

CRF Report for Study E8230249

Report run by Tamara Fisher at 14-AUG-2014 18:17:17

Report Parameters

Site: CDB_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: 2060

Ending patient: 2060

Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	Abc 123

All time stamps displayed in this report are in the timezone of the database server.

The data contained in this report is current at the time of printing (time as shown above)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Investigator:

FARMER

Information Correct?

☒ Yes ☐ No

REMOTE DATA CAPTURE CASE REPORT FORM

SWITCHING FROM USUAL BRAND CIGARETTES TO CAMEL "SNUS," CAMEL
DISSOLVABLE TOBACCO "STICKS," "STRIPS," OR "ORBS," DUAL USE OF USUAL
BRAND CIGARETTES AND SNUS, OR TOBACCO ABSTINENCE -
A MULTI-CENTER EVALUATION OF SELECT MODERN SMOKE-FREE TOBACCO PRODUCTS

Protocol No. CSD0901

Covance Study No. 8230249

for

R.J. Reynolds Tobacco Company
Bowman Gray Technical Center
950 Reynolds Boulevard
Winston-Salem, North Carolina 27105

by

Covance Clinical Pharmacology Inc.
3402 Kinsman Boulevard
Madison, Wisconsin 53704

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Page Version No. PAGE_01 (v1, 18-OCT-2010)

Document Number R346963513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

☐

Inclusion Criteria

Subjects who meet the following criteria may be included in the study. Did the subject meet the following criteria requirements for inclusion? (Check Yes or No)

		Yes	No*
01	Between 21 and 65 years of age, inclusive.	YES	
02	Self-reported daily use \geq 10 cigarettes/day for \geq 12 months.	YES	
03	Screening Fagerström dependence score of "low" or greater (ie, 3 to 10).	YES	
04	Screening urinary cotinine \geq 200 ng/mL (via NicCheck I Test Strips with a positive result).	YES	
05	Screening expired-air CO level \geq 15 ppm (sample taken 30-60 minutes after smoking a single UB cigarette).	YES	
06	No intent to quit smoking during the trial period.	YES	
07	Willing to either switch cigarette use to any one of the MSFT test products, or completely abstain from smoking or using any tobacco products, for a period of 5 consecutive days + the next morning.	YES	
08	After confinement, able to adhere to a controlled diet for the duration of the trial, that prohibits drinking "full-bodied" beer and eating grilled, charbroiled, smoked or smoke-flavored foods, almond nuts, and kale.	YES	
09	In the opinion of the Investigators, participants will be free of clinically significant health problems.	YES	
10	Negative tests for selected drugs of abuse at Screening and on Day -2.	YES	
11	Negative hepatitis panel (including HBsAg and anti-HCV) and negative HIV antibody screens (for participants who self-report they have been immunized against hepatitis B, a positive test result is not exclusionary).	YES	

*If No, document on Subject Eligibility Page.

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Page Version No. PAGE_02 (v1, 18-OCT-2010)

Document Number R350258813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

☐

Inclusion Criteria

Subjects who meet the following criteria may be included in the study. Did the subject meet the following criteria requirements for inclusion? (Check Yes or No)

Yes No*

1.2

Females will be non-pregnant (for all females, the urine pregnancy test results must be negative at Screening; and for all females of child-bearing potential, the pregnancy test results must be negative at Day -2), non lactating, and either postmenopausal (as verified by follicle stimulating hormone [FSH] levels) for at least 1 year, surgically sterile (tubal ligation, hysterectomy, etc.) for at least 90 days, or agree to use from the time of signing the informed consent until 30 days after Day 6 (or Trial Completion) a form of contraception considered acceptable to the Investigators: a non-hormonal IUD with spermicide; female condom with spermicide; contraceptive sponge with spermicide; diaphragm with spermicide; cervical cap with spermicide; an intravaginal system (eg, NuvaRing); oral, implantable, transdermal, or injectable contraceptives; a male sexual partner who agrees to use a male condom with spermicide; or a sterile sexual partner.

NAM

1.3

Able to read, understand and complete informed consent documents and questionnaires in English.

YES

*If No, document on Subject Eligibility Page.

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Page Version No. PAGE_03 (v1, 15-OCT-2010)

Document Number

R350258913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

☐

Exclusion Criteria

The following will exclude potential subjects from the study. Does the subject have any of the following?
(Check Yes or No)

	Yes*	No
01 Use of any type of smokeless tobacco or non-tobacco nicotine-containing product(s), or smoked marijuana-based materials within 30 days prior to trial start.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
02 Have any unacceptable 'safety' clinical evaluations.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
03 Use of injectable forms of medication (except birth control).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
04 Any self-reported or clinical indication(s) of acute or chronic health or psychiatric disorders that, in the Investigator(s)' opinion, would place participants in an unacceptable risk, or limit the participants ability to participate in and/or complete this clinical trial.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
05 Intent to become pregnant during trial period, or current pregnancy or breast feeding.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
06 History of hypersensitivity or allergies to any drug compound unless approved by the Investigator(s).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
07 Poor peripheral venous access.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
08 Donation of blood from 30 days prior to Screening through Day 6 (or Trial Completion), inclusive; or of plasma from 2 weeks prior to Screening through Day 6 (or Trial Completion), inclusive.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
09 Participant is an employee of Covance or RJRT.	<input type="checkbox"/>	<input checked="" type="checkbox"/>

*If Yes, document on Subject Eligibility Page.

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Page Version No. PAGE_04 (v1, 18-OCT-2010)

Document Number R350259013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Subject Eligibility

Date the Subject Signed the Informed Consent Form: 15-NOV-2010
DD/MMM/YYYY

Did the subject meet all of the inclusion/exclusion criteria? ☒ Yes ☐ No

If the subject did not meet all of the Inclusion/Exclusion criteria, provide criterion number and explanation below.

Category	Inclusion/ Exclusion No.	Explanation	Exemption Granted?	If Yes, Date Granted DD/MMM/YYYY
<input type="checkbox"/> Inclusion <input type="checkbox"/> Exclusion			<input type="checkbox"/> Yes <input type="checkbox"/> No	
<input type="checkbox"/> Inclusion <input type="checkbox"/> Exclusion			<input type="checkbox"/> Yes <input type="checkbox"/> No	
<input type="checkbox"/> Inclusion <input type="checkbox"/> Exclusion			<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Page Version No. PAGE_05 (v1, 15-OCT-2010)

Document Number R350259113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Tobacco Abstinence Question

Was Tobacco Abstinence Question asked? ☒ Yes ☐ No

Date

DD/MMM/YYYY

15-NOV-2010

Willing to be tobacco abstinent for a 5-day period?

☒ Yes ☐ No

Fagerström (FTND) Questionnaire

Was FTND Questionnaire administered? ☒ Yes ☐ No

Date

DD/MMM/YYYY

15-NOV-2010

Score

3

Comments

Urine Cotinine Screen

Date

DD/MMM/YYYY

15-NOV-2010

Actual Time
24-hour clock

12:41

NicCheck I
Results

☒ Positive
☐ Negative

Not Done

☐

Comments

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Page Version No. PAGE_06 (v1, 18-OCT-2010)

Document Number R350259213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

MSFT Taste Test

Was MSFT Taste Test administered? ☒ Yes ☐ No

Date

DD/MMM/YYYY

15-NOV-2010

Product

Is taste of product acceptable? (Note: only one 'Yes' for SNUS is required)

SNUS Frost

☒ Yes ☐ No

SNUS Mellow

☒ Yes ☐ No

Preferred SNUS Type

☐ Frost ☒ Mellow ☐ None

Sticks

☒ Yes ☐ No

Strips

☒ Yes ☐ No

Orbs

☒ Yes ☐ No

Demographics

Date

DD/MMM/YYYY

15-NOV-2010

Date of Birth

DD/MMM/YYYY

(b) (6)

Gender

☒ Male

☐ Female

Ethnicity

☐ Hispanic or Latino

☒ Not Hispanic or Latino

Race

☒ White

☐ Black or African American

☐ Asian

☐ Native Hawaiian or Other Pacific Islander

☐ American Indian/Alaskan Native

☐ Other:

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☒ Approved

☒ Locked

☒ Frozen

☒

Page Version No. PAGE_07 (v1, 15-OCT-2010)

Document Number

R350259313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

15-NOV-2010

Actual Time
24-hour clock

14:28

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

119

Diastolic Blood Pressure

mmHg

078

Pulse

beats/minute

059

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

036.6

Body Measurements

Were Body Measurements Collected? ☒ Yes ☐ No

Date

DD/MMM/YYYY

15-NOV-2010

Parameter

Unit

Result

Height

cm

171.0

Weight

kg

065.1

BMI

kg/m²

22.3

Note: Body Mass Index will be derived.

Verified



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Page Version No. PAGE_08 (v1, 15-OCT-2010)

Document Number

R350259413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Laboratory Evaluations

Were the scheduled laboratory samples obtained?

☒ Yes ☐ No (Specify samples not done, reason):

Date

DD/MMM/YYYY

15-NOV-2010

Evaluations: Chem-19 and HgbA1c (fasted at least 8 hours), CBC, and Urinalysis; FSH & Estradiol (women only); Hepatitis Panel & HIV Screen

Requisition Number 1:

G805846

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Requisition Number 4 (if applicable):

Requisition Number 5 (if applicable):

Were there any clinically significant labs? ☐ Yes (specify below) ☒ No

Requisition Number

Test Name

Test Code ID

Verified



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Page Version No. PAGE_09 (v1, 15-OCT-2010)

Document Number

R350259513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Urine Drug Screen

Was Urine Drug Screen Performed? ☒ Yes ☐ No

Date

DD/MMM/YYYY

15-NOV-2010

Urine Drug Screen Result

☐ Positive ☒ Negative

Urine Pregnancy Test

Was Urine Pregnancy Test performed? ☐ Yes ☐ No ☒ NA, Male

Date

DD/MMM/YYYY

Urine Pregnancy Test Result

☐ Positive ☐ Negative

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Page Version No. PAGE_10 (v1, 15-OCT-2010)

Document Number R350259613

Links to Discrepancy and Audit Sections

[Click here to navigate to audit history for this CRF](#)

Document Number R350259713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Supine 12-Lead Electrocardiogram Report

Was ECG performed?	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	DD/MMM/YYYY	24-hour clock
	15-NOV-2010	14:34

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	052
PR Interval	milliseconds	152
QRS Duration	milliseconds	098
QT Interval	milliseconds	434
QTc Interval	milliseconds	404

ECG Interpretation:

☒ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

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Page Version No. PAGE_12 (v1, 15-OCT-2010)

Document Number R350259813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Complete Physical Examination

Does the subject have any relevant findings?

☐ Yes ☒ No

Date

DD/MMM/YYYY

19-NOV-2010

Consider the following systems when performing the assessment:

01 General Appearance

05 Pulmonary

09 Lymphatic

02 Skin

06 Chest

10 Musculoskeletal

03 Ears, Eyes, Nose, Throat

07 Cardiovascular

11 Neurological

04 Head/Neck

08 Abdomen and Liver/Spleen

Code

Findings

Verified



Approved



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Page Version No. PAGE_13 (v1, 15-OCT-2010)

Document Number

R350259913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Usual Brand Cigarette Pack Data

Date

DD/MMM/YYYY

19-NOV-2010

Parameter

Result

Usual Brand Name

MARLBORO MENTHOL

(Note: include color designation if any)

Filtered

☒ Yes ☐ No

Length

☐ 72 mm ☐ 100 mm

☒ 85 mm ☐ 120 mm

Width

☒ Regular ☐ Super Slims

☐ Slims ☐ Wides

Fire Standard Compliant?

☒ Yes ☐ No

Packaging

☐ Soft-pack ☒ Hard-pack (box)

Oral Health Examination

Was Oral Health Examination performed? ☒ Yes ☐ No

Date

DD/MMM/YYYY

19-NOV-2010

Exam Determination

Result

If Yes, Please Describe

Evidence of Leukoplakia?

☐ Yes ☒ No

Evidence of Other Oral Keratosis?

☐ Yes ☒ No

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☒ Locked

☒ Frozen

☒

Page Version No. PAGE_14 (v1, 15-OCT-2010)

Document Number

R350260013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Did Subject Smoke Single Cigarette? ☒ Yes ☐ No

Were Measurements Collected 30-60 Minutes Following Cigarette? ☒ Yes ☐ No

Date	Actual Time Cigarette Smoked 24-hour clock	Actual Time Vitals Collected 24-hour clock	Was HDYF? question asked?
DD/MMM/YYYY			
19-NOV-2010	14:10	14:49	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	126
Diastolic Blood Pressure	mmHg	074
Pulse	beats/minute	055
ECO	ppm	19

Urine Cotinine Screen

Not Applicable ☒

Date	Actual Time	NicCheck I Results	Not Done	Comments
DD/MMM/YYYY	24-hour clock			
		<input type="checkbox"/> Positive <input type="checkbox"/> Negative	<input type="checkbox"/>	

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Page Version No. PAGE_15 (v1, 18-OCT-2010)

Document Number R350260113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Randomization

Date

DD/MMM/YYYY

Randomization Number

Randomized Group

03-DEC-2010

2060

☒ SNUS

☐ Strips

☐ Dual Use of UB Cigarettes and SNUS

☐ Sticks

☐ Tobacco Abstinence

☐ Orbs

Verified



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Page Version No. PAGE_16 (v1, 15-OCT-2010)

Document Number

R350260213

Links to Discrepancy and Audit Sections

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[Click here to navigate to discrepancy details for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Actual Time
24-hour clock

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Urine Drug Screen

Was Urine Drug Screen Performed? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Urine Drug Screen Result

☐ Positive ☒ Negative

Urine Pregnancy Test

Was Urine Pregnancy Test performed? ☐ Yes ☐ No ☒ NA, Male

Date
DD/MMM/YYYY

Urine Pregnancy Test Result

☐ Positive ☐ Negative

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_17 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

04-DEC-2010

Actual Time
24-hour clock

08:30

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

108

Diastolic Blood Pressure

mmHg

066

Pulse

beats/minute

061

Respiratory Rate

breaths/minute

12

Oral Temperature

°C

36.8

Blood Collection for COHb

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

Not

Done

Comments

04-DEC-2010

22:00

22:44

☐

Expired Carbon Monoxide

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

ECO Level

(ppm)

% COHb

Not Done

Comments

04-DEC-2010

07:00

07:37

14

2.9

☐

04-DEC-2010

12:00

12:46

26

4.8

☐

04-DEC-2010

22:00

22:46

24

4.5

☐

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Page Version No. PAGE_18 (v1, 15-OCT-2010)

Document Number R350260413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

UB Cigarette Dispensation/Collection

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?	If No, Comment
1	04-DEC-2010	07:39	07:48	34	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
2	04-DEC-2010	07:57	08:06	31	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
3	04-DEC-2010	08:57	09:11	32	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
4	04-DEC-2010	09:48	09:58	30	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
5	04-DEC-2010	10:32	10:39	36	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
6	04-DEC-2010	11:29	11:38	36	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
7	04-DEC-2010	12:04	12:11	35	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
8	04-DEC-2010	12:47	12:54	36	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
9	04-DEC-2010	13:22	13:33	36	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
10	04-DEC-2010	14:56	15:03	36	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
11	04-DEC-2010	15:44	15:52	36	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
12	04-DEC-2010	16:43	16:51	35	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
13	04-DEC-2010	17:24	17:32	39	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
14	04-DEC-2010	17:55	18:02	34	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
04-DEC-2010	18	00:38	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_19 (v1, 15-OCT-2010)

Document Number R350260513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?	If No, Comment
15	04-DEC-2010	18:33	18:41	39	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
16	04-DEC-2010	19:07	19:16	37	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
17	04-DEC-2010	22:04	22:11	37	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
18	04-DEC-2010	22:48	22:55	38	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Page Version No. PAGE_19.1 (v1, 02-NOV-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Urine Collection

Scheduled Timepoint	Start Date/Time	Stop Date/Time	Total	Not	Comments
	DD/MMM/YYYY 24-hour clock	DD/MMM/YYYY 24-hour clock	Volume mL		
-24 HOURS TO 0 HOUR	04-DEC-2010 07:25	05-DEC-2010 07:25	2849	<input type="checkbox"/>	

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
04-DEC-2010	07:00	07:33	<input type="checkbox"/>	
04-DEC-2010	12:00	12:44	<input type="checkbox"/>	
04-DEC-2010	22:00	22:44	<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_20 (v1, 15-OCT-2010)

Document Number R350264913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Fecal Collection

Not Applicable

Scheduled Timepoint	Collection Date/Time DD/MMM/YYYY 24-hour clock	Weight g	Not Done	Comments
<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
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<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
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Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_21 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Questionnaires

Date of Assessment

DD/MMM/YYYY

04-DEC-2010

Scheduled Timepoint

19:00

Questionnaire

B-QSU

MNWS

Was Questionnaire Administered?

☒ Yes ☐ No

☒ Yes ☐ No

Maximum Use Level

Date

DD/MMM/YYYY

04-DEC-2010

Maximum Product Use

Allowed Per Day:

12

40% UB for Dual Use subjects:

☒ NA, Not Dual Use group

Comments

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Page Version No. PAGE_22 (v1, 02-NOV-2010)

Document Number R350265013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Actual Time
24-hour clock

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☐ Yes ☐ No ☒ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_23 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 1

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	05-DEC-2010	07:35	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	07:49
2	05-DEC-2010	08:10	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	08:45
3	05-DEC-2010	12:04	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	12:34
4	05-DEC-2010	14:26	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	14:54
5	05-DEC-2010	19:21	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	19:52
6	05-DEC-2010	22:04	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	22:43
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

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Page Version No. PAGE_24 (v1, 21-OCT-2010)

Document Number R350265713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
<input type="text" value="05-DEC-2010"/>	<input type="text" value="5"/>	<input type="text" value="02:57"/>	<input type="text" value="NO-ONLY 5 SNUS IN BOTTLE"/>

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Page Version No. PAGE_25 (v1, 21-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection

NA, Not Sticks group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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Page Version No. PAGE_26 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Page Version No. PAGE_27 (v1, 15-OCT-2010)

Document Number R349101813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_28 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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Page Version No. PAGE_29 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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Page Version No. PAGE_30 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_31 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?	If No, Comment
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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Page Version No. PAGE_32 (v1, 18-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Urine Collection

Scheduled Timepoint	Start Date/Time DD/MMM/YYYY 24-hour clock	Stop Date/Time DD/MMM/YYYY 24-hour clock	Total Volume mL	Not Done	Comments
0 HOUR TO 24 HOURS	05-DEC-2010 07:25	06-DEC-2010 07:25	3249	<input type="checkbox"/>	

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
05-DEC-2010	07:00	07:30	<input type="checkbox"/>	
05-DEC-2010	12:00	12:44	<input type="checkbox"/>	
05-DEC-2010	22:00	22:47	<input type="checkbox"/>	

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Page Version No. PAGE_33 (v1, 15-OCT-2010)

Document Number R350265913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Blood Collection for COHb

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
05-DEC-2010	22:00	22:47	<input type="checkbox"/>	

Expired Carbon Monoxide

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	ECO Level (ppm)	% COHb	Not Done	Comments
05-DEC-2010	07:00	07:33	13	2.7	<input type="checkbox"/>	
05-DEC-2010	12:00	12:46	8	1.9	<input type="checkbox"/>	
05-DEC-2010	22:00	22:49	4	1.3	<input type="checkbox"/>	

Questionnaires

Date of Assessment
DD/MMM/YYYY Scheduled Timepoint

Questionnaire Was Questionnaire Administered?

B-QSU	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
MNWS	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

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Page Version No. PAGE_34 (v1, 02-NOV-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

06-DEC-2010

Actual Time
24-hour clock

08:22

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

108

Diastolic Blood Pressure

mmHg

064

Pulse

beats/minute

053

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.8

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☐ Yes ☐ No ☒ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

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Page Version No. PAGE_35 (v1, 15-OCT-2010)

Document Number R350265213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	06-DEC-2010	07:57	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	08:13
2	06-DEC-2010	09:19	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	09:42
3	06-DEC-2010	11:29	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	11:48
4	06-DEC-2010	13:29	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	14:07
5	06-DEC-2010	15:11	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	15:44
6	06-DEC-2010	19:43	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	20:13
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

Verified



Approved



Locked



Frozen



Page Version No. PAGE_36 (v1, 21-OCT-2010)

Document Number

R350266113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
<input type="text" value="06-DEC-2010"/>	<input type="text" value="6"/>	<input type="text" value="01:50"/>	<input type="text" value="YES"/>

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Page Version No. PAGE_37 (v1, 21-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection

NA, Not Sticks group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_38 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_39 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_40 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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Page Version No. PAGE_41 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_42 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_43 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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Page Version No. PAGE_44 (v1, 18-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Actual Time
24-hour clock

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☐ Yes ☐ No ☒ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

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Page Version No. PAGE_45 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Subject Number: 2060

Subject Initials: (b) (6)

Visit Name DAY 3

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	07-DEC-2010	08:12	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	08:42
2	07-DEC-2010	10:05	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	10:42
3	07-DEC-2010	12:04	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	12:26
4	07-DEC-2010	16:24	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	16:45
5	07-DEC-2010	18:27	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	18:59
6	07-DEC-2010	20:20	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	20:38
7	07-DEC-2010	22:06	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	22:24
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

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Page Version No. PAGE_46 (v1, 21-OCT-2010)

Document Number R350266313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
<input type="text" value="07-DEC-2010"/>	<input type="text" value="7"/>	<input type="text" value="00:08"/>	<input type="text" value="YES"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_47 (v1, 21-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
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			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_48 (v1, 15-OCT-2010)

Document Number

R349144613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_49 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_50 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_51 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_52 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_53 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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Page Version No. PAGE_54 (v1, 18-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

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Page Version No. PAGE_54.1 (v1, 18-NOV-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Urine Collection

Scheduled Timepoint	Start Date/Time	Stop Date/Time	Total	Not	Comments
	DD/MMM/YYYY 24-hour clock	DD/MMM/YYYY 24-hour clock	Volume mL		
48 HOURS TO 72 HOURS	<input type="text" value="07-DEC-2010"/>	<input type="text" value="08-DEC-2010"/>	<input type="text" value="1949"/>	<input type="checkbox"/>	<input type="text"/>
	<input type="text" value="07:25"/>	<input type="text" value="07:25"/>			

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
<input type="text" value="07-DEC-2010"/>	<input type="text" value="07:00"/>	<input type="text" value="07:42"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text" value="07-DEC-2010"/>	<input type="text" value="12:00"/>	<input type="text" value="12:44"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text" value="07-DEC-2010"/>	<input type="text" value="22:00"/>	<input type="text" value="22:58"/>	<input type="checkbox"/>	<input type="text"/>

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Page Version No. PAGE_55 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Blood Collection for COHb

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
07-DEC-2010	22:00	22:58	<input type="checkbox"/>	

Expired Carbon Monoxide

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	ECO Level (ppm)	% COHb	Not Done	Comments
07-DEC-2010	07:00	07:45	2	1.0	<input type="checkbox"/>	
07-DEC-2010	12:00	12:49	4	1.3	<input type="checkbox"/>	
07-DEC-2010	22:00	22:02	4	1.3	<input type="checkbox"/>	

Questionnaires

Date of Assessment
DD/MMM/YYYY

Questionnaire

Was Questionnaire Administered?

B-QSU ☒ Yes ☐ No

MNWS ☒ Yes ☐ No

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Page Version No. PAGE_56 (v1, 02-NOV-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

08-DEC-2010

Actual Time
24-hour clock

08:42

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

110

Diastolic Blood Pressure

mmHg

064

Pulse

beats/minute

49

Respiratory Rate

breaths/minute

15

Oral Temperature

°C

36.7

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☐ Yes ☐ No ☒ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

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Page Version No. PAGE_57 (v1, 15-OCT-2010)

Document Number R350265413

Links to Discrepancy and Audit Sections

[Click here to navigate to discrepancy details for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	08-DEC-2010	08:09	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	08:29
2	08-DEC-2010	10:13	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	10:43
3	08-DEC-2010	11:53	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	12:11
4	08-DEC-2010	14:44	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	15:13
5	08-DEC-2010	18:24	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	18:53
6	08-DEC-2010	19:47	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	20:08
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

Verified



Approved



Locked



Frozen



Page Version No. PAGE_58 (v1, 21-OCT-2010)

Document Number

R350266713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
<input type="text" value="08-DEC-2010"/>	<input type="text" value="6"/>	<input type="text" value="23 : 35"/>	<input type="text" value="YES"/>

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Page Version No. PAGE_59 (v1, 21-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Page Version No. PAGE_60 (v1, 15-OCT-2010)

Document Number

R349146413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

Verified



Approved



Locked



Frozen



Page Version No. PAGE_61 (v1, 15-OCT-2010)

Document Number

R349146613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_62 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_63 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_64 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_65 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_66 (v1, 18-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

09-DEC-2010

Actual Time
24-hour clock

08:46

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

117

Diastolic Blood Pressure

mmHg

074

Pulse

beats/minute

049

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

37.0

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☐ Yes ☐ No ☒ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

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Page Version No. PAGE_67 (v1, 15-OCT-2010)

Document Number R350265513

Links to Discrepancy and Audit Sections

[Click here to navigate to discrepancy details for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	09-DEC-2010	07:45	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	08:11
2	09-DEC-2010	09:08	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	09:38
3	09-DEC-2010	10:47	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	11:40
4	09-DEC-2010	12:05	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	12:24
5	09-DEC-2010	14:07	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	14:29
6	09-DEC-2010	17:18	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	17:45
7	09-DEC-2010	18:40	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	19:18
8	09-DEC-2010	21:11	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	21:35
9	09-DEC-2010	22:04	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	22:28
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

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Page Version No. PAGE_68 (v1, 21-OCT-2010)

Document Number R350266913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
09-DEC-2010	9	23 : 59	YES

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Page Version No. PAGE_69 (v1, 21-OCT-2010)

Document Number R350267013

Links to Discrepancy and Audit Sections

[Click here to navigate to audit history for this CRF](#)

[Click here to navigate to discrepancy details for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Page Version No. PAGE_70 (v1, 15-OCT-2010)

Document Number R349147713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 5/EARLY TERM

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Completely Consumed?	If No, Length Returned (mm)?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Page Version No. PAGE_71 (v1, 15-OCT-2010)

Document Number R349147813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Strips Dispensation/Collection

NA, Not Strips group CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	

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Page Version No. PAGE_72 (v1, 15-OCT-2010)

Document Number R349148113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Strips Dispensation/Collection (Continued)

NA, Not Strips group CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Strip	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Strips	<input type="checkbox"/> No	

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Page Version No. PAGE_73 (v1, 15-OCT-2010)

Document Number R349148213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Orbs Dispensation/Collection

NA, Not Orbs Group CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	

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Page Version No. PAGE_74 (v1, 19-OCT-2010)

Document Number R349148413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group CHECKED

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	
			<input type="checkbox"/> 1 Orb	<input type="checkbox"/> Yes	
			<input type="checkbox"/> 2 Orbs	<input type="checkbox"/> No	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_75 (v1, 19-OCT-2010)

Document Number R349148713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

UB Cigarette Dispensation/Collection

NA, Not Dual Use group CHECKED

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group CHECKED

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_76 (v1, 18-OCT-2010)

Document Number R349148813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Urine Collection

Scheduled Timepoint	Start Date/Time	Stop Date/Time	Total	Not	Comments
	DD/MMM/YYYY 24-hour clock	DD/MMM/YYYY 24-hour clock	Volume mL		
96 HOURS TO 120 HOURS	09-DEC-2010 07:26	10-DEC-2010 07:25	2919	<input type="checkbox"/>	

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
09-DEC-2010	07:00	07:39	<input type="checkbox"/>	
09-DEC-2010	12:00	12:44	<input type="checkbox"/>	
09-DEC-2010	22:00	22:46	<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_77 (v1, 15-OCT-2010)

Document Number R350276813

Links to Discrepancy and Audit Sections

[Click here to navigate to audit history for this CRF](#)

[Click here to navigate to discrepancy details for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Fecal Collection

Not Applicable CHECKED

Scheduled Timepoint	Collection Date/Time DD/MMM/YYYY 24-hour clock	Weight g	Not Done	Comments
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	
			<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_78 (v1, 15-OCT-2010)

Document Number R348887213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Blood Collection for COHb

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
09-DEC-2010	22:00	22:46	<input type="checkbox"/>	

Expired Carbon Monoxide

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	ECO Level (ppm)	% COHb	Not Done	Comments
09-DEC-2010	07:00	07:42	2	1.0	<input type="checkbox"/>	
09-DEC-2010	12:00	12:46	3	1.1	<input type="checkbox"/>	
09-DEC-2010	22:00	20:50	2	1.0	<input type="checkbox"/>	

Questionnaires

Date of Assessment

DD/MMM/YYYY

09-DEC-2010

Scheduled Timepoint

19:00

Questionnaire

B-QSU

MNWS

Exit - Product Attributes

Was Questionnaire Administered?

☒ Yes ☐ No

☒ Yes ☐ No

☒ Yes ☐ No

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_79 (v1, 02-NOV-2010)

Document Number R350277413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Laboratory Evaluations

Were the scheduled laboratory samples obtained?

☒ Yes ☐ No (Specify samples not done, reason):

Date

DD/MMM/YYYY

09-DEC-2010

Evaluations: Chem-19 (fasted at least 8 hours), CBC, and Urinalysis

Requisition Number 1:

A973956

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Requisition Number 4 (if applicable):

Requisition Number 5 (if applicable):

Were there any clinically significant labs? ☐ Yes (specify below) ☒ No

Requisition Number

Test Name

Test Code ID

Urine Pregnancy Test

Was Urine Pregnancy Test performed? ☐ Yes ☐ No ☒ NA, Male

Date

DD/MMM/YYYY

Urine Pregnancy Test Result

☐ Positive ☐ Negative

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_80 (v1, 18-OCT-2010)

Document Number R350277513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Abbreviated Physical Examination

Does the subject have any relevant findings?

☐ Yes ☒ No

Date

DD/MMM/YYYY

09-DEC-2010

Consider the following systems when performing the assessment:

01 General Appearance

06 Chest

02 Skin

07 Cardiovascular

05 Pulmonary

08 Abdomen and Liver/Spleen

Code

Findings

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_81 (v1, 15-OCT-2010)

Document Number R350277613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Supine 12-Lead Electrocardiogram Report

Was ECG performed?	Date DD/MMM/YYYY	Actual Time 24-hour clock
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	09-DEC-2010	08:38

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	43
PR Interval	milliseconds	154
QRS Duration	milliseconds	100
QT Interval	milliseconds	438
QTc Interval	milliseconds	391

ECG Interpretation:

☐ Normal ☒ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

Oral Health Examination

Was Oral Health Examination performed? ☒ Yes ☐ No

Date
DD/MMM/YYYY

09-DEC-2010

Exam Determination

Result

If Yes, Please Describe

Evidence of Leukoplakia?

☐ Yes ☒ No

Evidence of Other Oral Keratosis?

☐ Yes ☒ No

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_82 (v1, 15-OCT-2010)

Document Number R350277713

Links to Discrepancy and Audit Sections

[Click here to navigate to discrepancy details for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DISCHARGE, DAY 6

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

10-DEC-2010

Actual Time
24-hour clock

07:19

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

112

Diastolic Blood Pressure

mmHg

072

Pulse

beats/minute

054

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.7

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_83 (v1, 15-OCT-2010)

Document Number R350265613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

PCM

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Previous and Concomitant Medications

Has the subject taken any medications prior to the first dose and/or during the study as restricted by the protocol?

☒ Yes, list below. ☐ No

Drug Name:

KEFLEX

Indication:

FURUNCLE/CELLULITIS

Dose:

500

Unit:

Select only one

☐ grams

☐ micrograms

☒ milligrams

☐ milliliter

☐ tablet

☐ other, specify:

Frequency: Select only one

☐ one time

☐ whenever necessary

☐ every morning

☐ at bedtime

☐ every day

☐ twice daily

☐ three times daily

☒ four times daily

☐ every four hours

☐ every other day

☐ every week

☐ other, specify:

Route:

Select only one

☒ Oral

☐ Topical

☐ Subcutaneous

☐ Intravenous

☐ Intramuscular

☐ Intradermal

☐ Ocular, Left

☐ Ocular, Right

☐ Ocular, Both

☐ Sublingual

☐ Other, specify:

Start Date

DD/MMM/YYYY

10-DEC-2010

Stop Date

DD/MMM/YYYY

15-DEC-2010

☐ Ongoing

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

Page Version No. PAGE_84 (v1, 15-OCT-2010)

Document Number

R350267513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Previous and Concomitant Medications

Has the subject taken any medications prior to the first dose and/or during the study as restricted by the protocol?

☒ Yes, list below. ☐ No

Drug Name:

Indication:

Dose:

Unit: Select only one

☐ grams

☐ micrograms

☒ milligrams

☐ milliliter

☐ tablet

☐ other, specify:

Frequency: Select only one

☐ one time

☐ whenever necessary

☐ every morning

☐ at bedtime

☐ every day

☒ twice daily

☐ three times daily

☐ four times daily

☐ every four hours

☐ every other day

☐ every week

☐ other, specify:

Route: Select only one

☒ Oral

☐ Topical

☐ Subcutaneous

☐ Intravenous

☐ Intramuscular

☐ Intradermal

☐ Ocular, Left

☐ Ocular, Right

☐ Ocular, Both

☐ Sublingual

☐ Other, specify:

Start Date

DD/MMM/YYYY

Stop Date

DD/MMM/YYYY

☐ Ongoing

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_84 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Previous and Concomitant Medications

Has the subject taken any medications prior to the first dose and/or during the study as restricted by the protocol?

☒ Yes, list below. ☐ No

Drug Name:

Indication:

Dose:

Unit: Select only one

☐ grams

☐ micrograms

☐ milligrams

☐ milliliter

☐ tablet

☒ other, specify:

Frequency: Select only one

☐ one time

☒ whenever necessary

☐ every morning

☐ at bedtime

☐ every day

☐ twice daily

☐ three times daily

☐ four times daily

☐ every four hours

☐ every other day

☐ every week

☐ other, specify:

Route: Select only one

☐ Oral

☒ Topical

☐ Subcutaneous

☐ Intravenous

☐ Intramuscular

☐ Intradermal

☐ Ocular, Left

☐ Ocular, Right

☐ Ocular, Both

☐ Sublingual

☐ Other, specify:

Start Date

DD/MMM/YYYY

Stop Date

DD/MMM/YYYY

☐ Ongoing

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_84 (v1, 15-OCT-2010)

Document Number

Links to Discrepancy and Audit Sections

[Click here to navigate to audit history for this CRF](#)

[Click here to navigate to discrepancy details for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

AE

Subject Number:

2060

Subject Initials:

(b) (6)

Is Blank

Adverse Events

Did the subject experience any adverse events? ☒ Yes, list below. ☐ No

Event Number:

1

Adverse Event:

HEARTBURN

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

04-DEC-2010

22:20

04-DEC-2010

23:00

☐ Ongoing

Severity: Select only one

☒ Mild

☐ Moderate

☐ Severe

Action Taken Select only one

with Study

☐ Dose increased

☐ Treatment interrupted

Treatment:

☐ Dose not changed

☐ Treatment withdrawn

☐ Dose reduced

☒ Not applicable

Other Action Select all that apply

Taken with ☒ None

Subject: ☐ Required concomitant medication

☐ Required withdrawal from study

☐ Other, Specify:

Relationship Select only one

to Study Treatment: ☒ Not Related

☐ Possible

☐ Probable

☐ Definite

Serious Event: Select only one

☐ Yes

☒ No

Outcome: Select only one

☒ Recovered/Resolved

☐ Recovered/Resolved with Sequelae

☐ Recovering/Resolving

☐ Fatal

☐ Not Recovered/Not Resolved

☐ Unknown

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

Page Version No. PAGE_85 (v1, 19-OCT-2010)

Document Number

R350267813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Adverse Events

Did the subject experience any adverse events? ☒ Yes, list below. ☐ No

Event Number:

Adverse Event:

Onset Date	Onset Time	Resolved Date	Resolved Time
DD/MMM/YYYY	24-hour clock	DD/MMM/YYYY	24-hour clock
<input type="text" value="08-DEC-2010"/>	<input type="text" value="15:00"/>	<input type="text" value="20-JAN-2011"/>	<input type="text" value="17:42"/>
<input type="checkbox"/> Ongoing			

Severity: Select only one

- ☒ Mild
☐ Moderate
☐ Severe

Action Taken Select only one

- with Study ☐ Dose increased ☐ Treatment interrupted
Treatment: ☒ Dose not changed ☐ Treatment withdrawn
☐ Dose reduced ☐ Not applicable

Other Action Select all that apply

- Taken with ☐ None
Subject: ☒ Required concomitant medication
☐ Required withdrawal from study
☒ Other, Specify:

Relationship Select only one
to Study Treatment: ☒ Not Related

- ☐ Possible
☐ Probable
☐ Definite

Serious Event: Select only one

- ☐ Yes
☒ No

Outcome: Select only one

- ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae
☐ Recovering/Resolving ☐ Fatal
☐ Not Recovered/Not Resolved ☐ Unknown

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_85 (v1, 19-OCT-2010)

Document Number

OverFlow Section For Document Number R350267913

- 1 WARM PACK APPLIED EVERY 2 HOURS FOR 20 MINUTES

Links to Discrepancy and Audit Sections

[Click here to navigate to audit history for this CRF](#)

[Click here to navigate to discrepancy details for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name VS ADDITIONAL

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Additional Assessments - Vital Signs

Were any additional vital signs collected? ☐ Yes, list below. ☒ No

Date DD/MMM/YYYY
Actual Time 24-hour clock
Position

☐ Standing

☐ Supine

☐ Seated

☐ Other, Specify:

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	
Diastolic Blood Pressure	mmHg	
Pulse	beats/minute	
Respiratory Rate	breaths/minute	
Oral Temperature	°C	

Date DD/MMM/YYYY
Actual Time 24-hour clock
Position

☐ Standing

☐ Supine

☐ Seated

☐ Other, Specify:

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	
Diastolic Blood Pressure	mmHg	
Pulse	beats/minute	
Respiratory Rate	breaths/minute	
Oral Temperature	°C	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_86 (v1, 18-OCT-2010)

Document Number R350267113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name LB ADDITIONAL

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Additional Assessments - Laboratory Evaluations

Were any additional laboratory evaluations collected? ☐ Yes, list below. ☒ No

Date	Requisition	Clinically	Test Name	Test Code ID	
DD/MMM/YYYY	Number	Significant?	CS Labs Only	CS Labs Only	Comments
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_87 (v1, 15-OCT-2010)

Document Number R350267213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name EG ADDITIONAL

Subject Number: 2060

Subject Initials: (b) (6)

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

Were any additional 12-lead ECGs collected? ☐ Yes, list below. ☒ No

Date DD/MMM/YYYY Actual Time 24-hour clock

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	<input type="text"/>
PR Interval	milliseconds	<input type="text"/>
QRS Duration	milliseconds	<input type="text"/>
QT Interval	milliseconds	<input type="text"/>
QTc Interval	milliseconds	<input type="text"/>

ECG Interpretation:

☐ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

Date DD/MMM/YYYY Actual Time 24-hour clock

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	<input type="text"/>
PR Interval	milliseconds	<input type="text"/>
QRS Duration	milliseconds	<input type="text"/>
QT Interval	milliseconds	<input type="text"/>
QTc Interval	milliseconds	<input type="text"/>

ECG Interpretation:

☐ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_88 (v1, 15-OCT-2010)

Document Number R350267313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name **STUDY COMPLETION**

Subject Number: **2060**

Subject Initials: **(b) (6)**

Is Blank

Study Completion

Date the subject completed OR withdrew from the study: **10-DEC-2010**
DD/MMM/YYYY

Reason for Withdrawal (check one):

☒ NA, Completed Study

☐ Adverse Event, specify:

☐ Terminated by Sponsor

☐ Consent Withdrawn

☐ Lost to Follow-up

☐ Other, specify:

Investigator Comments (if none, leave blank):

By electronically approving this case report form, I have reviewed the data
and found them to be complete and accurate.

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. **PAGE_89 (v1, 15-OCT-2010)**

Document Number **R350267413**

Appendix: Audit and Discrepancy Information

Audit History Report

This section lists audited data that meets the parameters set when the report was run. It may not include all of the audited data in a particular CRF. Refer to the documentation for a complete description of the parameters that can affect this report.

Document #: R350259613

Patient	Visit	CRF
Site	Visit Date	CRF Page
2060	Screen 1	Page_10
CDB_001		010

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Drugscr	Page number	10	Screen 1

Group #	Group Name
1	DRUG

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Urine Drug	POSITIVE		29-JAN-2011 01:52:28	Data Entry Error
Screen Result	NEGATIVE		Cara Rogers	
1				

Document #: R350260213

Patient	Visit	CRF
Site	Visit Date	CRF Page
2060	Screen 2	Page_16
CDB_001		016

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Sc	Page number	16	Screen 2

Group #	Group Name
1	SC

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Date	19-NOV-2010		23-FEB-2011 10:02:46	Investigator
1	03-DEC-2010		Christina Breedlove	Correction

Document #: R350267013

Patient Site	Visit Visit Date	CRF CRF Page	
2060	Day 5/Early Term	Page_69	
CDB_001		069	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eod_Snus	Page number	69	Day 5/Early Term

Group #	Group Name
1	INDYN

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
End-of-Day Total	8		23-FEB-2011 11:12:40	Investigator
SNUS Count	9		Christina Breedlove	Correction
1				

Document #: R350276813

Patient Site	Visit Visit Date	CRF CRF Page	
2060	Day 5/Early Term	Page_77	
CDB_001		077	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcu	Page number	77	Day 5/Early Term

Group #	Group Name
1	PCU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Stop Date	09-DEC-2010		23-FEB-2011 11:25:10	Investigator
1	10-DEC-2010		Christina Breedlove	Correction

Document #: R350267713

Patient	Visit	CRF
Site	Visit Date	CRF Page
2060	Pcm.2	Page_84
CDB_001		

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Pcm	Page number	84	Pcm.2

Group #	Group Name
1	CM

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Dose	DAB		31-MAR-2011 14:58:45	Investigator
1	1		Christina Breedlove	Correction
				Fingertip amount
				of salve to the
				affected area as
				needed.
				Application was
				noted to be used
				over a 3 day
				period
other, specify:	DAB		31-MAR-2011 14:58:45	Investigator
(Unit) (1)	FINGERTIP		Christina Breedlove	Correction
1				Fingertip amount
				of salve to the
				affected area as
				needed.
				Application was
				noted to be used
				over a 3 day
				period

Document #: R350267913

Patient Site	Visit Visit Date	CRF CRF Page
2060	Ae.1	Page_85
CDB_001		

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	85	Ae.1

Group #	Group Name
1	AE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Adverse Event 1	FURUNCLE/CELLULITIS FURUNCLE WITH CELLULITIS	30-SEP-2011 17:09:29 Christina Breedlove	Investigator Correction
High Level Group Code 1	10021879	04-OCT-2011 10:28:07 Carol Kraucyk	Data Change
High Level Group Term 1	INFECTIONS - PATHOGEN UNSPECIFIED	04-OCT-2011 10:28:07 Carol Kraucyk	Data Change
High Level Term 1	SKIN STRUCTURES AND SOFT TISSUE INFECTIONS	04-OCT-2011 10:28:07 Carol Kraucyk	Data Change
High Level Term Code 1	10040786	04-OCT-2011 10:28:07 Carol Kraucyk	Data Change
Lower Level Term 1	FURUNCLE	04-OCT-2011 10:28:07 Carol Kraucyk	Data Change
Lower Level Term Code 1	10017553	04-OCT-2011 10:28:07 Carol Kraucyk	Data Change
Preferred Term 1	FURUNCLE	04-OCT-2011 10:28:07 Carol Kraucyk	Data Change
Preferred Term Code 1	10017553	04-OCT-2011 10:28:07 Carol Kraucyk	Data Change
Required concomitant medication 1	CHECK	23-FEB-2011 11:36:24 Christina Breedlove	Investigator Correction
System Organ Class 1	INFECTIONS AND INFESTATIONS	04-OCT-2011 10:28:07 Carol Kraucyk	Data Change
System Organ Class Code 1	10021881	04-OCT-2011 10:28:07 Carol Kraucyk	Data Change
Verbatim 1	FURUNCLE/CELLULITIS FURUNCLE WITH CELLULITIS	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change

Discrepancy Detail Report

Document #: R350260213

Discrepancy ID:	299908911	Site:	CDB_001	Patient:	2060
Visit:	SCREEN 2	Visit Date:			
CRF:	PAGE_16	Section:	SC	Qualifying Value:	16
Field:	Date			Row:	1
Value Text:	20101203				
Type:	MANUAL	Status:	CURRENT		
Review Status:	Resolved-Response Edited				
Discrepancy:	Please verify date. For others in this study group, date of 03-DEC-2010 was used.				
Internal Comment:					
Resolution Type:	Confirmed				
Resolution Text:					

Document #: R350265413

Discrepancy ID: 294451911 **Site:** CDB_001 **Patient:** 2060
Visit: DAY 4 **Visit Date:**
CRF: PAGE_57 **Section:** VS **Qualifying Value:** 57
Field: Pulse (beats/minute) **Row:** 1
Value Text: 49
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value of 49 for Pulse (beats/minute) below expected minimum of 50
Internal Comment: pulse ranges are 40-100. Subjects pulse rate was 49
Resolution Type: Confirmed
Resolution Text: pulse ranges are 40-100. Subjects pulse rate was 49

Document #: R350265513

Discrepancy ID: 294452011 **Site:** CDB_001 **Patient:** 2060
Visit: DAY 5/EARLY TER **Visit Date:**
CRF: PAGE_67 **Section:** VS **Qualifying Value:** 67
Field: Pulse (beats/minute) **Row:** 1
Value Text: 049
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value of 049 for Pulse (beats/minute) below expected minimum of 50
Internal Comment: pulse ranges are 40-100. Subjects pulse rate was 49
Resolution Type: Confirmed
Resolution Text: pulse ranges are 40-100. Subjects pulse rate was 49

Document #: R350267013

Discrepancy ID: 299960811 **Site:** CDB_001 **Patient:** 2060
Visit: DAY 5/EARLY TER **Visit Date:**
CRF: PAGE_69 **Section:** EOD_SNUS **Qualifying Value:** 69
Field: End-of-Day Total SNUS Count **Row:** 1
Value Text: 9
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify count. Source indicates 9 used and count agrees.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R350276813

Discrepancy ID: 299961511 **Site:** CDB_001 **Patient:** 2060
Visit: DAY 5/EARLY TER **Visit Date:**
CRF: PAGE_77 **Section:** PCU **Qualifying Value:** 77
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please record the total volume for Day 5 Urine collection (2919 mL).
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R350277713

Discrepancy ID: 294453011 **Site:** CDB_001 **Patient:** 2060
Visit: DAY 5/EARLY TER **Visit Date:**
CRF: PAGE_82 **Section:** EG **Qualifying Value:** 82
Field: Ventricular Heart Rate (beats/minute) **Row:** 1
Value Text: 43
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value of 43 for Ventricular Heart Rate (beats/minute) below expected minimum of 50
Internal Comment: confirmed to be 43bpm
Resolution Type: Confirmed
Resolution Text: confirmed to be 43bpm

Document #: R350267713

Discrepancy ID: 320369111 **Site:** CDB_001 **Patient:** 2060

Visit: PCM.2 **Visit Date:**

CRF: PAGE_84 **Section:** PCM **Qualifying Value:** 84

Field: Dose **Row:** 1

Value Text: 1

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please remove 'Dab' as this is not a Dose. Please provide the number of dabs used.

Internal Comment: Fingertip amount of salve to the affected area as needed. Application was noted to be used over a 3 day period

Resolution Type: Due Diligence

Resolution Text: Fingertip amount of salve to the affected area as needed. Application was noted to be used over a 3 day period

Document #: R350267913

Discrepancy ID: 413666011 **Site:** CDB_001 **Patient:** 2060
Visit: AE.1 **Visit Date:**
CRF: PAGE_85 **Section:** AE **Qualifying Value:** 85
Field: Adverse Event **Row:** 1
Value Text: FURUNCLE WITH CELLULITIS
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please split into two separate AEs.
Internal Comment: confirmed with Sub-Investigator that this is one AE.
Resolution Type: No Action Required
Resolution Text:

Discrepancy ID: 299963111 **Site:** CDB_001 **Patient:** 2060
Visit: AE.1 **Visit Date:**
CRF: PAGE_85 **Section:** AE **Qualifying Value:** 85
Field: Required concomitant medication **Row:** 1
Value Text: CHECK
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify if "required concomitant medication" should also be checked here.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Deleted CRFs Report