

CRF Report for Study E8230249

Report run by Tamara Fisher at 15-AUG-2014 10:07:32

Report Parameters

Site: CDB_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: 2040

Ending patient: 2040

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: 2040

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 R346960613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

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*
<input type="text" value="01"/>	Between 21 and 65 years of age, inclusive.	<input type="text" value="YES"/>	
<input type="text" value="02"/>	Self-reported daily use \geq 10 cigarettes/day for \geq 12 months.	<input type="text" value="YES"/>	
<input type="text" value="03"/>	Screening Fagerström dependence score of "low" or greater (ie, 3 to 10).	<input type="text" value="YES"/>	
<input type="text" value="04"/>	Screening urinary cotinine \geq 200 ng/mL (via NicCheck I Test Strips with a positive result).	<input type="text" value="YES"/>	
<input type="text" value="05"/>	Screening expired-air CO level \geq 15 ppm (sample taken 30-60 minutes after smoking a single UB cigarette).	<input type="text" value="YES"/>	
<input type="text" value="06"/>	No intent to quit smoking during the trial period.	<input type="text" value="YES"/>	
<input type="text" value="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.	<input type="text" value="YES"/>	
<input type="text" value="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.	<input type="text" value="YES"/>	
<input type="text" value="09"/>	In the opinion of the Investigators, participants will be free of clinically significant health problems.	<input type="text" value="YES"/>	
<input type="text" value="10"/>	Negative tests for selected drugs of abuse at Screening and on Day -2.	<input type="text" value="YES"/>	
<input type="text" value="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).	<input type="text" value="YES"/>	

*If No, document on Subject Eligibility Page.

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2040

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.

YES

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 R348318813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2040

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 R348340613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2040

Subject Initials:

(b) (6)

Is Blank

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

22-OCT-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="text"/>	<input type="text"/>	<input type="checkbox"/> Yes	<input type="text"/>
<input type="checkbox"/> Exclusion			<input type="checkbox"/> No	
<input type="checkbox"/> Inclusion	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes	<input type="text"/>
<input type="checkbox"/> Exclusion			<input type="checkbox"/> No	
<input type="checkbox"/> Inclusion	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes	<input type="text"/>
<input type="checkbox"/> Exclusion			<input type="checkbox"/> No	

Verified



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

Document Number

R348340813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Tobacco Abstinence Question

Was Tobacco Abstinence Question asked? ☒ Yes ☐ No

Date

DD/MMM/YYYY

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

Score

Comments

Urine Cotinine Screen

Date

DD/MMM/YYYY

Actual Time
24-hour clock

NicCheck I
Results

☒ Positive
☐ Negative

Not Done

☐

Comments

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2040

Subject Initials:

(b) (6)

Is Blank

MSFT Taste Test

Was MSFT Taste Test administered? ☒ Yes ☐ No

Date

DD/MMM/YYYY

22-OCT-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

22-OCT-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:

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

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

Document Number

R348341413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2040

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

22-OCT-2010

Actual Time
24-hour clock

11:57

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

108

Diastolic Blood Pressure

mmHg

064

Pulse

beats/minute

057

Respiratory Rate

breaths/minute

14

Oral Temperature

°C

36.6

Body Measurements

Were Body Measurements Collected? ☒ Yes ☐ No

Date

DD/MMM/YYYY

22-OCT-2010

Parameter

Unit

Result

Height

cm

156.0

Weight

kg

056.9

BMI

kg/m²

23.4

Note: Body Mass Index will be derived.

Verified



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

Document Number

R348341713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2040

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

22-OCT-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:

Y305375

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

R348342413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number: 2040

Subject Initials: (b) (6)

Is Blank

Urine Drug Screen

Was Urine Drug Screen Performed? ☒ Yes ☐ No

Date

DD/MMM/YYYY

22-OCT-2010

Urine Drug Screen Result

☐ Positive ☒ Negative

Urine Pregnancy Test

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

Date

DD/MMM/YYYY

22-OCT-2010

Urine Pregnancy Test Result

☐ Positive ☒ Negative

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

Document Number R348343713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

2040

Subject Initials:

(b) (6)

Is Blank

Medical History

Does the subject have any relevant medical history?

☒ Yes ☐ No

Date

DD/MMM/YYYY

22-OCT-2010

Consider the following systems when performing the assessment:

01 Skin

02 Ears, Eyes, Nose, Throat (EENT)

03 Breasts

04 Respiratory

05 Cardiovascular

06 Lymphatic/Hematologic

07 Gastrointestinal

08 Genitourinary

09 Musculoskeletal

10 Endocrine

11 Neurological

12 Immunological

13 Psychological

14 Allergies

Code	Diagnosis/Procedure	Date of Onset DD/MMM/YYYY	Date of Resolution DD/MMM/YYYY	
CARDIO	HYPERCHOLESTEROLEMIA	00-JUN-2007		<input checked="" type="checkbox"/> Ongoing
GASTRO	FREQUENT HEARTBURN	00-000-2008		<input checked="" type="checkbox"/> Ongoing
MUSCULO	UPPER AND LOWER BACK PAIN	00-MAR-2005		<input checked="" type="checkbox"/> Ongoing
GASTRO	INDIGESTION	00-000-2008		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Verified



Approved



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Page Version No. PAGE_11 (v1, 15-OCT-2010)

Document Number

R348343913

Links to Discrepancy and Audit Sections

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number: 2040

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
	22-OCT-2010	12:01

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	54
PR Interval	milliseconds	174
QRS Duration	milliseconds	96
QT Interval	milliseconds	450
QTc Interval	milliseconds	434

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 R348344013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

2040

Subject Initials:

(b) (6)

Is Blank

Complete Physical Examination

Does the subject have any relevant findings?

☐ Yes ☒ No

Date

DD/MMM/YYYY

29-OCT-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

R348281113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

2040

Subject Initials:

(b) (6)

Is Blank

Usual Brand Cigarette Pack Data

Date

DD/MMM/YYYY

29-OCT-2010

Parameter

Result

Usual Brand Name

305'S SILVER 100'S (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

29-OCT-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_14 (v1, 15-OCT-2010)

Document Number

R348281713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

2040

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			
29-OCT-2010	14:06	14:50	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	110
Diastolic Blood Pressure	mmHg	070
Pulse	beats/minute	083
ECO	ppm	33

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"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R348282113

Links to Discrepancy and Audit Sections

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

2040

Subject Initials:

(b) (6)

Is Blank

Randomization

Date

DD/MMM/YYYY

Randomization Number

Randomized Group

06-NOV-2010

2040

☐ SNUS

☐ Strips

☒ Dual Use of UB Cigarettes and SNUS

☐ Sticks

☐ Tobacco Abstinence

☐ Orbs

Verified



Approved



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Frozen



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

Document Number

R348282813

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: 2040

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

07-NOV-2010

Actual Time
24-hour clock

08:41

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

102

Diastolic Blood Pressure

mmHg

064

Pulse

beats/minute

074

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.7

Blood Collection for COHb

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

Not

Done

Comments

07-NOV-2010

22:00

22:42

☐

Expired Carbon Monoxide

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

ECO Level

(ppm)

% COHb

Not Done

Comments

07-NOV-2010

07:00

07:41

11

2.4

☐

07-NOV-2010

12:00

12:56

29

5.3

☐

07-NOV-2010

22:00

22:44

27

5.0

☐

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R348286313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 2040

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	07-NOV-2010	07:44	07:59	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	07-NOV-2010	08:00	08:13	40	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	07-NOV-2010	08:13	08:25	40	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	07-NOV-2010	09:14	09:23	41	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	07-NOV-2010	09:23	09:37	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	07-NOV-2010	10:10	10:21	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
7	07-NOV-2010	10:22	10:40	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
8	07-NOV-2010	10:41	11:48	30	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	NO COMMENT RECORD ₁
9	07-NOV-2010	11:48	12:01	40	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
10	07-NOV-2010	12:01	12:17	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
11	07-NOV-2010	13:45	14:02	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
12	07-NOV-2010	14:03	14:20	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
13	07-NOV-2010	14:21	15:38	29	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	NO COMMENT RECORD ₂
14	07-NOV-2010	15:38	16:01	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
07-NOV-2010	23	01:38	NO- 2 BUTTS WERE NOT PROCESSED

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R348288313

OverFlow Section For Document Number R348288313

- 1 NO COMMENT RECORDED
- 2 NO COMMENT RECORDED

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 BASELINE, DAY -1

Subject Number: 2040

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
15	07-NOV-2010	16:02	16:26	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
16	07-NOV-2010	17:38	17:55	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
17	07-NOV-2010	18:41	18:55	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
18	07-NOV-2010	18:56	19:09	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
19	07-NOV-2010	19:25	19:38	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
20	07-NOV-2010	19:39	19:55	47	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
21	07-NOV-2010	19:56	20:11	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
22	07-NOV-2010	21:22	21:40	40	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
23	07-NOV-2010	21:41	21:52	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
24	07-NOV-2010	22:00	22:08	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
25	07-NOV-2010	22:50	23:02	37	<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	

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

Document Number R348293513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 2040

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	07-NOV-2010 07:21	08-NOV-2010 07:22	2749	<input type="checkbox"/>	

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
07-NOV-2010	07:00	07:27	<input type="checkbox"/>	
07-NOV-2010	12:00	12:52	<input type="checkbox"/>	
07-NOV-2010	22:00	22:42	<input type="checkbox"/>	

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

Document Number R348297213

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"/>
<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"/>
<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"/>
<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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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: 2040

Subject Initials: (b) (6)

Is Blank

Questionnaires

Date of Assessment

DD/MMM/YYYY

07-NOV-2010

Scheduled Timepoint

19:00

Questionnaire

B-QSU

MNWS

Was Questionnaire Administered?

☒ Yes ☐ No

☒ Yes ☐ No

Maximum Use Level

Date

DD/MMM/YYYY

07-NOV-2010

Maximum Product Use

Allowed Per Day:

11

40% UB for Dual Use subjects:

10

☐ NA, Not Dual Use group

Comments

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

Document Number R348299613

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_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: 2040

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-NOV-2010	11:15	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	11:22
2	08-NOV-2010	11:59	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	12:08
3	08-NOV-2010	16:40	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	16:50
4	08-NOV-2010	19:45	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	20:01
5	08-NOV-2010	22:00	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	22:04
			<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	
			<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 R348304313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

2040

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
08-NOV-2010	5	00:43	YES

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

Document Number

R348305513

Links to Discrepancy and Audit Sections

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

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"/>
<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

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_27 (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_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
<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_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"/>
<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_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"/>
<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_31 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 1

Subject Number: 2040

Subject Initials: (b) (6)

Is Blank

UB Cigarette Dispensation/Collection

NA, Not Dual Use group NOTCHECK

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	08-NOV-2010	07:54	08:11	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	08-NOV-2010	09:22	09:35	31	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	08-NOV-2010	10:32	10:52	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	08-NOV-2010	13:40	13:52	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	08-NOV-2010	15:21	15:30	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	08-NOV-2010	17:36	17:50	29	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	NO COMMENT RECORD
7	08-NOV-2010	18:36	18:46	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
8	08-NOV-2010	20:16	20:34	32	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
9	08-NOV-2010	21:38	21:47	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
10	08-NOV-2010	22:54	23:03	37	<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	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group NOTCHECK

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
08-NOV-2010	9	00:43	NO-BUTT # 6 WAS NOT PROCESSED

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

Document Number R348307613

OverFlow Section For Document Number R348307613

1 NO COMMENT RECORDED

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Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

2040

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		
0 HOUR TO 24 HOURS	08-NOV-2010	09-NOV-2010	3449	<input type="checkbox"/>	
	07:22	07:20			

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
08-NOV-2010	07:00	07:29	<input type="checkbox"/>	
08-NOV-2010	12:00	12:41	<input type="checkbox"/>	
08-NOV-2010	22:00	22:49	<input type="checkbox"/>	

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

Document Number R348311113

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
08-NOV-2010	22:00	22:49	<input type="checkbox"/>	

Expired Carbon Monoxide

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	ECO Level (ppm)	% COHb	Not Done	Comments
08-NOV-2010	07:00	07:47	11	2.4	<input type="checkbox"/>	
08-NOV-2010	12:00	12:48	8	1.9	<input type="checkbox"/>	
08-NOV-2010	22:00	22:50	15	3.0	<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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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:

2040

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

09-NOV-2010

Actual Time
24-hour clock

08:40

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

104

Diastolic Blood Pressure

mmHg

065

Pulse

beats/minute

065

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.6

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_35 (v1, 15-OCT-2010)

Document Number R348301013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

2040

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-NOV-2010	21:30	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	21:45
			<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	
			<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

R348322313

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

2040

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-NOV-2010	1	23:33	YES

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

Document Number

R348322813

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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"/>
<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"/>

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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
1	09-NOV-2010	07:26	07:39	33	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	09-NOV-2010	08:44	08:51	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	09-NOV-2010	09:18	09:34	32	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	09-NOV-2010	10:25	10:40	31	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	BURNT FILTER
5	09-NOV-2010	12:36	12:51	33	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	09-NOV-2010	13:37	13:54	31	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	BURNT FILTER
7	09-NOV-2010	17:34	17:48	30	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	BURNT FILTER
8	09-NOV-2010	18:43	19:02	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
9	09-NOV-2010	20:37	20:51	30	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	BURNT FILTER
10	09-NOV-2010	22:40	23:00	31	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	BURNT FILTER
					<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
09-NOV-2010	5	23:33	NO- 5 BUTTS WERE NOT PROCESSED

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

Document Number

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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

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

SNUS Dispensation/Collection

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" value="1"/>	<input type="text" value="10-NOV-2010"/>	<input type="text" value="ND"/>	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text" value="ND"/>
<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"/>
<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"/>

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

Document Number

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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="10-NOV-2010"/>	<input type="text" value="0"/>	<input type="text" value="ND"/>	<input type="text" value="NO PRODUCT USED ON THIS DAY"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

Links to Discrepancy and Audit Sections

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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"/>
<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_48 (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_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"/>

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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"/>
<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"/>

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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"/>

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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

DAY 3

Subject Number:

2040

Subject Initials:

(b) (6)

Is Blank

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

NOTCHECK

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	10-NOV-2010	07:46	08:02	31	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	10-NOV-2010	08:57	09:07	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	10-NOV-2010	10:05	10:17	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	10-NOV-2010	12:03	12:13	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	10-NOV-2010	13:38	13:58	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	10-NOV-2010	16:16	16:31	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
7	10-NOV-2010	18:35	18:55	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
8	10-NOV-2010	20:31	20:44	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
9	10-NOV-2010	21:59	22:06	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
10	10-NOV-2010	22:50	23:03	35	<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	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

NOTCHECK

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
10-NOV-2010	10	23:45	YES

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

Document Number R348346413

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Links to Discrepancy and Audit Sections

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

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="10-NOV-2010"/>	<input type="text" value="11-NOV-2010"/>	<input type="text" value="3649"/>	<input type="checkbox"/>	<input type="text"/>
	<input type="text" value="07:21"/>	<input type="text" value="07:21"/>			

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="10-NOV-2010"/>	<input type="text" value="07:00"/>	<input type="text" value="07:28"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text" value="10-NOV-2010"/>	<input type="text" value="12:00"/>	<input type="text" value="12:40"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text" value="10-NOV-2010"/>	<input type="text" value="22:00"/>	<input type="text" value="22:44"/>	<input type="checkbox"/>	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

DAY 3

Subject Number:

2040

Subject Initials:

(b) (6)

Is Blank

Blood Collection for COHb

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

Expired Carbon Monoxide

Date	Scheduled Timepoint	Actual Time	ECO Level	% COHb	Not Done	Comments
DD/MMM/YYYY		24-hour clock	(ppm)			
10-NOV-2010	07:00	07:32	7	1.8	<input type="checkbox"/>	
10-NOV-2010	12:00	12:42	13	2.7	<input type="checkbox"/>	
10-NOV-2010	22:00	22:47	15	3.0	<input type="checkbox"/>	

Questionnaires

Date of Assessment

DD/MMM/YYYY

Scheduled Timepoint

10-NOV-2010

19:00

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 R348347313

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_57 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

2040

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	11-NOV-2010	ND	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	ND
			<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	
			<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

R348347513

Links to Discrepancy and Audit Sections

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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="11-NOV-2010"/>	<input type="text" value="0"/>	<input type="text" value="ND"/>	<input type="text" value="SUBJECT DID NOT USE ANY SNUS ON DAY 4"/>

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

Document Number

Links to Discrepancy and Audit Sections

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

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R348527913

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_61 (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_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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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"/>

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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

DAY 4

Subject Number:

2040

Subject Initials:

(b) (6)

Is Blank

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

NOTCHECK

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	11-NOV-2010	07:25	07:35	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	11-NOV-2010	09:03	09:19	30	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	11-NOV-2010	10:12	10:26	30	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	11-NOV-2010	11:52	12:02	34	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	11-NOV-2010	13:43	13:52	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	11-NOV-2010	16:47	17:13	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
7	11-NOV-2010	18:39	19:01	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
8	11-NOV-2010	20:12	20:19	32	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
9	11-NOV-2010	22:08	22:22	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
10	11-NOV-2010	22:35	22:44	37	<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	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

NOTCHECK

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
11-NOV-2010	10	23:30	YES

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

Document Number R348348013

Links to Discrepancy and Audit Sections

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Document Number R348348113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

12-NOV-2010

Actual Time
24-hour clock

08:46

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

115

Diastolic Blood Pressure

mmHg

066

Pulse

beats/minute

052

Respiratory Rate

breaths/minute

15

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R348185213

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 DAY 5/EARLY TERM

Subject Number: 2040

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	12-NOV-2010	ND	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	ND
			<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	
			<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_68 (v1, 21-OCT-2010)

Document Number R348348713

Links to Discrepancy and Audit Sections

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

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
12-NOV-2010	0	ND	NO SNUS USED ON DAY 5

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

Document Number R348348913

Links to Discrepancy and Audit Sections

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

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 R348528613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

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	
			<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 R348349113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

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 R348528713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

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 R348528813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

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	

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

Document Number R348528913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

Subject Initials: (b) (6)

Is Blank

UB Cigarette Dispensation/Collection

NA, Not Dual Use group NOTCHECK

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	12-NOV-2010	07:46	07:56	40	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	12-NOV-2010	09:10	09:25	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	12-NOV-2010	10:27	10:37	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	12-NOV-2010	12:00	12:08	38	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	12-NOV-2010	13:33	13:52	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	12-NOV-2010	17:10	17:21	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
7	12-NOV-2010	18:31	18:47	34	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
8	12-NOV-2010	19:28	19:36	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
9	12-NOV-2010	22:00	22:07	40	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
10	12-NOV-2010	22:50	23:00	44	<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	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group NOTCHECK

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
12-NOV-2010	10	23:41	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R348349213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

Subject Initials: (b) (6)

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	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_76.1 (v1, 18-NOV-2010)

Document Number R348349413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

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
96 HOURS TO 120 HOURS	12-NOV-2010 07:22	13-NOV-2010 07:24	2999	<input type="checkbox"/>	

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
12-NOV-2010	07:00	07:39	<input type="checkbox"/>	
12-NOV-2010	12:00	12:40	<input type="checkbox"/>	
12-NOV-2010	22:00	22:45	<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R348349613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

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 R346965113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

Subject Initials: (b) (6)

Is Blank

Blood Collection for COHb

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
12-NOV-2010	22:00	22:45	<input type="checkbox"/>	

Expired Carbon Monoxide

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	ECO Level (ppm)	% COHb	Not Done	Comments
12-NOV-2010	07:00	07:44	6	1.6	<input type="checkbox"/>	
12-NOV-2010	12:00	12:43	13	2.7	<input type="checkbox"/>	
12-NOV-2010	22:00	22:46	16	3.2	<input type="checkbox"/>	

Questionnaires

Date of Assessment

DD/MMM/YYYY

12-NOV-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 R349850813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

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

12-NOV-2010

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

Requisition Number 1:

A974047

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

12-NOV-2010

Urine Pregnancy Test Result

☐ Positive ☒ Negative

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R349851313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

Subject Initials: (b) (6)

Is Blank

Abbreviated Physical Examination

Does the subject have any relevant findings?

☐ Yes ☒ No

Date

DD/MMM/YYYY

12-NOV-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 R349851413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 2040

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	12-NOV-2010	08:38

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	70
PR Interval	milliseconds	180
QRS Duration	milliseconds	92
QT Interval	milliseconds	404
QTc Interval	milliseconds	425

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

12-NOV-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 R349851813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DISCHARGE, DAY 6

Subject Number: 2040

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

13-NOV-2010

Actual Time
24-hour clock

07:32

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

106

Diastolic Blood Pressure

mmHg

065

Pulse

beats/minute

064

Respiratory Rate

breaths/minute

15

Oral Temperature

°C

36.5

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R348349813

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

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](#)

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

PCM

Subject Number:

2040

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:

TUMS

Indication:

HEARTBURN

Dose:

1

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

00-000-2008

Stop Date

DD/MMM/YYYY

☒ Ongoing

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

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

Document Number

R348351513

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

AE

Subject Number:

2040

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

1

Adverse Event:

IRRITATION GUMS/TEETH

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

09-NOV-2010

08:00

10-NOV-2010

08:00

☐ 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

R348351613

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:

2040

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

2

Adverse Event:

ROUGH FEELING ON TEETH

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

09-NOV-2010

08:30

☒ 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

R348352113

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: 2040

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 R348352413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name LB ADDITIONAL

Subject Number: 2040

Subject Initials: (b) (6)

Is Blank

Additional Assessments - Laboratory Evaluations

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

Date DD/MMM/YYYY	Requisition Number	Clinically Significant?	Test Name CS Labs Only	Test Code ID 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 R348353213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name EG ADDITIONAL

Subject Number: 2040

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 R348353513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name **STUDY COMPLETION**

Subject Number: **2040**

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

Is Blank

Study Completion

Date the subject completed OR withdrew from the study: **13-NOV-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 **R348353613**

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 #: R348343913

Patient Site	Visit Visit Date	CRF CRF Page
2040	Screen 1	Page_11
CDB_001		011

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Mh	Page number	11	Screen 1

Group #	Group Name
1	MH

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Diagnosis/Procedure 1	HIGH CHOLESTEROL HYPERCHOLESTEROLEMIA	28-SEP-2011 16:39:00 Christina Breedlove	Investigator Correction clarified medical condition
High Level Group Code 1	10024580 10013317	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change
High Level Group Term 1	LIPID ANALYSES LIPID METABOLISM DISORDERS	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change
High Level Term 1	CHOLESTEROL ANALYSES ELEVATED CHOLESTEROL	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change
High Level Term Code 1	10008651 10014476	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change
Lower Level Term 1	HIGH CHOLESTEROL HYPERCHOLESTEROLEMIA	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change
Lower Level Term Code 1	10020049 10020604	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change
Preferred Term 1	BLOOD CHOLESTEROL INCREASED HYPERCHOLESTEROLAEMIA	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change
Preferred Term Code 1	10005425 10020603	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change
System Organ Class 1	INVESTIGATIONS METABOLISM AND NUTRITION DISORDERS	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change
System Organ Class Code 1	10022891 10027433	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change
Verbatim 1	HIGH CHOLESTEROL HYPERCHOLESTEROLEMIA	03-OCT-2011 15:44:41 Carol Kraucyk	Data Change
Date of Onset 2	00-00-2008 00-000-2008	14-APR-2011 14:27:09 Christina Breedlove	Investigator Correction

Document #: R348343913

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Screen 1	Page_11
CDB_001		011

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Mh	Page number	11	Screen 1

Group #	Group Name
1	MH

Diagnosis/Procedure 2	FREQUENT HEARTBURN/INDIGESTION FREQUENT HEARTBURN	30-MAR-2011 13:18:41 Christina Breedlove	Investigator Correction
Code 4	MUSCULO <Row Deleted>	09-FEB-2011 15:53:27 Christina Breedlove	Investigator Correction not needed
Code 4	GASTRO	30-MAR-2011 13:18:41 Christina Breedlove	Row Inserted
Date of Onset 4	00-00-1964 <Row Deleted>	09-FEB-2011 15:53:27 Christina Breedlove	Investigator Correction not needed
Date of Onset 4	00-00-2008	30-MAR-2011 13:18:41 Christina Breedlove	Row Inserted
Date of Onset 4	00-00-2008 00-000-2008	14-APR-2011 14:27:09 Christina Breedlove	Investigator Correction
Date of Resolution 4	<Row Deleted>	09-FEB-2011 15:53:27 Christina Breedlove	Investigator Correction not needed
Date of Resolution 4		30-MAR-2011 13:18:41 Christina Breedlove	Row Inserted
Diagnosis/Procedure 4	SCOLIOSIS <Row Deleted>	09-FEB-2011 15:53:27 Christina Breedlove	Investigator Correction not needed
Diagnosis/Procedure 4	INDIGESTION	30-MAR-2011 13:18:41 Christina Breedlove	Row Inserted
Ongoing 4	CHECKED <Row Deleted>	09-FEB-2011 15:53:27 Christina Breedlove	Investigator Correction not needed
Ongoing 4	CHECKED	30-MAR-2011 13:18:41 Christina Breedlove	Row Inserted
Code 5	GENITOURINARY <Row Deleted>	09-FEB-2011 15:53:27 Christina Breedlove	Investigator Correction not needed
Date of Onset 5	00-00-1985 <Row Deleted>	09-FEB-2011 15:53:27 Christina Breedlove	Investigator Correction not needed

Document #: **R348343913**

Patient Site	Visit Visit Date	CRF CRF Page
2040	Screen 1	Page_11
CDB_001		011

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Mh	Page number	11	Screen 1

Group #	Group Name
1	MH

Date of Resolution 5	<Row Deleted>	09-FEB-2011 15:53:27 Christina Breedlove	Investigator Correction not needed
Diagnosis/Proced ure 5	POST MENOPAUSAL <Row Deleted>	09-FEB-2011 15:53:27 Christina Breedlove	Investigator Correction not needed
Ongoing 5	CHECKED <Row Deleted>	09-FEB-2011 15:53:27 Christina Breedlove	Investigator Correction not needed

Document #: R348282113

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Screen 2	Page_15
CDB_001		015

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Vs	Page number	15	Screen 2

Group #	Group Name
1	VS

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Actual Time	1400		19-JAN-2011 09:09:01	Data Entry Error
Cigarette Smoked	1406		Christina Breedlove	changed to end
(2)				time
1				

Document #: R348288313

Patient Site	Visit Visit Date	CRF CRF Page	
2040	Baseline, Day -1	Page_19	
CDB_001		019	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eod	Page number	19	Baseline, Day -1

Group #	Group Name		
1	INDYN		

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does Count Agree with Usage Log-Comment 1	DISPENSED ON 07NOV2010 & PROCESSING COMPLETED AT 07:38 ON 08NOV2010 NO-DISPENSED ON 07NOV2010 & PROCESSING COMPLETED AT 07:38 ON 08NOV2010	13-JAN-2011 11:26:08 Christina Breedlove	Data Entry Error
Does Count Agree with Usage Log-Comment 1	NO-DISPENSED ON 07NOV2010 & PROCESSING COMPLETED AT 07:38 ON 08NOV2010 YES-DISPENSED ON 07NOV2010 & PROCESSING COMPLETED AT 07:38 ON 08NOV2010	13-JAN-2011 11:27:17 Christina Breedlove	Data Entry Error
Does Count Agree with Usage Log-Comment 1	YES-DISPENSED ON 07NOV2010 & PROCESSING COMPLETED AT 07:38 ON 08NOV2010 NO- 2 BUTTS WERE NOT PROCESSED	09-FEB-2011 15:56:30 Christina Breedlove	Investigator Correction
End-of-Day Total Tip Count 1	25 23	09-FEB-2011 15:56:30 Christina Breedlove	Investigator Correction

Document #: R348305513

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
2040	Day 1	Page_25	
CDB_001		025	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Snus_Dis	Page number	25	Day 1

Group #	Group Name
0	Section Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCM Blank flag	N		27-JAN-2011 14:36:48	Key Change
1	Y		Christina Breedlove	

Document #: R348307613

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
2040	Day 1	Page_32	
CDB_001		032	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Eod	Page number	32	Day 1

Group #	Group Name
1	INDYN

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Does Count Agree with Usage Log-Comment 1	YES NO-BUTT # 6 WAS NOT PROCESSED		09-FEB-2011 15:59:03 Christina Breedlove	Investigator Correction
End-of-Day Total Tip Count 1	10 9		09-FEB-2011 15:59:03 Christina Breedlove	Investigator Correction

Document #: R348310513

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
2040	Day 1	Page_32.1	
CDB_001		032A	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			

Group #	Group Name
0	CRF Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCI Blank Flag	Y		17-JAN-2011 01:21:51	CRA Correction
1	N		Cindy Van Zuuk	
DCI Blank Flag	N		27-JAN-2011 14:42:05	Validation Status
1	Y		Christina Breedlove	changed

Document #: R348322313

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Day 2	Page_36
CDB_001		036

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Snus_Dis	Page number	36	Day 2

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Date	19-NOV-2010		13-JAN-2011 13:24:03	Data Entry Error
1	09-NOV-2010		Christina Breedlove	

Document #: R348322813

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
2040	Day 2	Page_37	
CDB_001		037	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Snus_Dis	Page number	37	Day 2

Group #	Group Name
0	Section Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCM Blank flag	N		23-JAN-2011 21:07:54	Key Change
1	Y		Laurie Rydstrom	

Document #: R348344413

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Day 2	Page_44
CDB_001		044

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Eod	Page number	44	Day 2

Group #	Group Name
1	INDYN

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Does Count Agree with Usage Log-Comment 1	YES NO- 5 BUTTS WERE NOT PROCESSED		09-FEB-2011 16:18:07 Christina Breedlove	Investigator Correction
End-of-Day Total Tip Count 1	10 5		09-FEB-2011 16:18:07 Christina Breedlove	Investigator Correction

Document #: R348314913

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Day 2	Page_44.1
CDB_001		044A

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			

Group #	Group Name
0	CRF Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCI Blank Flag	N		13-JAN-2011 15:22:48	Data Entry Error
1	Y		Christina Breedlove	entered on 2nd
				page in error.
DCI Blank Flag	Y		17-JAN-2011 01:26:34	CRA Correction
1	N		Cindy Van Zuuk	
DCI Blank Flag	N		27-JAN-2011 14:48:37	Validation Status
1	Y		Christina Breedlove	changed

Document #: R348314913

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Day 2	Page_44.1
CDB_001		044A

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Ub_Dis	Page number	44A	Day 2

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
NA, Not Dual Use				
group				
1	CHECKED		17-JAN-2011 01:26:34	Row Inserted
			Cindy Van Zuuk	

Document #: R348346013

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
2040	Day 3	Page_46	
CDB_001		046	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Snus_Dis	Page number	46	Day 3

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Amount Dispensed (1) 1	1		13-JAN-2011 15:31:04 Christina Breedlove	Data Entry Error
Flavor Dispensed (2) 1	FROST		13-JAN-2011 15:31:04 Christina Breedlove	Data Entry Error
Seq. 1	1		13-JAN-2011 15:31:04 Christina Breedlove	Data Entry Error

Document #: R348346313

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Day 3	Page_47
CDB_001		047

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Snus_Dis	Page number	47	Day 3

Group #	Group Name
0	Section Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCM Blank flag	N		27-JAN-2011 14:25:52	Data Entry Error
1	Y		Christina Breedlove	

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Amount Dispensed			13-JAN-2011 15:36:12	Data Entry Error
(1)			Christina Breedlove	
1	1			
Amount Dispensed	1		27-JAN-2011 14:16:58	Data Entry Error
(1)			Christina Breedlove	
1				
Date	10-NOV-2010		27-JAN-2011 14:16:58	Data Entry Error
1			Christina Breedlove	
Flavor Dispensed			13-JAN-2011 15:36:12	Validation Status
(2)	FROST		Christina Breedlove	changed
1				
Flavor Dispensed	FROST		27-JAN-2011 14:16:58	Investigator
(2)			Christina Breedlove	Correction
1				
NA, Not SNUS or	NOTCHECK		27-JAN-2011 14:16:58	Investigator
Dual Use group			Christina Breedlove	Correction
1				
Time Dispensed	ND		27-JAN-2011 14:16:58	Investigator
(1)			Christina Breedlove	Correction
1				
Time Returned	ND		27-JAN-2011 14:16:58	Investigator
(2)			Christina Breedlove	Correction
1				

Document #: R348346313

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Day 3	Page_47
CDB_001		047

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Eod_Snus	Page number	47	Day 3

Group #	Group Name
0	Section Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCM Blank flag	N		27-JAN-2011 14:16:58	Data Entry Error
1	Y		Christina Breedlove	
DCM Blank flag	Y		27-JAN-2011 14:25:52	Data Entry Error
1	N		Christina Breedlove	

Group #	Group Name
1	INDYN

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Date			27-JAN-2011 14:25:52	Row Inserted
1	10-NOV-2010		Christina Breedlove	
Does Count Agree			27-JAN-2011 14:25:52	Row Inserted
with Usage Log-			Christina Breedlove	
Comment	NO PRODUCT USED ON THIS			
1	DAY			
End-of-Day Total			27-JAN-2011 14:25:52	Row Inserted
SNUS Count			Christina Breedlove	
1	0			
NA, Not SNUS or			27-JAN-2011 14:25:52	Row Inserted
Dual Use group	NOTCHECK		Christina Breedlove	
1				
Time of Day			27-JAN-2011 14:25:52	Row Inserted
Frozen (-70C)	ND		Christina Breedlove	
1				

Document #: R348346413

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Day 3	Page_54
CDB_001		054

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Ub_Dis	Page number	54	Day 3

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Cigarette Butt	36		09-FEB-2011 16:21:07	Investigator
Length (mm)	35		Christina Breedlove	Correction
10				

Document #: R348346613

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
2040	Day 3	Page_54.1	
CDB_001		054A	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			

Group #	Group Name
0	CRF Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCI Blank Flag	Y		17-JAN-2011 01:32:18	CRA Correction
1	N		Cindy Van Zuuk	
DCI Blank Flag	N		27-JAN-2011 14:30:34	Validation Status
1	Y		Christina Breedlove	changed

Document #: R348347713

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Day 4	Page_59
CDB_001		059

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Snus_Dis	Page number	59	Day 4

Group #	Group Name
0	Section Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCM Blank flag	N		27-JAN-2011 14:33:44	Validation Status
1	Y		Christina Breedlove	changed

Document #: R348348013

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Day 4	Page_66
CDB_001		066

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			

Group #	Group Name
0	CRF Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCI Blank Flag	Y		13-JAN-2011 16:07:39	Data Entry Error
1	N		Christina Breedlove	

Document #: R348185213

Patient Site	Visit Visit Date	CRF CRF Page	
2040	Day 5/Early Term	Page_67	
CDB_001		067	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	67	Day 5/Early Term

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Pulse	057	09-FEB-2011 16:24:18	Investigator
(beats/minute)	052	Christina Breedlove	Correction
1			

Document #: R348348913

Patient Site	Visit Visit Date	CRF CRF Page	
2040	Day 5/Early Term	Page_69	
CDB_001		069	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Snus_Dis	Page number	69	Day 5/Early Term
Group #	Group Name		
0	Section Header		
Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCM Blank flag	N	27-JAN-2011 14:35:47	Validation Status
1	Y	Christina Breedlove	changed

Document #: R348350013

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Pcm	Page_84
CDB_001		084

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

Group #	Group Name
1	CM

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Drug Name	LOVESTATIN		09-FEB-2011 16:26:58	Investigator
1	LOVASTATIN		Christina Breedlove	Correction
Indication	HYPERCHOLERTROLEMIA		09-FEB-2011 16:26:58	Investigator
1	HYPERCHOLETROLEMIA		Christina Breedlove	Correction
Indication	HYPERCHOLETROLEMIA		24-FEB-2011 18:51:29	Investigator
1	HYPERCHOLESTEROLEMIA		Christina Breedlove	Correction

Document #: R348350713

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Pcm.1	Page_84
CDB_001		

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Pcm	Page number	84	Pcm.1

Group #	Group Name
1	CM

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
ATC1	CARDIOVASCULAR SYSTEM, C	20-SEP-2011 17:20:11		Class. Change
1	MUSCULO-SKELETAL SYSTEM, M	Carol Kraucyk		
ATC1 Code	C	20-SEP-2011 17:20:11		Class. Change
1	M	Carol Kraucyk		
ATC2	CARDIAC THERAPY, C01	20-SEP-2011 17:20:11		Class. Change
1	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	Carol Kraucyk		
ATC2 Code	C01	20-SEP-2011 17:20:11		Class. Change
1	M01	Carol Kraucyk		
ATC3	OTHER CARDIAC PREPARATIONS, C01E	20-SEP-2011 17:20:11		Class. Change
1	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-S, M01A	Carol Kraucyk		
ATC3 Code	C01E	20-SEP-2011 17:20:11		Class. Change
1	M01A	Carol Kraucyk		
ATC4	OTHER CARDIAC PREPARATIONS, C01EB	20-SEP-2011 17:20:11		Class. Change
1	PROPIONIC ACID DERIVATIVES, M01AE	Carol Kraucyk		
ATC4 Code	C01EB	20-SEP-2011 17:20:11		Class. Change
1	M01AE	Carol Kraucyk		

Document #: R348351613

Patient Site	Visit Visit Date	CRF CRF Page
2040	Ae	Page_85
CDB_001		085

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

Group #	Group Name
1	AE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Adverse Event 1	IRRATATION GUMS/TEETH IRRITATION GUMS/TEETH	24-FEB-2011 18:50:28 Christina Breedlove	Investigator Correction
High Level Group Code 1	10031013	04-OCT-2011 10:28:07 Carol Kraucyk	Class. Change
High Level Group Term 1	ORAL SOFT TISSUE CONDITIONS	04-OCT-2011 10:28:07 Carol Kraucyk	Class. Change
High Level Term 1	STOMATITIS AND ULCERATION	04-OCT-2011 10:28:07 Carol Kraucyk	Class. Change
High Level Term Code 1	10042129	04-OCT-2011 10:28:07 Carol Kraucyk	Class. Change
Lower Level Term 1	MOUTH IRRITATION	04-OCT-2011 10:28:07 Carol Kraucyk	Class. Change
Lower Level Term Code 1	10028026	04-OCT-2011 10:28:07 Carol Kraucyk	Class. Change
Preferred Term 1	STOMATITIS	04-OCT-2011 10:28:07 Carol Kraucyk	Class. Change
Preferred Term Code 1	10042128	04-OCT-2011 10:28:07 Carol Kraucyk	Class. Change
System Organ Class 1	GASTROINTESTINAL DISORDERS	04-OCT-2011 10:28:07 Carol Kraucyk	Class. Change
System Organ Class Code 1	10017947	04-OCT-2011 10:28:07 Carol Kraucyk	Class. Change

Document #: R348352113

Patient	Visit	CRF
Site	Visit Date	CRF Page
2040	Ae.1	Page_85
CDB_001		

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

Group #	Group Name
1	AE

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Ongoing			09-FEB-2011 16:41:05	Investigator
1	CHECK		Christina Breedlove	Correction
Resolved Date	13-JAN-2011		09-FEB-2011 16:41:05	Investigator
1			Christina Breedlove	Correction
Resolved Time	1705		09-FEB-2011 16:41:05	Investigator
1			Christina Breedlove	Correction

Discrepancy Detail Report

Document #: R348343913

Discrepancy ID: 328294211 **Site:** CDB_001 **Patient:** 2040
Visit: SCREEN 1 **Visit Date:**
CRF: PAGE_11 **Section:** MH **Qualifying Value:** 11
Field: Date of Onset **Row:** 2
Value Text: 00-000-2008
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value of 00-000-2008 for Date of Onset is not a valid DATE

Internal Comment:

Resolution Type: Data value changed. Disc no longer applicable.

Resolution Text:

Discrepancy ID: 328294311 **Site:** CDB_001 **Patient:** 2040
Visit: SCREEN 1 **Visit Date:**
CRF: PAGE_11 **Section:** MH **Qualifying Value:** 11
Field: Date of Onset **Row:** 4
Value Text: 00-000-2008
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value of 00-000-2008 for Date of Onset is not a valid DATE

Internal Comment:

Resolution Type: Data value changed. Disc no longer applicable.

Resolution Text:

Discrepancy ID: 413670411 **Site:** CDB_001 **Patient:** 2040
Visit: SCREEN 1 **Visit Date:**
CRF: PAGE_11 **Section:** MH **Qualifying Value:** 11
Field: Diagnosis/Procedure **Row:** 1
Value Text: HYPERCHOLESTEROLEMIA
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: For coding purposes, please query to update to hypercholesterolemia since hypercholesterolemia codes to a medical condition and high cholesterol codes to a specific lab result.

Internal Comment:

Resolution Type: Data value changed. Disc no longer applicable.

Resolution Text:

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Discrepancy ID: 319547811 **Site:** CDB_001 **Patient:** 2040
Visit: SCREEN 1 **Visit Date:**
CRF: PAGE_11 **Section:** MH **Qualifying Value:** 11
Field: Diagnosis/Procedure **Row:** 2
Value Text: FREQUENT HEARTBURN
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please split this into two separate events, not one.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R348288313

Discrepancy ID: 296893711 **Site:** CDB_001 **Patient:** 2040
Visit: BASELINE, DAY -1 **Visit Date:**
CRF: PAGE_19 **Section:** EOD **Qualifying Value:** 19
Field: Does Count Agree with Usage Log-Comment **Row:** 1
Value Text: NO- 2 BUTTS WERE NOT PROCESSED
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify answer should be NO since source indicates 2 butts were not collected.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 296893611 **Site:** CDB_001 **Patient:** 2040
Visit: BASELINE, DAY -1 **Visit Date:**
CRF: PAGE_19 **Section:** EOD **Qualifying Value:** 19
Field: End-of-Day Total Tip Count **Row:** 1
Value Text: 23
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify total should be 23 since source indicates 2 butts were not collected.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R348307613

Discrepancy ID: 297787711 **Site:** CDB_001 **Patient:** 2040

Visit: DAY 1 **Visit Date:**

CRF: PAGE_32 **Section:** EOD **Qualifying Value:** 32

Field: Does Count Agree with Usage Log-Comment **Row:** 1

Value Text: NO-BUTT # 6 WAS NOT PROCESSED

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify response. Should it be NO since butt # 6 was not processed per source log?

Internal Comment:

Resolution Type: Data value changed. Disc no longer applicable.

Resolution Text:

Discrepancy ID: 297787611 **Site:** CDB_001 **Patient:** 2040

Visit: DAY 1 **Visit Date:**

CRF: PAGE_32 **Section:** EOD **Qualifying Value:** 32

Field: End-of-Day Total Tip Count **Row:** 1

Value Text: 9

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify total. Should it be 9 as butt # 6 was not processed per source log?

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R348322813

Discrepancy ID: 289257711 **Site:** CDB_001 **Patient:** 2040
 Visit: DAY 2 **Visit Date:**
 CRF: PAGE_37 **Section:** SNUS_DISP **Qualifying Value:** 37
 Field: **Row:**
 Value Text:
 Type: MANUAL HEADER **Status:** CURRENT
 Review Status: Resolved-Response Edited
 Discrepancy: Please mark module blank, subject is in this group
Internal Comment:
 Resolution Type: No Action Required
 Resolution Text:

Document #: R348344413

Discrepancy ID: 297788811 **Site:** CDB_001 **Patient:** 2040

Visit: DAY 2 **Visit Date:**

CRF: PAGE_44 **Section:** EOD **Qualifying Value:** 44

Field: Does Count Agree with Usage Log-Comment **Row:** 1

Value Text: NO- 5 BUTTS WERE NOT PROCESSED

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Should response be NO due to 5 burnt filter butts were not collected?

Internal Comment:

Resolution Type: Data value changed. Disc no longer applicable.

Resolution Text:

Discrepancy ID: 297788711 **Site:** CDB_001 **Patient:** 2040

Visit: DAY 2 **Visit Date:**

CRF: PAGE_44 **Section:** EOD **Qualifying Value:** 44

Field: End-of-Day Total Tip Count **Row:** 1

Value Text: 5

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Should this response be 5, since 5 butts not processed due to burnt filter?

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R348346013

Discrepancy ID: 283745411

Site: CDB_001

Patient: 2040

Visit: DAY 3

Visit Date:

CRF: PAGE_46

Section: SNUS_DISP

Qualifying Value: 46

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: 'NA, Not SNUS or Dual Use Group' is not ticked, but details have not been recorded.
Please reconcile.

Internal Comment: subject did not use any Snus product on Day 3. Data entered per instruction from
Jasmine's email received on 12Jan2011

Resolution Type: No Action Required

Resolution Text: subject did not use any Snus product on Day 3. Data entered per instruction from
Jasmine's email received on 12Jan2011

Document #: R348346313

Discrepancy ID: 293697411

Site: CDB_001

Patient: 2040

Visit: DAY 3

Visit Date:

CRF: PAGE_47

Section: EOD_SNUS

Qualifying Value: 47

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: 'NA, Not SNUS or Dual Use Group' is not ticked, but details have not been recorded.
Please reconcile.

Internal Comment: NO PRODUCT USED ON THIS DAY

Resolution Type: No Action Required

Resolution Text:

Document #: R348346413

Discrepancy ID: 297790911 **Site:** CDB_001 **Patient:** 2040
Visit: DAY 3 **Visit Date:**
CRF: PAGE_54 **Section:** UB_DISP **Qualifying Value:** 54
Field: Cigarette Butt Length (mm) **Row:** 10
Value Text: 35
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify length for this butt was 35 (mm), per source.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R348347513

Discrepancy ID: 283748211

Site: CDB_001

Patient: 2040

Visit: DAY 4

Visit Date:

CRF: PAGE_58

Section: SNUS_DISP

Qualifying Value: 58

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: 'NA, Not SNUS or Dual Use Group' is not ticked, but details have not been recorded.
Please reconcile.

Internal Comment: Subject did not use any Snus product on Day 4. Data was entered as instructed per Jasmine's email that was received on 12Jan2011

Resolution Type: No Action Required

Resolution Text: Subject did not use any Snus product on Day 4. Data was entered as instructed per Jasmine's email that was received on 12Jan2011

Document #: R348347713

Discrepancy ID: 283751711 **Site:** CDB_001 **Patient:** 2040
Visit: DAY 4 **Visit Date:**
CRF: PAGE_59 **Section:** EOD_SNUS **Qualifying Value:** 59
Field: **Row:**
Value Text:
Type: MULTIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: 'NA, Not SNUS or Dual Use Group' is not ticked, but details have not been recorded.
Please reconcile.
Internal Comment: subject did not use any product on this day. Entered as instructed.
Resolution Type: No Action Required
Resolution Text: subject did not use any product on this day. Entered as instructed.

Document #: R348185213

Discrepancy ID: 296893911 **Site:** CDB_001 **Patient:** 2040
Visit: DAY 5/EARLY TER **Visit Date:**
CRF: PAGE_67 **Section:** VS **Qualifying Value:** 67
Field: Pulse (beats/minute) **Row:** 1
Value Text: 052
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify value for Pulse (52).
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R348348713

Discrepancy ID: 283754711 **Site:** CDB_001 **Patient:** 2040
Visit: DAY 5/EARLY TER **Visit Date:**
CRF: PAGE_68 **Section:** SNUS_DISP **Qualifying Value:** 68
Field: **Row:**
Value Text:
Type: MULTIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: 'NA, Not SNUS or Dual Use Group' is not ticked, but details have not been recorded.
Please reconcile.
Internal Comment: no snus product used on Day5
Resolution Type: No Action Required
Resolution Text: no snus product used on Day5

Discrepancy ID:	283755511	Site:	CDB_001	Patient:	2040
Visit:	DAY 5/EARLY TER	Visit Date:			
CRF:	PAGE_69	Section:	EOD_SNUS	Qualifying Value:	69
Field:				Row:	
Value Text:					
Type:	MULTIVARIATE	Status:	CURRENT		
Review Status:	Resolved-Response Edited				
Discrepancy:	'NA, Not SNUS or Dual Use Group' is not ticked, but details have not been recorded. Please reconcile.				
Internal Comment:	no product used on day 5				
Resolution Type:	No Action Required				
Resolution Text:	no product used on day 5				

Document #: R348350013

Discrepancy ID: 297792311 **Site:** CDB_001 **Patient:** 2040
Visit: PCM **Visit Date:**
CRF: PAGE_84 **Section:** PCM **Qualifying Value:** 84
Field: Drug Name **Row:** 1
Value Text: LOVASTATIN
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify correct spelling, LOVASTATIN
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 297792411 **Site:** CDB_001 **Patient:** 2040
Visit: PCM **Visit Date:**
CRF: PAGE_84 **Section:** PCM **Qualifying Value:** 84
Field: Indication **Row:** 1
Value Text: HYPERCHOLESTEROLEMIA
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify if correct spelling should be "hypercholesterolemia"
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R348351513

Discrepancy ID: 283758711 **Site:** CDB_001 **Patient:** 2040
Visit: PCM.3 **Visit Date:**
CRF: PAGE_84 **Section:** PCM **Qualifying Value:** 84
Field: Start Date **Row:** 1
Value Text: 00-000-2008
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value of 00-000-2008 for Start Date is not a valid DATE
Internal Comment: RDC system will not pre-fill 00 for unknown dates as per guidelines
Resolution Type: Confirmed
Resolution Text:

Document #: R348351613

Discrepancy ID: 303223611 **Site:** CDB_001 **Patient:** 2040
Visit: AE **Visit Date:**
CRF: PAGE_85 **Section:** AE **Qualifying Value:** 85
Field: Adverse Event **Row:** 1

Value Text: IRRITATION GUMS/TEETH

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Could you further clarify this AE and split it if possible. This subject also has an AE of ROUGH FEELING ON TEETH which started on the same date so maybe that is the tooth irritation they are talking about and then this term could be updated to just Irritation Gums. Several other subjects have Irritated Gums as an AE so it would be nice to be consistent with them if applicable.

Internal Comment: Confirmed with Sub-I AE is correct as is

Resolution Type: No Action Required

Resolution Text:

Discrepancy ID: 297792911 **Site:** CDB_001 **Patient:** 2040
Visit: AE **Visit Date:**
CRF: PAGE_85 **Section:** AE **Qualifying Value:** 85
Field: **Row:**

Value Text:

Type: MANUAL HEADER **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: ACTION TAKEN WITH STUDY TREATMENT: Please provide a response.

Internal Comment:

Resolution Type: Due Diligence

Resolution Text: subject did not use any Snus on Days 3, 4, &5.

Document #: R348352113

Discrepancy ID: 297794011

Site: CDB_001

Patient: 2040

Visit: AE.1

Visit Date:

CRF: PAGE_85

Section: AE

Qualifying Value: 85

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please provide all missing details and then mark the page as complete.

Internal Comment:

Resolution Type: Data value changed. Disc no longer applicable.

Resolution Text:

Deleted CRFs Report