ZRHM-REXA-08-US

Source document:

SES questionnaire_US_19Nov2013

This document was translated by two or more professionals with adequate experience and qualifications in the medical field to properly interpret and translate such documents.

IRVINE, CALIFORNIA
December 13, 2013

Crystal Sotelo
Senior Project Manager
GLOBAL LANGUAGE SOLUTIONS



Cuestionario sobre el nivel socioeconómico (socioeconomic status, SES) Protocolo: ZRHM-REXA-08-US

Nº de Sujeto: Visita: ☐ Día 4Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)

P1. ¿Cuál es el nivel de educación más alto que ha terminado?	
1 <input type="checkbox"/>	Menos de educación secundaria
2 <input type="checkbox"/>	Graduado de escuela secundaria
3 <input type="checkbox"/>	Algo de universidad
4 <input type="checkbox"/>	Graduado universitario
5 <input type="checkbox"/>	Maestría o doctorado
P2. ¿Cuál es su estado ocupacional actual?	
1 <input type="checkbox"/>	Actualmente tengo trabajo
2 <input type="checkbox"/>	Desempleado temporalmente, licencia por enfermedad o licencia por maternidad
3 <input type="checkbox"/>	Estoy buscando trabajo, desempleado
4 <input type="checkbox"/>	Retirado
5 <input type="checkbox"/>	Discapacitado, permanente o temporalmente
6 <input type="checkbox"/>	Tareas domésticas
7 <input type="checkbox"/>	Estudiante
8 <input type="checkbox"/>	Otro (ESPECIFICAR):
P3. ¿Cuántas personas viven actualmente en su casa, incluido usted?	
<input type="text"/> <input type="text"/>	
P4. De estas personas, ¿cuántas son niños?	
<input type="text"/> <input type="text"/>	
P5. De estas personas, ¿cuántas son adultos?	
<input type="text"/> <input type="text"/>	
P6. De los adultos, ¿cuántos generan ingresos para el hogar?	
<input type="text"/> <input type="text"/>	

Cuestionario sobre el nivel socioeconómico (*socioeconomic status, SES*) Protocolo: ZRHM-REXA-08-USNº de Sujeto: Visita: ☐ Día 4Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)

P7. ¿Cuál de las siguientes categorías describe mejor su ingreso familiar total combinado correspondiente a los últimos 12 meses? Esto debe incluir ingresos (sin deducir impuestos) provenientes de todas las fuentes, salarios, alquiler de propiedades, seguro social, beneficios por discapacidad y/o para veteranos, beneficios por desempleo, compensación laboral, ayuda de familiares (incluidas pensiones alimentarias y ayuda para hijos), etc.

- | | | |
|----|--------------------------|------------------------------|
| 1 | <input type="checkbox"/> | Menos de \$10 000 |
| 2 | <input type="checkbox"/> | Entre \$10 000 y \$29 999 |
| 3 | <input type="checkbox"/> | De \$30 000 hasta \$44 999 |
| 4 | <input type="checkbox"/> | De \$45 000 hasta \$59 999 |
| 5 | <input type="checkbox"/> | De \$60 000 hasta \$74 999 |
| 6 | <input type="checkbox"/> | De \$75 000 hasta \$99 999 |
| 7 | <input type="checkbox"/> | De \$100 000 hasta \$149 999 |
| 8 | <input type="checkbox"/> | \$150 000 o más |
| 9 | <input type="checkbox"/> | No sé |
| 10 | <input type="checkbox"/> | No responde |



16.1.2.3.8 CURRENT AND PAST SMOKING BEHAVIOUR



I, Crystal Sotelo of Global Language Solutions, hereby certify that the foregoing document, to the best of our knowledge and belief, is a true, complete and accurate Spanish (US) language translation of the attached English language document,

Protocol No.: ZRHM-REXA-08-US

Source document:

Smoking questionnaire_19Nov2013

This document was translated by two or more professionals with adequate experience and qualifications in the medical field to properly interpret and translate such documents.

IRVINE, CALIFORNIA
December 13, 2013

Crystal Sotelo
Senior Project Manager
GLOBAL LANGUAGE SOLUTIONS

**Cuestionario sobre el hábito de fumar (SQ)****Protocolo: ZRHM-REXA-08-US**Nº de Sujeto: Visita: ☐ Día -1 ☐ Día 5Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)*Autoadministrado para que lo respondan los sujetos*

1. ¿Cuál es su conducta actual relacionada con el hábito de fumar cigarrillos (incluidos los cigarrillos hechos a mano)?
A Fumador diario (al menos un cigarrillo por día, sin tener en cuenta el ayuno religioso)..... <input type="checkbox"/>
B Fumador ocasional (menos de un cigarrillo por día) <input type="checkbox"/>
C Ex fumador de cigarrillos <input type="checkbox"/>
D No fuma cigarrillos <input type="checkbox"/>
2. ¿Alguna vez ha fumado 100 cigarrillos o más en su vida?
A Sí..... <input type="checkbox"/>
B No <input type="checkbox"/>
3. ¿Alguna vez ha fumado cigarrillos con regularidad; es decir, al menos 1 cigarrillo por día?
A Sí..... <input type="checkbox"/>
B No <input type="checkbox"/>
4. Si alguna vez ha fumado cigarrillos con regularidad: ¿A qué edad comenzó a hacerlo?
<input type="text"/> <input type="text"/> años
5. Si es un ex fumador de cigarrillos: ¿Hace cuánto que dejó de fumar?
<input type="text"/> <input type="text"/> años más <input type="text"/> <input type="text"/> meses más <input type="text"/> <input type="text"/> días
6. Si alguna vez dejó de fumar cigarrillos con regularidad: ¿Por cuánto tiempo dejó de fumar completamente? (Sume todos los períodos separados en los que dejó de fumar).
<input type="text"/> <input type="text"/> años más <input type="text"/> <input type="text"/> meses más <input type="text"/> <input type="text"/> días



Cuestionario sobre el hábito de fumar (SQ)

Protocolo: ZRHM-REXA-08-US

Nº de Sujeto: Visita: ☐ Día -1 ☐ Día 5Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)

7. ¿Qué marca de cigarrillos/tabaco hecho a mano fumó predominantemente en los últimos 12 meses?

Nombre de la marca: _____

8. ¿En promedio, cuántos cigarrillos, puros o pipas fuma o fumaba por día?

		Cigarrillos fabricados	Cigarrillos hechos a mano	Puros	Pipas
A	Actualmente (últimos 3 meses)	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día
B	Hace 1 año	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día
C	Hace 5 años	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día
D	Hace 10 años	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día
E	Hace 15 años	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día
F	Hace 20 años	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día
G	Hace más de 20 años	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día	<input type="checkbox"/> ninguno <input type="checkbox"/> menos de 1 por día <input type="text"/> por día

**Cuestionario sobre el hábito de fumar (SQ)****Protocolo: ZRHM-REXA-08-US**Nº de Sujeto: Visita: ☐ Día -1 ☐ Día 5Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)

Se requiere la edad y el sexo de la persona que responde el cuestionario para realizar una evaluación exhaustiva; no obstante, esta información no se incluye en el cuestionario. Se supone que se obtiene por separado.



16.1.2.3.9 META-SMOKING QUESTIONNAIRE COMPARATOR



I, Crystal Sotelo of Global Language Solutions, hereby certify that the foregoing document, to the best of our knowledge and belief, is a true, complete and accurate Spanish (US) language translation of the attached English language document,

Protocol No.: ZRHM-REXA-08-US

Source document:

smoking questionnaire comparator_19Nov2013

This document was translated by two or more professionals with adequate experience and qualifications in the medical field to properly interpret and translate such documents.

IRVINE, CALIFORNIA
December 13, 2013

Crystal Sotelo
Senior Project Manager
GLOBAL LANGUAGE SOLUTIONS

**Metacuestionario (para responder después del Cuestionario sobre el hábito de fumar)****Protocolo: ZRHM-REXA-08-US**N° de Sujeto: Visita: ☐ Día -1 ☐ Día 5Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)*Pregunta 1 para que responda el investigador*

1. ¿Cuánto tiempo le llevó al sujeto responder el Cuestionario sobre el hábito de fumar (*Smoking Questionnaire, SQ*)?

 minutos*Las preguntas 2 a 8 son autoadministradas para que las respondan los sujetos*

2. ¿Consiguió el SQ captar plenamente su conducta relacionada con el hábito de fumar?

A Sí..... ☐B No ☐

3. ¿Consiguió el SQ captar correctamente su conducta relacionada con el hábito de fumar?

A Sí..... ☐B No ☐

4. ¿Consiguió el SQ captar plenamente sus antecedentes de tabaquismo?

A Sí..... ☐B No ☐

5. ¿Consiguió el SQ captar correctamente sus antecedentes de tabaquismo?

A Sí..... ☐B No ☐

**Metacuestionario (para responder después del Cuestionario sobre el hábito de fumar)****Protocolo: ZRHM-REXA-08-US**N° de Sujeto: Visita: ☐ Día -1 ☐ Día 5Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)

6. ¿Fue el SQ autoexplicativo?

A Sí..... ☐B No ☐

7. ¿Fue el SQ fácil de usar?

A Sí..... ☐B No ☐

8. Comentarios (sin plazo definido)



16.1.2.3.10 PROCHASKA 'STAGE OF CHANGE' QUESTIONNAIRE



I, Crystal Sotelo of Global Language Solutions, hereby certify that the foregoing document, to the best of our knowledge and belief, is a true, complete and accurate Spanish (US) language translation of the attached English language document,

Protocol No.: ZRHM-REXA-08-US

Source document:

Prochaska stage of change questionnaire_19Nov2013

This document was translated by two or more professionals with adequate experience and qualifications in the medical field to properly interpret and translate such documents.

IRVINE, CALIFORNIA
December 12, 2013

Crystal Sotelo
Senior Project Manager
GLOBAL LANGUAGE SOLUTIONS

**Cuestionario de Prochaska “Etapa de cambio” Protocolo: ZRHM-REXA-08-US**Nº de Sujeto: Visita: ☐ Selección ☐ Día -2 ☐ Día 30 ☐ Día 60 ☐ Día 90Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)Evaluación

1. ¿Es actualmente un fumador?

- Sí, actualmente fumo
- B) No, dejé de fumar en los últimos 6 meses
- C) No, dejé de fumar hace más de 6 meses
- D) No, nunca fumé

Solamente para fumadores

2. ¿Cuántas veces dejó de fumar durante al menos 24 horas en el último año? ____

3. ¿Está pensando seriamente dejar de fumar?

- A) Sí, dentro de los próximos 30 días
- B) Sí, dentro de los próximos 6 meses
- C) No, no pienso dejar de fumar



16.1.2.3.11 BEHAVIOURAL RISK FACTOR SURVEILLANCE SYSTEM
QUESTIONNAIRE



I, Crystal Sotelo of Global Language Solutions, hereby certify that the foregoing document, to the best of our knowledge and belief, is a true, complete and accurate Spanish (US) language translation of the attached English language document,

Protocol No.: ZRHM-REXA-08-US

Source document:

Behavioral Risk Factor Surveillance System Questionnaire 2011_19Nov2013

This document was translated by two or more professionals with adequate experience and qualifications in the medical field to properly interpret and translate such documents.

IRVINE, CALIFORNIA
December 13, 2013

Crystal Sotelo
Senior Project Manager
GLOBAL LANGUAGE SOLUTIONS



Cuestionario de vigilancia de factores de riesgo conductuales 2011 Protocolo: ZRHM-REXA-08-US

N.º de sujeto: Visita: ☐ Día -1 ☐ Día 5Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)

Sección 7: Uso de tabaco

Autoadministrado para que lo llenen los sujetos

1. ¿Alguna vez ha fumado 100 cigarrillos o más en su vida? NOTA: 5 paquetes = 100 cigarrillos
A Sí..... <input type="checkbox"/>
B No [vaya a la pregunta 5] <input type="checkbox"/>
C No sé/no estoy seguro [vaya a la pregunta 5] <input type="checkbox"/>
2. ¿Fuma actualmente cigarrillos todos los días, algunos días o nunca?
A Todos los días..... <input type="checkbox"/>
B Algunos días..... <input type="checkbox"/>
C Nunca [vaya a la pregunta 4]..... <input type="checkbox"/>
D No sé/no estoy seguro [vaya a la pregunta 5] <input type="checkbox"/>
3. Durante los últimos 12 meses, ¿dejó de fumar durante un día o más porque estaba intentando dejar el hábito?
A Sí..... <input type="checkbox"/>
B No [vaya a la pregunta 5] <input type="checkbox"/>
C No sé/no estoy seguro [vaya a la pregunta 5] <input type="checkbox"/>
4. ¿Cuánto hace que fumó un cigarrillo por última vez, incluso una o dos bocanadas?
A En el último mes (hace menos de 1 mes atrás)..... <input type="checkbox"/>
B En los últimos 3 meses (hace más de 1 mes pero menos de 3 meses atrás) <input type="checkbox"/>
C En los últimos 6 meses (hace más de 3 meses pero menos de 6 meses atrás) <input type="checkbox"/>
D En el último año (hace más de 6 meses pero menos de 1 año atrás)..... <input type="checkbox"/>
E En los últimos 5 años (hace más de 1 año pero menos de 5 años atrás)..... <input type="checkbox"/>
F En los últimos 10 años (hace más de 5 años pero menos de 10 años atrás)..... <input type="checkbox"/>



Cuestionario de vigilancia de factores de riesgo conductuales 2011 Protocolo: ZRHM-REXA-08-US

N.º de sujeto: Visita: ☐ Día -1 ☐ Día 5Fecha en que se llenó
(D D M M M A A A A)Hora en que se llenó (en formato de 24 horas)
(H H : M M)

Sección 7: Uso de tabaco

Autoadministrado para que lo llenen los sujetos

G	Hace 10 años o más	<input type="checkbox"/>
H	No sé/no estoy seguro [vaya a la pregunta 5]	<input type="checkbox"/>
5. ¿Usa actualmente tabaco para mascar, rapé o <i>smus</i> todos los días, algunos días o nunca?		
NOTA: el <i>smus</i> (rapé en sueco) es un tabaco sin humo húmedo que generalmente se vende en bolsas pequeñas que se colocan entre el labio y la encía.		
A	Todos los días	<input type="checkbox"/>
B	Algunos días	<input type="checkbox"/>
C	Nunca	<input type="checkbox"/>
No leo.		
D	Nunca	<input type="checkbox"/>



16.1.2.4 SUBJECT SMOKING DIARY ENGLISH



What tobacco/nicotine product
did you use today?

☐ THS 2.2

How many THS 2.2 tobacco sticks did
you use today?

☐ CC

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

☐ NRT

What NRT product did you used
today?

☐ nicotine
inhaler

how many times did you use an inhaler
today

☐ nicotine nasal
spray

how many times did you use a nasal spray
today

☐ nicotine gum

how many gums did you use today

☐ nicotine lozenge

how many lozenges did you use today

☐ nicotine patch

how many patches did you use today

☐ other NRT product

how many times did you use other NRT
products today not listed previously



- | | |
|---|---|
| <input type="checkbox"/> Other tobacco product | What other tobacco product did you smoked today? |
| <input type="checkbox"/> chewable/smokeless tobacco | how many times did you use chewable/smokeless tobacco today |
| <input type="checkbox"/> cigars/cigarillos | how many cigars/cigarillos did you smoke today |
| <input type="checkbox"/> pipe | how many time did you smoke a pipe today |
| <input type="checkbox"/> other tobacco product | how many time did you use a tobacco product today not listed previously |
| <input type="checkbox"/> electronic cigaretie | How many times did you use an electronic cigarette today ? |
| <input type="checkbox"/> None of the above | |



16.1.2.5 SUBJECT SMOKING DIARY LOCAL LANGUAGE



PM2953 DiaryPRO ZRHM-REXA-08-US, YVDR-REXA-13-US
PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

(b) (4) Diary Translation Acceptance Document

Study Code: PM2953

Language: esUS (Spanish, United States)

Document File Name: PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

Document ID: 8BDBABAC4DDA2DE3FF0E5566D7D44748

Instructions

On the following pages, compare the base language (English) screen on the left to the translated language screen on the right. Ensure that the translated screen is an accurate representation of the information on the English screen, then indicate whether or not you approve the translation.

1A. Review the English screen.

1B. Review the translated screen.

2. Is the translation correct? Highlight either **Yes** or **No**.

Approval: YES NO
SHARED TRANSLATOR NAME:
SHARED T17: 5

For each screen pair (usually one per page):

- Compare the English and translated screens. **Review the translated screen** to verify that it is correct, including:
 - Clear, accurate translation
→ When reviewing DTA version 1, **note only critical errors**. Stylistic changes and rewriting are not appropriate.
 - Correct translated text placement
 - Appropriate formatting of translated text (line breaks, boldface, italics, etc.)
- On the Approval line (under the screen pictures), **indicate whether or not you approve the screen** translation:
 - For **correct** translation and formatting: Highlight **Yes**.
 - For translation or formatting **errors**: Highlight **No**.
→ When reviewing DTA version 2 or higher, please confirm that the corrections to DTA version 1 (or the previous version) were implemented correctly; if correct, highlight **Yes** to approve the screens. No changes to previously approved text will be considered.

Additional Guidance for Reviewing Screens

- To accommodate longer translated text, the formatting on the translated screen may differ from the English screen. This is acceptable.
- Screens may appear in the document in a different order than they appear in the software.

After you review all the screens, follow the instructions on the last page of this document.




PM2953 DiaryPRO ZRHM-REXA-08-US, YVDR-REXA-13-US
PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS


Version 1


1.

English	Spanish
<p>What tobacco / nicotine product did you use today?</p> <p><input type="checkbox"/> THS 2.2</p> <p><input type="checkbox"/> Conventional Cigarette</p> <p><input type="checkbox"/> NRT</p> <p><input type="checkbox"/> Other Tobacco Product</p> <p><input type="checkbox"/> Electronic Cigarette</p> <p><input type="checkbox"/> None of the above</p>	<p>¿Qué producto de tabaco/nicotina usó hoy?</p> <p><input type="checkbox"/> THS 2.2</p> <p><input type="checkbox"/> Cigarrillo convencional</p> <p><input type="checkbox"/> Terapia de reemplazo de nicotina (Nicotine Replacement Therapy, NRT)</p> <p><input type="checkbox"/> Otro producto de tabaco</p> <p><input type="checkbox"/> Cigarrillo electrónico</p> <p><input type="checkbox"/> Ninguno de los anteriores</p>




9:57
?





9:57
?



Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 1, 2, 3, 4, 5, 6, 7









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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

2.

<p>How many THS 2.2 tobacco sticks did you use today?</p> <p> <input type="text"/></p>	<p>¿Cuántos palillos de tabaco THS 2.2 usó hoy?</p> <p> <input type="text"/></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 8









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DTA Translations esUS

Version 1

3.

<p>How many conventional cigarettes / roll-your-own cigarettes did you smoke today?</p> <p></p>	<p>¿Cuántos cigarrillos convencionales/hechos por usted fumó hoy?</p> <p></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 9



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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

4.

What NRT product did you use today?	¿Qué producto de NRT usó hoy?
<input type="checkbox"/> Nicotine Inhaler	<input type="checkbox"/> Inhalador de nicotina
<input type="checkbox"/> Nicotine Nasal Spray	<input type="checkbox"/> Aerosol nasal de nicotina
<input type="checkbox"/> Nicotine Gum	<input type="checkbox"/> Goma de mascar de nicotina
<input type="checkbox"/> Nicotine Lozenge	<input type="checkbox"/> Pastilla de nicotina
<input type="checkbox"/> Nicotine Patch	<input type="checkbox"/> Parche de nicotina
<input type="checkbox"/> Other NRT Product	<input type="checkbox"/> Otro producto de NRT



9:57
?



9:57
?

Do you approve the screen? (Highlight one.)
Script Translator Line: 10, 11, 12, 13, 14, 15, 16

YES NO









PM2953 DiaryPRO ZRHM-REXA-08-US, YVDR-REXA-13-US
PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

5.

<p>How many times did you use an inhaler today?</p> <p></p>	<p>¿Cuántas veces usó un inhalador hoy?</p> <p></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)
Script Translator Line: 17

YES NO









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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

6.

<p>How many times did you use a nasal spray today?</p> <p></p>	<p>¿Cuántas veces usó un aerosol nasal hoy?</p> <p></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 18









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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

7.

<p>How many pieces of gum did you chew today?</p> <p> <input type="text"/></p>	<p>¿Cuántas unidades de goma de mascar usó hoy?</p> <p> <input type="text"/></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 19









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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

8.

<p>How many lozenges did you use today?</p> <p> <input type="text"/></p>	<p>¿Cuántas pastillas usó hoy?</p> <p> <input type="text"/></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 20









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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

9.

<p>How many patches did you use today?</p> <p> <input type="text"/></p>	<p>¿Cuántos parches usó hoy?</p> <p> <input type="text"/></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 21









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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

10.

<p>How many times did you use other NRT products today not listed previously?</p> <p></p>	<p>¿Cuántas veces usó otros productos de NRT no mencionados anteriormente hoy?</p> <p></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 22



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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

11.

<p>What other tobacco product did you use today?</p> <p><input type="checkbox"/> Chewable / Smokeless Tobacco</p> <p><input type="checkbox"/> Cigars / Cigarillos</p> <p><input type="checkbox"/> Pipe</p> <p><input type="checkbox"/> Other Tobacco Product</p>	<p>¿Qué otro producto de tabaco usó hoy?</p> <p><input type="checkbox"/> Tabaco masticable/sin humo</p> <p><input type="checkbox"/> Puros</p> <p><input type="checkbox"/> Pipa</p> <p><input type="checkbox"/> Otro producto de tabaco</p>
--	--

Navigation bar with arrows and a timer showing 9:57.

Do you approve the screen? (Highlight one.)
Script Translator Line: 23, 24, 25, 26, 27

YES NO









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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

12.

<p>How many times did you use chewable / smokeless tobacco today?</p> <p></p>	<p>¿Cuántas veces usó tabaco masticable/sin humo hoy?</p> <p></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 28



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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

13.

<p>How many cigars / cigarillos did you smoke today?</p> <p> <input type="text"/></p>	<p>¿Cuántos puros fumó hoy?</p> <p> <input type="text"/></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 29









PM2953 DiaryPRO ZRHM-REXA-08-US, YVDR-REXA-13-US
PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

14.

<p>How many times did you smoke a pipe today?</p> <p></p>	<p>¿Cuántas veces fumó una pipa hoy?</p> <p></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 30









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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

15.

<p>How many times did you use a tobacco product today not listed previously?</p> <p></p>	<p>¿Cuántas veces usó un producto de tabaco no mencionado anteriormente hoy?</p> <p></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 31









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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

16.

<p>How many times did you use an electronic cigarette today?</p> <p></p>	<p>¿Cuántas veces usó un cigarrillo electrónico hoy?</p> <p></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)

YES

NO

Script Translator Line: 32



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DTA Translations esUS

Version 1

DTA Review Summary

Now that you have reviewed and approved or rejected each screen in the DTA, please work through the steps below to complete the DTA review process.

Review Results

Were all the screen translations approved? Please highlight one: **Yes** **No**

→ If Yes

1. **Save a copy** of the reviewed DTA for your records.
2. **Email a copy** of the reviewed DTA to your translation company project coordinator.

Reviewer Name (printed): _____

Reviewer Signature: _____

Review Completion Date (dd MON yyyy): _____

→ If No

1. In the table below, **list each screen that was not approved** (where you marked **No** on the approval line), enter the incorrect text or problem (such as a formatting error), then enter the correction.

Screen Number	Incorrect Text or Formatting	Correct Text or Formatting	Translation Vendor – Agree or Disagree*
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A

*Please use the "Translation Vendor – Agree or Disagree" column only for verifying Secondary Reviewer revisions.

2. If you are a Linguist, please **email** a copy of the reviewed DTA to your translation company project coordinator and they will return the reviewed DTA to (b) (4)

OR

If you are a Secondary Reviewer, such as an (b) (4) or assessment author, please **email** a copy of the reviewed DTA to (b) (4)



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PM2953_DiaryPRO_DTA_ProductUse_esUS_v1.doc

DTA Translations esUS

Version 1

DTA Revision History

Name	Modifications	Date	Version
Matthew Carulli	Initial DTA Creation	21-Jun-2013	1