

CRF Report for Study E8230249

Report run by Tamara Fisher at 15-AUG-2014 14:04:12

Report Parameters

Site: 47710

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: 3021

Ending patient: 3021

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:

3021

Subject Initials:

(b)

(b) (6)

Is Blank

Investigator:

STOLTZ

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

Verified



Approved



Locked



Frozen



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

Document Number

R346405513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3021

Subject Initials:

(b)

Is Blank

Inclusion Criteria

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

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

*If No, document on Subject Eligibility Page.

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

Document Number R346405713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3021

Subject Initials:

(b)

Is Blank

Inclusion Criteria

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

Yes No*

1.2

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

NAM

1.3

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

YES

*If No, document on Subject Eligibility Page.

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

Document Number

R346405913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3021

Subject Initials:

(b)

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 R346406413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Subject Eligibility

Date the Subject Signed the Informed Consent Form:
DD/MMM/YYYY

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

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

Category	Inclusion/ Exclusion No.	Explanation	Exemption Granted?	If Yes, Date Granted DD/MMM/YYYY
<input type="checkbox"/> Inclusion <input type="checkbox"/> Exclusion	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="checkbox"/> Inclusion <input type="checkbox"/> Exclusion	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="checkbox"/> Inclusion <input type="checkbox"/> Exclusion	<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_05 (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 ☐

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

Subject Number:

Subject Initials:

Is Blank ☐

MSFT Taste Test

Was MSFT Taste Test administered? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Product	Is taste of product acceptable? (Note: only one 'Yes' for SNUS is required)		
SNUS Frost	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
SNUS Mellow	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
Preferred SNUS Type	<input type="checkbox"/> Frost	<input checked="" type="checkbox"/> Mellow	<input type="checkbox"/> None
Sticks	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
Strips	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
Orbs	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	

Demographics

Date
DD/MMM/YYYY

Date of Birth
DD/MMM/YYYY

Gender

☒ Male

☐ Female

Ethnicity

☐ Hispanic or Latino

☒ Not Hispanic or Latino

Race

☐ White

☒ Black or African American

☐ Asian

☐ Native Hawaiian or Other Pacific Islander

☐ American Indian/Alaskan Native

☐ Other:

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3021

Subject Initials:

(b)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

10-NOV-2010

Actual Time
24-hour clock

10:47

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

144

Diastolic Blood Pressure

mmHg

98

Pulse

beats/minute

82

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.6

Body Measurements

Were Body Measurements Collected? ☒ Yes ☐ No

Date

DD/MMM/YYYY

10-NOV-2010

Parameter

Unit

Result

Height

cm

178.0

Weight

kg

69.4

BMI

kg/m²

21.9

Note: Body Mass Index will be derived.

Verified



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

Document Number

R346407913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3021

Subject Initials:

(b)

Is Blank

Laboratory Evaluations

Were the scheduled laboratory samples obtained?

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

Date

DD/MMM/YYYY

10-NOV-2010

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

Requisition Number 1:

Y247384

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

R346408813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number: 3021

Subject Initials:

(b)

Is Blank

Urine Drug Screen

Was Urine Drug Screen Performed? ☒ Yes ☐ No

Date

DD/MMM/YYYY

10-NOV-2010

Urine Drug Screen Result

☐ Positive ☒ Negative

Urine Pregnancy Test

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

Date

DD/MMM/YYYY

Urine Pregnancy Test Result

☐ Positive ☐ Negative

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

Document Number R346410713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3021

Subject Initials:

(b)

Is Blank

Medical History

Does the subject have any relevant medical history?

☒ Yes ☐ No

Date

DD/MMM/YYYY

10-NOV-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	
RESPIRATORY	CHRONIC OBSTRUCTIVE PULMONAL	00-00-2006		<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
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

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

Document Number

R346410813

OverFlow Section For Document Number R346410813

- 1 RESPIRATORY
- 2 CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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

SCREEN 1

Subject Number: 3021

Subject Initials:

(b)

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
	10-NOV-2010	10:59

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	65
PR Interval	milliseconds	168
QRS Duration	milliseconds	84
QT Interval	milliseconds	398
QTc Interval	milliseconds	413

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 R346411713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

3021

Subject Initials:

(b)

Is Blank

Complete Physical Examination

Does the subject have any relevant findings?

☐ Yes ☒ No

Date

DD/MMM/YYYY

23-NOV-2010

Consider the following systems when performing the assessment:

01 General Appearance

05 Pulmonary

09 Lymphatic

02 Skin

06 Chest

10 Musculoskeletal

03 Ears, Eyes, Nose, Throat

07 Cardiovascular

11 Neurological

04 Head/Neck

08 Abdomen and Liver/Spleen

Code

Findings

Verified



Approved



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

Document Number

R346412013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Usual Brand Cigarette Pack Data

Date
DD/MMM/YYYY

Parameter	Result
Usual Brand Name	<input type="text" value="KOOL"/> (Note: include color designation if any)
Filtered	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Length	<input type="checkbox"/> 72 mm <input checked="" type="checkbox"/> 100 mm <input type="checkbox"/> 85 mm <input type="checkbox"/> 120 mm
Width	<input checked="" type="checkbox"/> Regular <input type="checkbox"/> Super Slims <input type="checkbox"/> Slims <input type="checkbox"/> Wides
Fire Standard Compliant?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Packaging	<input type="checkbox"/> Soft-pack <input checked="" type="checkbox"/> Hard-pack (box)

Oral Health Examination

Was Oral Health Examination performed? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Exam Determination	Result	If Yes, Please Describe
Evidence of Leukoplakia?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
Evidence of Other Oral Keratosis?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_14 (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 ☐

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	Actual Time	Was HDYF?
DD/MMM/YYYY	Cigarette Smoked	Vitals Collected	question asked?
	24-hour clock	24-hour clock	
<input type="text" value="23-NOV-2010"/>	<input type="text" value="12:24"/>	<input type="text" value="12:55"/>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	<input type="text" value="147"/>
Diastolic Blood Pressure	mmHg	<input type="text" value="91"/>
Pulse	beats/minute	<input type="text" value="69"/>
ECO	ppm	<input type="text" value="22"/>

Urine Cotinine Screen

Not Applicable

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

3021

Subject Initials:

(b)

Is Blank

Randomization

Date

DD/MMM/YYYY

Randomization Number

Randomized Group

07-DEC-2010

3021

☐ SNUS

☐ Strips

☒ Dual Use of UB Cigarettes and SNUS

☐ Sticks

☐ Tobacco Abstinence

☐ Orbs

Verified



Approved



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

Document Number

R346412613

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

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: 3021

Subject Initials: (b)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

07-DEC-2010

Actual Time
24-hour clock

08:00

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

121

Diastolic Blood Pressure

mmHg

67

Pulse

beats/minute

65

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.6

Blood Collection for COHb

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time
24-hour clock

Not

Done

Comments

07-DEC-2010

22:00

22:00

☐

Expired Carbon Monoxide

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time
24-hour clock

ECO Level
(ppm)

% COHb

Not Done

Comments

07-DEC-2010

07:00

07:05

10

2.2

☐

07-DEC-2010

12:00

12:08

9

2.1

☐

07-DEC-2010

22:00

22:08

10

2.2

☐

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346412913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 3021

Subject Initials: (b)

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-DEC-2010	07:13	07:23	32	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	07-DEC-2010	09:58	10:06	32	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	07-DEC-2010	11:30	11:36	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	07-DEC-2010	13:46	13:54	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	07-DEC-2010	16:25	16:34	28	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	07-DEC-2010	19:22	19:31	32	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
7	07-DEC-2010	20:39	20:47	34	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
8	07-DEC-2010	21:30	21:37	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
9	07-DEC-2010	22:42	22:53	39	<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	

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-DEC-2010	9	23:36	YES

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

Document Number R346413113

Document Number R346413913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 3021

Subject Initials: (b)

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
-24 HOURS TO 0 HOUR	07-DEC-2010 06:57	08-DEC-2010 07:00	1276	<input type="checkbox"/>	

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
07-DEC-2010	07:00	07:01	<input type="checkbox"/>	
07-DEC-2010	12:00	12:00	<input type="checkbox"/>	
07-DEC-2010	22:00	22:00	<input type="checkbox"/>	

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

Document Number R346414213

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		Weight g	Not Done	Comments
	DD/MMM/YYYY	24-hour clock			
<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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 3021

Subject Initials: (b)

Is Blank

Questionnaires

Date of Assessment

DD/MMM/YYYY

07-DEC-2010

Scheduled Timepoint

19:00

Questionnaire

B-QSU

MNWS

Was Questionnaire Administered?

☒ Yes ☐ No

☒ Yes ☐ No

Maximum Use Level

Date

DD/MMM/YYYY

07-DEC-2010

Maximum Product Use

Allowed Per Day:

4

40% UB for Dual Use subjects:

4

☐ NA, Not Dual Use group

Comments

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346414913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Actual Time
24-hour clock

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 1

Subject Number: 3021

Subject Initials: (b)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	08-DEC-2010	11:31	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	11:48
2	08-DEC-2010	16:03	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	16:19
3	08-DEC-2010	20:12	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	20:31
4	08-DEC-2010	21:30	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	21:52
			<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_24 (v1, 21-OCT-2010)

Document Number R346415913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

3021

Subject Initials:

(b)

Is Blank

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

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

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
09-DEC-2010	4	00:46	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R346416113

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

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 1

Subject Number: 3021

Subject Initials: (b)

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-DEC-2010	07:25	07:32	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	08-DEC-2010	14:00	14:06	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	08-DEC-2010	19:17	19:22	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	08-DEC-2010	22:43	22:47	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

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-DEC-2010	4	00:46	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346417013

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](#)

Document Number R346417313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

3021

Subject Initials:

(b)

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-DEC-2010	09-DEC-2010	740	<input type="checkbox"/>	
	07:00	06:41			

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
08-DEC-2010	07:00	07:05	<input type="checkbox"/>	
08-DEC-2010	12:00	12:01	<input type="checkbox"/>	
08-DEC-2010	22:00	22:00	<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346417413

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-DEC-2010	22:00	22:00	<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-DEC-2010	07:00	07:13	9	2.1	<input type="checkbox"/>	
08-DEC-2010	12:00	12:03	7	1.8	<input type="checkbox"/>	
08-DEC-2010	22:00	22:04	7	1.8	<input type="checkbox"/>	

Questionnaires

Date of Assessment
DD/MMM/YYYY

Questionnaire

Was Questionnaire Administered?

B-QSU ☒ Yes ☐ No

MNWS ☒ Yes ☐ 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:

3021

Subject Initials:

(b)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

09-DEC-2010

Actual Time
24-hour clock

08:00

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

136

Diastolic Blood Pressure

mmHg

86

Pulse

beats/minute

48

Respiratory Rate

breaths/minute

15

Oral Temperature

°C

36.5

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

09-DEC-2010

If Yes, Specify Daily Amount

1

12-ounce serving of Ultralight Beer

0

6-ounce serving of White or Rose Wine

Verified



Approved



Locked



Frozen



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

Document Number

R346417913

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 2

Subject Number: 3021

Subject Initials: (b)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	09-DEC-2010	12:31	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	12:56
2	09-DEC-2010	15:46	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	16:03
3	09-DEC-2010	17:13	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	17:34
4	09-DEC-2010	22:21	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	22:36
			<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 R346418113

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="09-DEC-2010"/>	<input type="text" value="4"/>	<input type="text" value="23 : 38"/>	<input type="text" value="YES"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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"/>
<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_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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 2

Subject Number: 3021

Subject Initials: (b)

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	09-DEC-2010	09:51	09:57	33	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
2	09-DEC-2010	18:44	18:50	34	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
3	09-DEC-2010	21:26	21:30	34	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
4	09-DEC-2010	22:46	22:50	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	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group 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
09-DEC-2010	4	23:38	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346419713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

3021

Subject Initials:

(b)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

10-DEC-2010

Actual Time
24-hour clock

08:00

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

125

Diastolic Blood Pressure

mmHg

66

Pulse

beats/minute

51

Respiratory Rate

breaths/minute

18

Oral Temperature

°C

36.4

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

10-DEC-2010

If Yes, Specify Daily Amount

0

12-ounce serving of Ultralight Beer

1

6-ounce serving of White or Rose Wine

Verified

☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R346420313

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-DEC-2010"/>	<input type="text" value="11:30"/>	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	<input type="text" value="11:48"/>
<input type="text" value="2"/>	<input type="text" value="10-DEC-2010"/>	<input type="text" value="16:32"/>	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	<input type="text" value="16:57"/>
<input type="text" value="3"/>	<input type="text" value="10-DEC-2010"/>	<input type="text" value="21:32"/>	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	<input type="text" value="21:53"/>
<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

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-DEC-2010"/>	<input type="text" value="3"/>	<input type="text" value="23 : 47"/>	<input type="text" value="YES"/>

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

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

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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"/>

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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"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<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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<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"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
1	10-DEC-2010	09:45	09:52	29	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	10-DEC-2010	13:47	13:53	28	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	10-DEC-2010	19:22	19:31	28	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	10-DEC-2010	22:43	22:46	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	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
10-DEC-2010	4	23:47	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

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 3

Subject Number:

3021

Subject Initials:

(b)

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
48 HOURS TO 72 HOURS	10-DEC-2010 13:42	11-DEC-2010 06:54	848	<input type="checkbox"/>	VOIDED AT 13:

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
10-DEC-2010	07:00	07:00	<input type="checkbox"/>	
10-DEC-2010	12:00	12:00	<input type="checkbox"/>	
10-DEC-2010	22:00	22:02	<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346423913

OverFlow Section For Document Number R346423913

1 VOIDED AT 1342, BUT DID NOT COLLECT URINE

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Blood Collection for COHb

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
10-DEC-2010	22:00	22:02	<input type="checkbox"/>	

Expired Carbon Monoxide

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	ECO Level (ppm)	% COHb	Not Done	Comments
10-DEC-2010	07:00	07:04	5	1.4	<input type="checkbox"/>	
10-DEC-2010	12:00	12:05	5	1.4	<input type="checkbox"/>	
10-DEC-2010	22:00	22:09	6	1.6	<input type="checkbox"/>	

Questionnaires

Date of Assessment
DD/MMM/YYYY

Questionnaire

Was Questionnaire Administered?

B-QSU ☒ Yes ☐ No

MNWS ☒ Yes ☐ No

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

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: 3021

Subject Initials: (b)

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-DEC-2010	08:07	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	08:27
2	11-DEC-2010	15:55	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	16:30
3	11-DEC-2010	19:54	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	20:04
4	11-DEC-2010	21:58	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	22:11
			<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 R346424713

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-DEC-2010"/>	<input type="text" value="4"/>	<input type="text" value="00:14"/>	<input type="text" value="YES"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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](#)

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

3021

Subject Initials:

(b)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group

CHECKED

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346425213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_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"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<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"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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: 3021

Subject Initials: (b)

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-DEC-2010	09:42	09:45	32	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	11-DEC-2010	13:47	13:50	34	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	11-DEC-2010	18:57	19:02	31	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	11-DEC-2010	22:46	22:51	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

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-DEC-2010	4	00:14	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346426013

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

12-DEC-2010

Actual Time
24-hour clock

08:07

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

123

Diastolic Blood Pressure

mmHg

76

Pulse

beats/minute

52

Respiratory Rate

breaths/minute

18

Oral Temperature

°C

36.4

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

12-DEC-2010

If Yes, Specify Daily Amount

1

12-ounce serving of Ultralight Beer

0

6-ounce serving of White or Rose Wine

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346462613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

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-DEC-2010	08:14	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	08:18
2	12-DEC-2010	11:30	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	11:46
3	12-DEC-2010	16:47	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	16:59
4	12-DEC-2010	21:30	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input checked="" type="checkbox"/> Mellow	21:36
			<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_68 (v1, 21-OCT-2010)

Document Number R346462813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

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
13-DEC-2010	4	00:07	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346463213

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 5/EARLY TERM

Subject Number:

3021

Subject Initials:

(b)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group

CHECKED

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

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

Document Number

R346463313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

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 R346463413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

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 R346463613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

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	
			<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 R346463713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

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 R346463913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

Is Blank

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group CHECKED

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346464113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

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-DEC-2010	07:12	07:16	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	12-DEC-2010	13:37	13:43	40	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	12-DEC-2010	19:22	19:25	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	12-DEC-2010	22:51	22:56	30	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

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		Does Count Agree with Usage Log-Comment
		Frozen (-70C) 24-hour clock		
13-DEC-2010	4	00:07		YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346464313

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

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-DEC-2010 06:45	13-DEC-2010 05:26	1395	<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-DEC-2010	07:00	07:00	<input type="checkbox"/>	
12-DEC-2010	12:00	12:12	<input type="checkbox"/>	
12-DEC-2010	22:00	22:00	<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346465113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

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 R346466513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

Is Blank

Blood Collection for COHb

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
12-DEC-2010	22:00	22:00	<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-DEC-2010	07:00	07:06	6	1.6	<input type="checkbox"/>	
12-DEC-2010	12:00	12:14	6	1.6	<input type="checkbox"/>	
12-DEC-2010	22:00	22:04	6	1.6	<input type="checkbox"/>	

Questionnaires

Date of Assessment

DD/MMM/YYYY

12-DEC-2010

Scheduled Timepoint

19:00

Questionnaire

B-QSU

MNWS

Exit - Product Attributes

Was Questionnaire Administered?

☒ Yes ☐ No

☒ Yes ☐ No

☒ Yes ☐ No

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346466713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

Is Blank

Laboratory Evaluations

Were the scheduled laboratory samples obtained?

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

Date

DD/MMM/YYYY

12-DEC-2010

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

Requisition Number 1:

Y247511

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Requisition Number 4 (if applicable):

Requisition Number 5 (if applicable):

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

Requisition Number

Test Name

Test Code ID

Urine Pregnancy Test

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

Date

DD/MMM/YYYY

Urine Pregnancy Test Result

☐ Positive ☐ Negative

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346467013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

Is Blank

Abbreviated Physical Examination

Does the subject have any relevant findings?

☐ Yes ☒ No

Date

DD/MMM/YYYY

12-DEC-2010

Consider the following systems when performing the assessment:

01 General Appearance

06 Chest

02 Skin

07 Cardiovascular

05 Pulmonary

08 Abdomen and Liver/Spleen

Code

Findings

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346467213

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 5/EARLY TERM

Subject Number: 3021

Subject Initials: (b)

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-DEC-2010	07:50

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	53
PR Interval	milliseconds	152
QRS Duration	milliseconds	76
QT Interval	milliseconds	428
QTc Interval	milliseconds	401

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-DEC-2010

Exam Determination

Result

If Yes, Please Describe

Evidence of Leukoplakia?

☐ Yes ☒ No

Evidence of Other Oral Keratosis?

☐ Yes ☒ No

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346467413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DISCHARGE, DAY 6

Subject Number: 3021

Subject Initials: (b)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

13-DEC-2010

Actual Time
24-hour clock

06:55

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

141

Diastolic Blood Pressure

mmHg

85

Pulse

beats/minute

81

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.9

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346467613

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 discrepancy details for this CRF](#)

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

PCM

Subject Number:

3021

Subject Initials:

(b)

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:

ERY-TAB

Indication:

TINEA PEDIS LEFT FOOT

Dose:

500

Unit:

Select only one

☐ grams

☐ micrograms

☒ milligrams

☐ milliliter

☐ tablet

☐ other, specify:

Frequency: Select only one

☐ one time

☐ whenever necessary

☐ every morning

☐ at bedtime

☐ every day

☐ twice daily

☐ three times daily

☐ four times daily

☐ every four hours

☐ every other day

☐ every week

☒ other, specify: EVERY SIX HOURS

Route:

Select only one

☒ Oral

☐ Topical

☐ Subcutaneous

☐ Intravenous

☐ Intramuscular

☐ Intradermal

☐ Ocular, Left

☐ Ocular, Right

☐ Ocular, Both

☐ Sublingual

☐ Other, specify:

Start Date

DD/MMM/YYYY

21-DEC-2010

Stop Date

DD/MMM/YYYY

30-DEC-2010

☐ Ongoing

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

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

Document Number

R346468713

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

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:

3021

Subject Initials:

(b)

Is Blank

Adverse Events

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

Event Number:

1

Adverse Event:

LYMPHADENOPATHY

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

12-DEC-2010

16:47

16-DEC-2010

22:00

☐ 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

R346469713

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:

3021

Subject Initials:

(b)

Is Blank

Adverse Events

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

Event Number:

2

Adverse Event:

TINEA PEDIS LEFT FOOT

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

09-DEC-2010

05:00

25-JAN-2011

12:00

☐ 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

R350058613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name VS ADDITIONAL

Subject Number: 3021

Subject Initials: (b)

Is Blank

Additional Assessments - Vital Signs

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

Date DD/MMM/YYYY 10-NOV-2010
Actual Time 24-hour clock 10:53
Position ☐ Standing

☐ Supine

☒ Seated

☐ Other, Specify:

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	143
Diastolic Blood Pressure	mmHg	93
Pulse	beats/minute	ND
Respiratory Rate	breaths/minute	ND
Oral Temperature	°C	ND

Date DD/MMM/YYYY 23-NOV-2010
Actual Time 24-hour clock 12:56
Position ☐ Standing

☐ Supine

☒ Seated

☐ Other, Specify:

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	137
Diastolic Blood Pressure	mmHg	82
Pulse	beats/minute	ND
Respiratory Rate	breaths/minute	ND
Oral Temperature	°C	ND

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R346408413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name VS ADDITIONAL

Subject Number: 3021

Subject Initials: (b)

Is Blank

Additional Assessments - Vital Signs

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

Date DD/MM/YYYY 13-DEC-2010
Actual Time 24-hour clock 06:57
Position

☐ Standing

☐ Supine

☒ Seated

☐ Other, Specify:

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	146
Diastolic Blood Pressure	mmHg	78
Pulse	beats/minute	81
Respiratory Rate	breaths/minute	ND
Oral Temperature	°C	ND

Date DD/MM/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 R346467813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name LB ADDITIONAL

Subject Number: 3021

Subject Initials: (b)

Is Blank

Additional Assessments - Laboratory Evaluations

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

Date	Requisition	Clinically	Test Name	Test Code ID	
DD/MMM/YYYY	Number	Significant?	CS Labs Only	CS Labs Only	Comments
23-NOV-2010	1111160996	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
08-DEC-2010	1111162982	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
21-DEC-2010	1111166324	<input type="checkbox"/> Yes <input checked="" 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 R346409713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name EG ADDITIONAL

Subject Number: 3021

Subject Initials: (b)

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 R346470413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name **STUDY COMPLETION**

Subject Number: **3021**

Subject Initials:

(b)

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

13-DEC-2010

DD/MMM/YYYY

Reason for Withdrawal (check one):

☒ NA, Completed Study

☐ Adverse Event, specify:

☐ Terminated by Sponsor

☐ Consent Withdrawn

☐ Lost to Follow-up

☐ Other, specify:

Investigator Comments (if none, leave blank):

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number **R346470513**

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 #: R346410813

Patient Site	Visit Visit Date	CRF CRF Page	
3021	Screen 1	Page_11	
47710		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
Does the subject have any relevant medic 1	YES	08-FEB-2011 13:30:45 Lana Glaser	Pass1

Document #: R346417013

Patient Site	Visit Visit Date	CRF CRF Page
3021	Day 1	Page_32
47710		032

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ub_Disp	Page number	32	Day 1

Group #	Group Name
1	SU

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Time UB	0400	27-JAN-2011 15:20:16	Data Entry Error
Dispensed (1)	1400	Kim Freschly	
2			

Document #: R346417013

Patient Site	Visit Visit Date	CRF CRF Page
3021	Day 1	Page_32
47710		032

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eod	Page number	32	Day 1

Group #	Group Name
1	INDYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date	09-DEC-2010	27-JAN-2011 15:21:02	Data Entry Error
1	08-DEC-2010	Kim Freschly	

Document #: R346422213

Patient	Visit	CRF
Site	Visit Date	CRF Page
3021	Day 3	Page_54
47710		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
Time UB Returned (2) 2	0353 1353		27-JAN-2011 15:23:34 Kim Freschly	Data Entry Error
Time UB Returned (2) 4	0246 2246		27-JAN-2011 15:23:34 Kim Freschly	Data Entry Error

Document #: R346423913

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
3021	Day 3	Page_55	
47710		055	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Pcu	Page number	55	Day 3

Group #	Group Name
1	PCU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Comments				
1	VOIDED AT 1342, BUT DID NOT COLLECT URINE		27-JAN-2011 15:25:25 Kim Freschly	Data Entry Error
Start Time	0641		27-JAN-2011 15:25:25	Data Entry Error
1	0645		Kim Freschly	
Start Time	0645		04-FEB-2011 15:46:42	Data Entry Error
1	1342		Lana Glaser	
Stop Date	10-DEC-2010		29-MAR-2011 09:14:15	Data Entry Error
1	11-DEC-2010		Kim Freschly	

Document #: **R346425013**

Patient Site	Visit Visit Date	CRF CRF Page
3021	Day 4	Page_59
47710		059

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

Group #	Group Name
1	INDYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date	12-NOV-2010	29-MAR-2011 09:15:16	Data Entry Error
1	11-DEC-2010	Kim Freschly	

Document #: R346467213

Patient Site	Visit Visit Date	CRF CRF Page	
3021	Day 5/Early Term	Page_81	
47710		081	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	81	Day 5/Early Term

Group #	Group Name		
1	PE		

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Code 1	SKIN <Row Deleted>	27-JAN-2011 15:27:35 Kim Freschly	Data Entry Error
Does the subject have any relevant findi 1	YES NO	27-JAN-2011 15:27:35 Kim Freschly	Data Entry Error
Findings 1	FUNGAL RASH NOTED BETWEEN TOES LEFT FOOT <Row Deleted>	27-JAN-2011 15:27:35 Kim Freschly	Data Entry Error

Document #: R346468713

Patient Site	Visit Visit Date	CRF CRF Page
3021	Pcm.1	Page_84
47710		

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

Group #	Group Name
1	CM

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 1	DERMATOLOGICALS, D ANTIINFECTIVES FOR SYSTEMIC USE, J	20-SEP-2011 17:20:11 Carol Kraucyk	Class. Change
ATC1 Code 1	D J	20-SEP-2011 17:20:11 Carol Kraucyk	Class. Change
ATC2 1	ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGIC, D06 ANTIBACTERIALS FOR SYSTEMIC USE, J01	20-SEP-2011 17:20:11 Carol Kraucyk	Class. Change
ATC2 Code 1	D06 J01	20-SEP-2011 17:20:11 Carol Kraucyk	Class. Change
ATC3 1	ANTIBIOTICS FOR TOPICAL USE, D06A MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, J01F	20-SEP-2011 17:20:11 Carol Kraucyk	Class. Change
ATC3 Code 1	D06A J01F	20-SEP-2011 17:20:11 Carol Kraucyk	Class. Change
ATC4 1	OTHER ANTIBIOTICS FOR TOPICAL USE, D06AX MACROLIDES, J01FA	20-SEP-2011 17:20:11 Carol Kraucyk	Class. Change
ATC4 Code 1	D06AX J01FA	20-SEP-2011 17:20:11 Carol Kraucyk	Class. Change

Discrepancy Detail Report

Document #: R346412613

Discrepancy ID: 285777311 Site: 47710 Patient: 3021

Visit: SCREEN 2

Visit Date:

CRF: PAGE_16

Section: SC

Qualifying Value: 16

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Date of Randomization 07-DEC-2010 is more than 28 days prior to or is after Check-in Day -2 06-DEC-2010 or is less than 3 days after Screening Visit 1 10-NOV-2010. Please reconcile.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R346416113

Discrepancy ID: 277529611

Site: 47710

Patient: 3021

Visit: DAY 1

Visit Date:

CRF: PAGE_25

Section: EOD_SNUS

Qualifying Value: 25

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Date is not the scheduled number of days from Day 1 08-DEC-2010. Please verify date of collection.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R346417013

Discrepancy ID: 282514011	Site: 47710	Patient: 3021
Visit: DAY 1	Visit Date:	
CRF: PAGE_32	Section: UB_DISP	Qualifying Value: 32
Field: Time UB Dispensed		Row: 2
Value Text: 1400		
Type: MANUAL	Status: CURRENT	
Review Status: Resolved-Response Edited		
Discrepancy: please review		
Internal Comment: CORRECTED		
Resolution Type: Confirmed		
Resolution Text:		

Document #: R346417913

Discrepancy ID: 277530311 **Site:** 47710 **Patient:** 3021
 Visit: DAY 2 **Visit Date:**
 CRF: PAGE_35 **Section:** VS **Qualifying Value:** 35
 Field: Pulse (beats/minute) **Row:** 1
 Value Text: 48
 Type: UNIVARIATE **Status:** CURRENT
 Review Status: Resolved-Response Edited
 Discrepancy: Value of 48 for Pulse (beats/minute) below expected minimum of 50
Internal Comment:
 Resolution Type: Confirmed
 Resolution Text:

Document #: R346422213

Discrepancy ID: 282521411 **Site:** 47710 **Patient:** 3021
Visit: DAY 3 **Visit Date:**
CRF: PAGE_54 **Section:** UB_DISP **Qualifying Value:** 54
Field: Time UB Returned **Row:** 2
Value Text: 1353
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: please review
Internal Comment: CORRECTED
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 282521511 **Site:** 47710 **Patient:** 3021
Visit: DAY 3 **Visit Date:**
CRF: PAGE_54 **Section:** UB_DISP **Qualifying Value:** 54
Field: Time UB Returned **Row:** 4
Value Text: 2246
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: please review
Internal Comment: CORRECTED
Resolution Type: Confirmed
Resolution Text:

Document #: R346423913

Discrepancy ID: 282522011 **Site:** 47710 **Patient:** 3021
Visit: DAY 3 **Visit Date:**
CRF: PAGE_55 **Section:** PCU **Qualifying Value:** 55
Field: Comments **Row:** 1
Value Text: VOIDED AT 1342, BUT DID NOT COLLECT URINE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: please add coment, it appears void at 13:42 was not collected.
Internal Comment: COMMENT ADDED
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 282521911 **Site:** 47710 **Patient:** 3021
Visit: DAY 3 **Visit Date:**
CRF: PAGE_55 **Section:** PCU **Qualifying Value:** 55
Field: Start Time **Row:** 1
Value Text: 1342
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: please review
Internal Comment: please review if start time was actually 13:42, as void at 06:45 was discarded and void at 13:42 (footnote) was not collected.
TO BE CONSISTENT CORRECT AS ENTERED
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 305508511 **Site:** 47710 **Patient:** 3021
Visit: DAY 3 **Visit Date:**
CRF: PAGE_55 **Section:** PCU **Qualifying Value:** 55
Field: Stop Date **Row:** 1
Value Text: 20101211
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify the date, as it appears incorrect. It seems like the date should be the next calandar day since the collection is a 24hr window.
Internal Comment: date corrected
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R346425013

Discrepancy ID: 319862811

Site: 47710

Patient: 3021

Visit: DAY 4

Visit Date:

CRF: PAGE_59

Section: EOD_SNUS

Qualifying Value: 59

Field: Date

Row: 1

Value Text: 20101211

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please confirm the date/time. The current date/time occurs before any product was dispensed. Since the time is 00:14, it appears that the date should be 12-DEC-2011.

Internal Comment: per sponsor request we are to use date dispensed

Resolution Type: No Action Required

Resolution Text:

Document #: R346426013

Discrepancy ID: 277531211

Site: 47710

Patient: 3021

Visit: DAY 4

Visit Date:

CRF: PAGE_66

Section: EOD

Qualifying Value: 66

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Date is not the scheduled number of days from Day 1 08-DEC-2010. Please verify date of collection.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R346463213

Discrepancy ID: 277670111 **Site:** 47710 **Patient:** 3021
 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: Date is not the scheduled number of days from Day 1 08-DEC-2010. Please verify date of collection.
Internal Comment:
 Resolution Type: Confirmed
 Resolution Text:

Document #: R346464313

Discrepancy ID: 277670211 **Site:** 47710 **Patient:** 3021
 Visit: DAY 5/EARLY TER **Visit Date:**
 CRF: PAGE_76 **Section:** EOD **Qualifying Value:** 76
 Field: **Row:**
 Value Text:
 Type: MULTIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
 Discrepancy: Date is not the scheduled number of days from Day 1 08-DEC-2010. Please verify date of collection.
Internal Comment:
 Resolution Type: Confirmed
 Resolution Text:

Document #: R346468213

Discrepancy ID: 282584511

Site: 47710

Patient: 3021

Visit: PCM

Visit Date:

CRF: PAGE_84

Section: PCM

Qualifying Value: 84

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: please enter when med hx is complete

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R346469113

Discrepancy ID: 282585511 **Site:** 47710 **Patient:** 3021
Visit: PCM.2 **Visit Date:**
CRF: PAGE_84 **Section:** PCM **Qualifying Value:** 84
Field: Indication **Row:** 1
Value Text: LYMPHADENOPATHY
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please confirm if conmed was taken as prescribed (per footnote 2).
Internal Comment: Source/progress note requested
Resolution Type: Confirmed
Resolution Text:

Document #: R346469713

Discrepancy ID: 282587411 **Site:** 47710 **Patient:** 3021
Visit: AE **Visit Date:**
CRF: PAGE_85 **Section:** AE **Qualifying Value:** 85
Field: Adverse Event **Row:** 1
Value Text: LYMPHADENOPATHY
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: please add additional AE, when source available.
Internal Comment: ADDED
Resolution Type: Confirmed
Resolution Text:

Deleted CRFs Report