

# CRF Report for Study E8230249

Report run by Tamara Fisher at 15-AUG-2014 14:04:46

## Report Parameters

Site: 47710

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: 3025

Ending patient: 3025

## Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	<b>Abc</b> 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:

3025

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

R346780413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3025

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 R346780913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3025

Subject Initials:

(b)

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### Inclusion Criteria

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

Yes No\*

1.2

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

YES

1.3

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

YES

\*If No, document on Subject Eligibility Page.

Verified



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Page Version No. PAGE\_03 (v1, 15-OCT-2010)

Document Number

R346782313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3025

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.	NO	
02 Have any unacceptable 'safety' clinical evaluations.	NO	
03 Use of injectable forms of medication (except birth control).	NO	
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.	NO	
05 Intent to become pregnant during trial period, or current pregnancy or breast feeding.	NO	
06 History of hypersensitivity or allergies to any drug compound unless approved by the Investigator(s).	NO	
07 Poor peripheral venous access.	NO	
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.	NO	
09 Participant is an employee of Covance or RJRT.	NO	

\*If Yes, document on Subject Eligibility Page.

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Page Version No. PAGE\_04 (v1, 18-OCT-2010)

Document Number R346782613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3025

Subject Initials:

(b)

Is Blank

### Subject Eligibility

Date the Subject Signed the Informed Consent Form:

11-NOV-2010

DD/MMM/YYYY

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

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

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

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Document Number

R346782813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3025

Subject Initials:

(b)

Is Blank

#### Tobacco Abstinence Question

Was Tobacco Abstinence Question asked? ☒ Yes ☐ No

Date

DD/MMM/YYYY

11-NOV-2010

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

☒ Yes ☐ No

#### Fagerström (FTND) Questionnaire

Was FTND Questionnaire administered? ☒ Yes ☐ No

Date

DD/MMM/YYYY

11-NOV-2010

Score

6

Comments

#### Urine Cotinine Screen

Date

DD/MMM/YYYY

11-NOV-2010

Actual Time  
24-hour clock

10:26

NicCheck I  
Results

☒ Positive  
☐ Negative

Not Done

☐

Comments

Verified

☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_06 (v1, 18-OCT-2010)

Document Number

R346783013



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3025

Subject Initials:

(b)

Is Blank

#### MSFT Taste Test

Was MSFT Taste Test administered? ☒ Yes ☐ No

Date

DD/MMM/YYYY

11-NOV-2010

Product

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

SNUS Frost

☒ Yes ☐ No

SNUS Mellow

☒ Yes ☐ No

Preferred SNUS Type

☒ Frost ☐ Mellow ☐ None

Sticks

☒ Yes ☐ No

Strips

☒ Yes ☐ No

Orbs

☒ Yes ☐ No

#### Demographics

Date

DD/MMM/YYYY

11-NOV-2010

Date of Birth

DD/MMM/YYYY

(b) (6)

Gender

☐ Male

☒ Female

Ethnicity

☐ Hispanic or Latino

☒ Not Hispanic or Latino

Race

☒ White

☐ Black or African American

☐ Asian

☐ Native Hawaiian or Other Pacific Islander

☐ American Indian/Alaskan Native

☐ Other:

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

Page Version No. PAGE\_07 (v1, 15-OCT-2010)

Document Number

R346784113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3025

Subject Initials:

(b)

Is Blank

#### Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date

DD/MMM/YYYY

11-NOV-2010

Actual Time

24-hour clock

12:20

Was HDYF?

question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

120

Diastolic Blood Pressure

mmHg

75

Pulse

beats/minute

87

Respiratory Rate

breaths/minute

22

Oral Temperature

°C

36.5

#### Body Measurements

Were Body Measurements Collected? ☒ Yes ☐ No

Date

DD/MMM/YYYY

11-NOV-2010

Parameter

Unit

Result

Height

cm

162.8

Weight

kg

60.5

BMI

kg/m<sup>2</sup>

22.8

Note: Body Mass Index will be derived.

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Page Version No. PAGE\_08 (v1, 15-OCT-2010)

Document Number R346784513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

3025

Subject Initials:

(b)

Is Blank

### Laboratory Evaluations

Were the scheduled laboratory samples obtained?

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

Date

DD/MMM/YYYY

11-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:

Y247291

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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Document Number

R346785013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number: 3025

Subject Initials:

(b)

Is Blank

#### Urine Drug Screen

Was Urine Drug Screen Performed? ☒ Yes ☐ No

Date

DD/MMM/YYYY

01-DEC-2010

Urine Drug Screen Result

☐ Positive ☒ Negative

#### Urine Pregnancy Test

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

Date

DD/MMM/YYYY

16-NOV-2010

Urine Pregnancy Test Result

☐ Positive ☒ Negative

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Page Version No. PAGE\_10 (v1, 15-OCT-2010)

Document Number R346785913

## **Links to Discrepancy and Audit Sections**

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

Document Number R346786913

## **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

SCREEN 1

Subject Number: 3025

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	11-NOV-2010	12:23

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	76
PR Interval	milliseconds	158
QRS Duration	milliseconds	82
QT Interval	milliseconds	378
QTc Interval	milliseconds	425

ECG Interpretation:

☒ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_12 (v1, 15-OCT-2010)

Document Number R346787313



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

3025

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

R346787713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

3025

Subject Initials:

(b)

Is Blank

#### Usual Brand Cigarette Pack Data

Date

DD/MMM/YYYY

23-NOV-2010

Parameter

Result

Usual Brand Name

CAMEL TURKISH AND

(Note: include color designation if any)

Filtered

☒ Yes ☐ No

Length

☐ 72 mm ☐ 100 mm

☒ 85 mm ☐ 120 mm

Width

☐ Regular ☐ Super Slims

☐ Slims ☒ Wides

Fire Standard Compliant?

☒ Yes ☐ No

Packaging

☐ Soft-pack ☒ Hard-pack (box)

#### Oral Health Examination

Was Oral Health Examination performed? ☒ Yes ☐ No

Date

DD/MMM/YYYY

23-NOV-2010

Exam Determination

Result

If Yes, Please Describe

Evidence of Leukoplakia?

☐ Yes ☒ No

Evidence of Other Oral Keratosis?

☐ Yes ☒ No

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

Page Version No. PAGE\_14 (v1, 15-OCT-2010)

Document Number

R346788213

## OverFlow Section For Document Number R346788213

1 CAMEL TURKISH AND DOMESTIC BLEND

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

3025

Subject Initials:

(b)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Did Subject Smoke Single Cigarette? ☒ Yes ☐ No

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

Date	Actual Time Cigarette Smoked 24-hour clock	Actual Time Vitals Collected 24-hour clock	Was HDYF? question asked?
DD/MMM/YYYY			
23-NOV-2010	12:26	12:57	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	122
Diastolic Blood Pressure	mmHg	79
Pulse	beats/minute	97
ECO	ppm	15

Urine Cotinine Screen

Not Applicable ☒

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_15 (v1, 18-OCT-2010)

Document Number R346788413

## **Links to Discrepancy and Audit Sections**

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

### Randomization

Date

DD/MMM/YYYY

Randomization Number

Randomized Group

☐ SNUS

☐ Strips

☒ Dual Use of UB Cigarettes and SNUS

☐ Sticks

☐ Tobacco Abstinence

☐ Orbs

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_16 (v1, 15-OCT-2010)

Document Number

## **Links to Discrepancy and Audit Sections**

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name CHECK-IN, DAY -2

Subject Number: 3025

Subject Initials: (b)

Is Blank

#### Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

06-DEC-2010

Actual Time  
24-hour clock

13:06

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

113

Diastolic Blood Pressure

mmHg

79

Pulse

beats/minute

83

Respiratory Rate

breaths/minute

14

Oral Temperature

°C

36.4

#### Urine Drug Screen

Was Urine Drug Screen Performed? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

06-DEC-2010

Urine Drug Screen Result

☐ Positive ☒ Negative

#### Urine Pregnancy Test

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

Date  
DD/MMM/YYYY

06-DEC-2010

Urine Pregnancy Test Result

☐ Positive ☒ Negative

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_17 (v1, 15-OCT-2010)

Document Number R346789613



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 3025

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

08:16

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

113

Diastolic Blood Pressure

mmHg

55

Pulse

beats/minute

65

Respiratory Rate

breaths/minute

14

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

22:18

☐

#### 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

07:18

3

1.1

☐

07-DEC-2010

12:00

12:19

7

1.8

☐

07-DEC-2010

22:00

22:22

9

2.1

☐

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_18 (v1, 15-OCT-2010)

Document Number R346790013

## **Links to Discrepancy and Audit Sections**

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

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 3025

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	07:25	07:38	28	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	07-DEC-2010	11:46	11:55	41	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	07-DEC-2010	13:40	13:50	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	07-DEC-2010	17:05	17:09	48	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	07-DEC-2010	19:03	19:13	40	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	07-DEC-2010	21:46	21:52	44	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<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	6	23:36	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_19 (v1, 15-OCT-2010)

Document Number R346791013

R346791813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 3025

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		
-24 HOURS TO 0 HOUR	07-DEC-2010 07:08	08-DEC-2010 07:19	938	<input type="checkbox"/>	

### Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
07-DEC-2010	07:00	07:16	<input type="checkbox"/>	
07-DEC-2010	12:00	12:17	<input type="checkbox"/>	
07-DEC-2010	22:00	22:18	<input type="checkbox"/>	

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Page Version No. PAGE\_20 (v1, 15-OCT-2010)

Document Number R346792113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Fecal Collection

Not Applicable

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

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Page Version No. PAGE\_21 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 3025

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:

3

40% UB for Dual Use subjects:

2

☐ NA, Not Dual Use group

Comments

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_22 (v1, 02-NOV-2010)

Document Number R346792913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

3025

Subject Initials:

(b)

Is Blank

#### Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

08-DEC-2010

Actual Time  
24-hour clock

08:16

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

107

Diastolic Blood Pressure

mmHg

68

Pulse

beats/minute

76

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.7

#### Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment  
DD/MMM/YYYY

08-DEC-2010

If Yes, Specify Daily Amount

0

12-ounce serving of Ultralight Beer

0

6-ounce serving of White or Rose Wine

Verified

☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_23 (v1, 15-OCT-2010)

Document Number

R346793413



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

3025

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	11:51	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow	12:02
2	08-DEC-2010	21:36	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow	21:53
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_24 (v1, 21-OCT-2010)

Document Number

R346794713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

3025

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
08-DEC-2010	2	00:46	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_25 (v1, 21-OCT-2010)

Document Number

R346795313

## **Links to Discrepancy and Audit Sections**

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

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



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

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"/>

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"/>

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Page Version No. PAGE\_30 (v1, 19-OCT-2010)

Document Number



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

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

Document Number R346798013

## **Links to Discrepancy and Audit Sections**

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

R346799013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

3025

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
0 HOUR TO 24 HOURS	08-DEC-2010 07:19	09-DEC-2010 07:05	908	<input type="checkbox"/>	

### Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	Not Done	Comments
08-DEC-2010	07:00	07:25	<input type="checkbox"/>	
08-DEC-2010	12:00	12:25	<input type="checkbox"/>	
08-DEC-2010	22:00	22:56	<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_33 (v1, 15-OCT-2010)

Document Number R346799313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

3025

Subject Initials:

(b)

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

22:56

☐

### 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

07:29

2

1.0

☐

08-DEC-2010

12:00

12:27

3

1.1

☐

08-DEC-2010

22:00

23:03

4

1.3

☐

### Questionnaires

Date of Assessment

DD/MMM/YYYY

Scheduled Timepoint

08-DEC-2010

19:00

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

R346803313

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\_35 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
<input type="text" value="1"/>	<input type="text" value="09-DEC-2010"/>	<input type="text" value="ND"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text"/>
<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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_36 (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 2

Subject Number:

3025

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	0	23 : 38	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_37 (v1, 21-OCT-2010)

Document Number

R346805513

## **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 2

Subject Number:

3025

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_38 (v1, 15-OCT-2010)

Document Number

R346806113

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"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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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"/>

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Page Version No. PAGE\_41 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

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

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Page Version No. PAGE\_42 (v1, 19-OCT-2010)

Document Number



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Completely Consumed?	If No, then Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Orb <input type="checkbox"/> 2 Orbs	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
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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\_43 (v1, 19-OCT-2010)

Document Number

Document Number R346807613



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

3025

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

08:17

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

99

Diastolic Blood Pressure

mmHg

70

Pulse

beats/minute

67

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.3

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

2

12-ounce serving of Ultralight Beer

0

6-ounce serving of White or Rose Wine

Verified

☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_45 (v1, 15-OCT-2010)

Document Number

R346808713

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="11:46"/>	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text" value="12:02"/>
<input type="text" value="2"/>	<input type="text" value="10-DEC-2010"/>	<input type="text" value="21:47"/>	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow	<input type="text" value="21:56"/>
<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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<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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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="2"/>	<input type="text" value="23:47"/>	<input type="text" value="YES"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_47 (v1, 21-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

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"/>

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Strip <input type="checkbox"/> 2 Strips	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE\_51 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

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

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Page Version No. PAGE\_52 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

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

Document Number R346812213

Document Number R346812813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

3025

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 07:00	11-DEC-2010 06:56	634	<input type="checkbox"/>	

### 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	07:19	<input type="checkbox"/>	
10-DEC-2010	12:00	12:22	<input type="checkbox"/>	
10-DEC-2010	22:00	22:16	<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_55 (v1, 15-OCT-2010)

Document Number R346813213

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	22:16	<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	07:21	2	1.0	<input type="checkbox"/>	
10-DEC-2010	12:00	12:26	4	1.3	<input type="checkbox"/>	
10-DEC-2010	22:00	22:18	5	1.4	<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

DAY 4

Subject Number:

3025

Subject Initials:

(b)

Is Blank

#### Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date  
DD/MMM/YYYY

11-DEC-2010

Actual Time  
24-hour clock

08:16

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

105

Diastolic Blood Pressure

mmHg

69

Pulse

beats/minute

83

Respiratory Rate

breaths/minute

16

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

11-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\_57 (v1, 15-OCT-2010)

Document Number

R346813913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

3025

Subject Initials:

(b)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

NOTCHECK

Seq.	Date DD/MM/YY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	11-DEC-2010	ND	<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	ND
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_58 (v1, 21-OCT-2010)

Document Number

R346814513

## **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 ☐

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="0"/>	<input type="text" value="00:14"/>	<input type="text" value="YES"/>

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Page Version No. PAGE\_59 (v1, 21-OCT-2010)

Document Number

## **Links to Discrepancy and Audit Sections**

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

[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:

3025

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\_61 (v1, 15-OCT-2010)

Document Number

R346815913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

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

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Page Version No. PAGE\_62 (v1, 15-OCT-2010)

Document Number



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

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

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Page Version No. PAGE\_63 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

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

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Page Version No. PAGE\_64 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

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

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

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	11-DEC-2010	17:07	17:11	45	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

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
12-DEC-2010	1	00:14	YES

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Page Version No. PAGE\_66 (v1, 18-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 DAY 5/EARLY TERM

Subject Number: 3025

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

08:16

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

108

Diastolic Blood Pressure

mmHg

80

Pulse

beats/minute

93

Respiratory Rate

breaths/minute

16

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

12-DEC-2010

If Yes, Specify Daily Amount

1

12-ounce serving of Ultralight Beer

0

6-ounce serving of White or Rose Wine

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Page Version No. PAGE\_67 (v1, 15-OCT-2010)

Document Number R346823813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3025

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	11:46	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow	11:55
2	12-DEC-2010	21:46	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow	21:53
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_68 (v1, 21-OCT-2010)

Document Number R346824713



R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3025

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	2	00:07	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_69 (v1, 21-OCT-2010)

Document Number R346825213

## **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: 3025

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	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_71 (v1, 15-OCT-2010)

Document Number R346826013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3025

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	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_72 (v1, 15-OCT-2010)

Document Number R346826413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3025

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	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_73 (v1, 15-OCT-2010)

Document Number R346826813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3025

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	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_74 (v1, 19-OCT-2010)

Document Number R346827113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3025

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 R346827413



Document Number R346827813

## **Links to Discrepancy and Audit Sections**

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Document Number R346828313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3025

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 07:02	13-DEC-2010 06:57	1141	<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	07:45	<input type="checkbox"/>	
12-DEC-2010	12:00	12:22	<input type="checkbox"/>	
12-DEC-2010	22:00	22:16	<input type="checkbox"/>	

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_77 (v1, 15-OCT-2010)

Document Number R346828613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3025

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 R346830313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3025

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	22:16	<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	07:49	2	1.0	<input type="checkbox"/>	
12-DEC-2010	12:00	12:25	2	1.0	<input type="checkbox"/>	
12-DEC-2010	22:00	22:19	2	1.0	<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 R346830713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 3025

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:

Y247507

Requisition Number 2 (if applicable):

1111163770

Requisition Number 3 (if applicable):

Requisition Number 4 (if applicable):

Requisition Number 5 (if applicable):

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

Requisition Number

Test Name

Test Code ID


### Urine Pregnancy Test

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

Date

DD/MMM/YYYY

12-DEC-2010

Urine Pregnancy Test Result

☐ Positive ☒ Negative

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_80 (v1, 18-OCT-2010)

Document Number R346831313

## **Links to Discrepancy and Audit Sections**

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Document Number R346832113

## **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: 3025

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	08:31

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	74
PR Interval	milliseconds	168
QRS Duration	milliseconds	80
QT Interval	milliseconds	364
QTc Interval	milliseconds	404

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 R346832513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DISCHARGE, DAY 6

Subject Number: 3025

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

07:11

Was HDYF?  
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

107

Diastolic Blood Pressure

mmHg

63

Pulse

beats/minute

76

Respiratory Rate

breaths/minute

18

Oral Temperature

°C

36.5

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_83 (v1, 15-OCT-2010)

Document Number R346833013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

### Previous and Concomitant Medications

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

☒ Yes, list below. ☐ No

Drug Name:

Indication:

Dose:

Unit: Select only one

☐ grams

☐ micrograms

☒ milligrams

☐ milliliter

☐ tablet

☐ other, specify:

Frequency: Select only one

☐ one time

☐ whenever necessary

☐ every morning

☐ at bedtime

☐ every day

☒ twice daily

☐ three times daily

☐ four times daily

☐ every four hours

☐ every other day

☐ every week

☐ other, specify:

Route: Select only one

☒ Oral

☐ Topical

☐ Subcutaneous

☐ Intravenous

☐ Intramuscular

☐ Intradermal

☐ Ocular, Left

☐ Ocular, Right

☐ Ocular, Both

☐ Sublingual

☐ Other, specify:

Start Date

DD/MMM/YYYY

Stop Date

DD/MMM/YYYY

☐ Ongoing

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_84 (v1, 15-OCT-2010)

Document Number

## **Links to Discrepancy and Audit Sections**

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

#### Previous and Concomitant Medications

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

☒ Yes, list below. ☐ No

Drug Name:

Indication:

Dose:

Unit: Select only one

☐ grams

☐ micrograms

☒ milligrams

☐ milliliter

☐ tablet

☐ other, specify:

Frequency: Select only one

☒ one time

☐ whenever necessary

☐ every morning

☐ at bedtime

☐ every day

☐ twice daily

☐ three times daily

☐ four times daily

☐ every four hours

☐ every other day

☐ every week

☐ other, specify:

Route: Select only one

☒ Oral

☐ Topical

☐ Subcutaneous

☐ Intravenous

☐ Intramuscular

☐ Intradermal

☐ Ocular, Left

☐ Ocular, Right

☐ Ocular, Both

☐ Sublingual

☐ Other, specify:

Start Date

DD/MMM/YYYY

Stop Date

DD/MMM/YYYY

☐ Ongoing

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_84 (v1, 15-OCT-2010)

Document Number

## **Links to Discrepancy and Audit Sections**

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

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

AE

Subject Number:

3025

Subject Initials:

(b)

Is Blank

#### Adverse Events

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

Event Number:

1

Adverse Event:

HEADACHE

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

07-DEC-2010

04:10

07-DEC-2010

09:16

☐ 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

R346836113

## **Links to Discrepancy and Audit Sections**

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

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

#### Adverse Events

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

Event Number:

Adverse Event:

Onset Date	Onset Time	Resolved Date	Resolved Time
DD/MMM/YYYY	24-hour clock	DD/MMM/YYYY	24-hour clock
<input type="text" value="07-DEC-2010"/>	<input type="text" value="16:15"/>	<input type="text" value="07-DEC-2010"/>	<input type="text" value="18:30"/>
<input type="checkbox"/> Ongoing			

Severity: Select only one

- ☒ Mild  
☐ Moderate  
☐ Severe

Action Taken Select only one

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

Other Action Select all that apply

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

Relationship Select only one  
to Study Treatment: ☒ Not Related

- ☐ Possible  
☐ Probable  
☐ Definite

Serious Event: Select only one

- ☐ Yes  
☒ No

Outcome: Select only one

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_85 (v1, 19-OCT-2010)

Document Number

## **Links to Discrepancy and Audit Sections**

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

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

AE

Subject Number:

3025

Subject Initials:

(b)

Is Blank

#### Adverse Events

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

Event Number:

3

Adverse Event:

DYSPEPSIA

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

08-DEC-2010

00:01

08-DEC-2010

02:00

☐ 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: GAVE SIERRA MIST 240

Relationship to Study Treatment: Select only one  
☒ 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

R346891613

## OverFlow Section For Document Number R346891613

1 GAVE SIERRA MIST 240 ML

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

AE

Subject Number:

3025

Subject Initials:

(b)

Is Blank

#### Adverse Events

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

Event Number:

4

Adverse Event:

DYSPEPSIA

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

08-DEC-2010

07:20

09-DEC-2010

19:00

☐ 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

R346891813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

AE

Subject Number:

3025

Subject Initials:

(b)

Is Blank

#### Adverse Events

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

Event Number:

5

Adverse Event:

DYSMENORRHEA

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

11-DEC-2010

UNK

11-DEC-2010

UNK

☐ 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

R350732913



## **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 VS ADDITIONAL

Subject Number: 3025

Subject Initials: (b)

Is Blank

### Additional Assessments - Vital Signs

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

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

☐ Standing

☐ Supine

☐ Seated

☐ Other, Specify:

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

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

☐ Standing

☐ Supine

☐ Seated

☐ Other, Specify:

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_86 (v1, 18-OCT-2010)

Document Number R346892013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

LB ADDITIONAL

Subject Number:

3025

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
16-NOV-2010	Y247668	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
23-NOV-2010	1111161000	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
23-NOV-2010	1111160998	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
01-DEC-2010	1111162346	<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			

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE\_87 (v1, 15-OCT-2010)

Document Number

R346785413

## **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 EG ADDITIONAL

Subject Number: 3025

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 R346892413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank

☐

### Study Completion

Date the subject completed OR withdrew from the study:

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

## 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 #:** R346786913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
3025	Screen 1	Page_11	
47710		011	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Mh	Page number	11	Screen 1

<b>Group #</b>	<b>Group Name</b>
1	MH

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Code 1	GASTRO	02-FEB-2011 15:06:33 Kim Freschly	Row Inserted
Date of Onset 1	00-00-2009	02-FEB-2011 15:06:33 Kim Freschly	Row Inserted
Date of Resolution 1		02-FEB-2011 15:06:33 Kim Freschly	Row Inserted
Diagnosis/Procedure 1	INTERMITTENT INDIGESTION	02-FEB-2011 15:06:33 Kim Freschly	Row Inserted
Does the subject have any relevant medication 1	NO YES	02-FEB-2011 15:05:46 Kim Freschly	Data Entry Error
Ongoing 1	CHECKED	02-FEB-2011 15:06:33 Kim Freschly	Row Inserted

**Document #:** R346788413

Patient Site	Visit Visit Date	CRF CRF Page
3025	Screen 2	Page_15
47710		015

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

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ECO (ppm) (2)	18	28-JAN-2011 13:04:12	Data Entry Error
1	15	Lana Glaser	

**Document #:**     **R346789313**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
3025	Screen 2	Page_16
47710		016

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Sc	Page number	16	Screen 2

<b>Group #</b>	<b>Group Name</b>
1	SC

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Randomized Group	SNUS	28-JAN-2011 13:12:07	Data Entry Error
1	DUAL	Lana Glaser	

**Document #:** R346790013

<b>Patient</b>	<b>Visit</b>	<b>CRF</b>	
<b>Site</b>	<b>Visit Date</b>	<b>CRF Page</b>	
3025	Baseline, Day -1	Page_18	
47710		018	
<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			
Eco	Page number	18	Baseline, Day -1

  

<b>Group #</b>	<b>Group Name</b>		
1	PCB		
<b>Field</b>	<b>Changed From</b>	<b>Impact on</b>	<b>Reason</b>
<b>Row</b>	<b>Changed To</b>	<b>On</b>	<b>Comment</b>
		<b>resequence</b>	
		<b>By</b>	
% COHb (2)	1.	28-JAN-2011 13:08:55	Data Entry Error
2	1.8	Lana Glaser	

**Document #:**      **R346795313**

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
3025	Day 1	Page_25
47710		025

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Eod_Snus	Page number	25	Day 1

<b>Group #</b>	<b>Group Name</b>
1	INDYN

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Date	09-DEC-2010	05-JAN-2011 09:26:58	Data Entry Error
1	08-DEC-2010	Lana Glaser	

Document #: R346804713

Patient Site	Visit Visit Date	CRF CRF Page	
3025	Day 2	Page_36	
47710		036	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit

Group #	Group Name		
0	CRF Header		
Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag	Y	28-JAN-2011 13:14:01	Data Entry Error
1	N	Lana Glaser	

**Document #:** R346804713

Patient Site	Visit Visit Date	CRF CRF Page
3025	Day 2	Page_36
47710		036

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

Group #	Group Name
1	SU

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Seq. 1	1	28-JAN-2011 13:15:46 Lana Glaser	Data Entry Error



Document #: R346805513

Patient Site	Visit Visit Date	CRF CRF Page
3025	Day 2	Page_37
47710		037

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag	Y	28-JAN-2011 13:17:56	Data Entry Error
1	N	Lana Glaser	

**Document #:** R346805513

<b>Patient</b>	<b>Visit</b>	<b>CRF</b>	
<b>Site</b>	<b>Visit Date</b>	<b>CRF Page</b>	
3025	Day 2	Page_37	
47710		037	
<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			
Eod_Snus	Page number	37	Day 2

<b>Group #</b>	<b>Group Name</b>
1	INDYN

<b>Field</b>	<b>Changed From</b>	<b>Impact on</b>	<b>On</b>	<b>Reason</b>
<b>Row</b>	<b>Changed To</b>	<b>resequence</b>	<b>By</b>	<b>Comment</b>
Date	ND		20-APR-2011 10:36:29	Data Entry Error
1	09-DEC-2010		Lana Glaser	
Time of Day	NA		29-MAR-2011 09:37:39	Data Entry Error
Frozen (-70C)	UNK		Kim Freschly	
1				
Time of Day	UNK		20-APR-2011 10:37:04	Data Entry Error
Frozen (-70C)	2338		Lana Glaser	
1				

Document #: R346814513

Patient Site	Visit Visit Date	CRF CRF Page	
3025	Day 4	Page_58	
47710		058	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit

Group #	Group Name		
0	CRF Header		
Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag	Y		
1	N	04-FEB-2011 08:56:21 Kim Freschly	Data Entry Error

**Document #:** R346814813

<b>Patient</b>	<b>Visit</b>	<b>CRF</b>	
<b>Site</b>	<b>Visit Date</b>	<b>CRF Page</b>	
3025	Day 4	Page_59	
47710		059	
<b>Section</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
<b>Section Date</b>			
Eod_Snus	Page number	59	Day 4

<b>Group #</b>	<b>Group Name</b>
1	INDYN

<b>Field</b>	<b>Changed From</b>	<b>Impact on</b>	<b>On</b>	<b>Reason</b>
<b>Row</b>	<b>Changed To</b>	<b>resequence</b>	<b>By</b>	<b>Comment</b>
Date	12-DEC-2010		04-FEB-2011 08:51:52	Data Entry Error
1	11-DEC-2010		Kim Freschly	
Time of Day	0014		28-JAN-2011 13:20:52	Data Entry Error
Frozen (-70C)	NA		Lana Glaser	
1				
Time of Day	NA		29-MAR-2011 09:39:36	Data Entry Error
Frozen (-70C)	UNK		Kim Freschly	
1				
Time of Day	UNK		20-APR-2011 10:38:52	Data Entry Error
Frozen (-70C)	0014		Lana Glaser	
1				

**Document #:** R346831313

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
3025	Day 5/Early Term	Page_80	
47710		080	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Lb	Page number	80	Day 5/Early Term
<b>Group #</b>	<b>Group Name</b>		
1	LB		
<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Requisition Number 2 (if applicable): (2)	1111163770	28-JAN-2011 13:23:25 Lana Glaser	Data Entry Error
1			

**Document #:** R346832113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
3025	Day 5/Early Term	Page_81	
47710		081	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pe	Page number	81	Day 5/Early Term

  

<b>Group #</b>	<b>Group Name</b>		
1	PE		

  

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Does the subject have any relevant findi 1	YES NO	05-JAN-2011 10:57:41 Lana Glaser	Data Entry Error

**Document #:** R346834213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
3025	Pcm	Page_84
47710		084

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	84	Pcm

<b>Group #</b>	<b>Group Name</b>
1	CM

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Frequency	ONCE	05-JAN-2011 11:07:24	Data Entry Error
1	TWICE DAILY	Lana Glaser	

**Document #:** R346835013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
3025	Pcm.1	Page_84
47710		

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	84	Pcm.1

<b>Group #</b>	<b>Group Name</b>
1	CM

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Indication	MENSTRUAL CRAMPS	02-FEB-2011 15:13:57	Data Entry Error
1	DYSMENORRHEA	Kim Freschly	



**Document #:** R346836113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
3025	Ae	Page_85
47710		085

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Ae	Page number	85	Ae

<b>Group #</b>	<b>Group Name</b>
1	AE

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Action Taken with Study Treatment 1	NOT CHANGED NA	06-APR-2011 13:43:26 Lana Glaser	Data Entry Error

**Document #:** R346891513

Patient Site	Visit Visit Date	CRF CRF Page
3025	Ae.1	Page_85
47710		

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

Group #	Group Name
1	AE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Taken with Study Treatment 1	NOT CHANGED NA	29-MAR-2011 09:43:12 Kim Freschly	Data Entry Error

**Document #:** R346785413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
3025	Lb Additional	Page_87	
47710		087	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Lb	Page number	87	Lb Additional

<b>Group #</b>	<b>Group Name</b>
1	LB

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Clinically Significant? (Additional) 5	NO <Row Deleted>	28-JAN-2011 13:27:53 Lana Glaser	Data Entry Error
Comments 5	<Row Deleted>	28-JAN-2011 13:27:53 Lana Glaser	Data Entry Error
Date 5	12-DEC-2010 <Row Deleted>	28-JAN-2011 13:27:53 Lana Glaser	Data Entry Error
Requisition Number (Additional) (6) 5	1111163770 <Row Deleted>	28-JAN-2011 13:27:53 Lana Glaser	Data Entry Error
Test Code ID (CS Labs Only) 5	<Row Deleted>	28-JAN-2011 13:27:53 Lana Glaser	Data Entry Error
Test Name (CS Labs Only) 5	<Row Deleted>	28-JAN-2011 13:27:53 Lana Glaser	Data Entry Error

# Discrepancy Detail Report

Document #: R346785913

Discrepancy ID: 318682811 Site: 47710 Patient: 3025

Visit: SCREEN 1

Visit Date:

CRF: PAGE\_10

Section: DRUGSCR

Qualifying Value: 10

Field: Date

Row: 1

Value Text: 20101201

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify the date, as all other assessments were performed in November. Also, if this was performed on 01DEC2010, please write a NTSF since Screen 2 is not 3 or more days after Screen 1.

Internal Comment: date correct as entered, please NTF

Resolution Type: No Action Required

Resolution Text:

**Document #: R346786913**

**Discrepancy ID:** 297822811 **Site:** 47710 **Patient:** 3025

**Visit:** SCREEN 1

**Visit Date:**

**CRF:** PAGE\_11

**Section:** MH

**Qualifying Value:** 11

**Field:** Date of Onset

**Row:** 1

**Value Text:** 2009

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** please review med hx source indicates "for about 7 years, on and off"

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:** Source clarified

**Discrepancy ID:** 283529611 **Site:** 47710 **Patient:** 3025

**Visit:** SCREEN 1

**Visit Date:**

**CRF:** PAGE\_11

**Section:** MH

**Qualifying Value:** 11

**Field:** Does the subject have any relevant medic

**Row:** 1

**Value Text:** YES

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** please review relevance of indigestion and menstrual cramps due to on study conmed use or AE

**Internal Comment:** Source document updates requested.  
SOURCE AND CRF CORRECTED

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R346788413**

<b>Discrepancy ID:</b> 283163811	<b>Site:</b> 47710	<b>Patient:</b> 3025
<b>Visit:</b> SCREEN 2	<b>Visit Date:</b>	
<b>CRF:</b> PAGE_15	<b>Section:</b> VS	<b>Qualifying Value:</b> 15
<b>Field:</b> ECO (ppm)		<b>Row:</b> 1
<b>Value Text:</b> 15		
<b>Type:</b> MANUAL	<b>Status:</b> CURRENT	
<b>Review Status:</b> Resolved-Response Edited		
<b>Discrepancy:</b> please review - ECO		
<b>Internal Comment:</b>		
<b>Resolution Type:</b> Confirmed		
<b>Resolution Text:</b>		

**Document #: R346789313**

**Discrepancy ID:** 283163011                      **Site:** 47710                      **Patient:** 3025  
**Visit:** SCREEN 2                      **Visit Date:**  
**CRF:** PAGE\_16                      **Section:** SC                      **Qualifying Value:** 16  
**Field:** Randomized Group                      **Row:** 1  
**Value Text:** DUAL  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** please review

**Internal Comment:**

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

**Resolution Text:**

**Discrepancy ID:** 283163611                      **Site:** 47710                      **Patient:** 3025  
**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 11-NOV-2010. Please  
reconcile.

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R346790013**

**Discrepancy ID:** 283164111                      **Site:** 47710                      **Patient:** 3025  
**Visit:** BASELINE, DAY -1   **Visit Date:**  
**CRF:** PAGE\_18                      **Section:** ECO                      **Qualifying Value:** 18  
**Field:** % COHb                      **Row:** 2  
**Value Text:** 1.8  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** please review  
**Internal Comment:**  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**



**Document #: R346795313**

**Discrepancy ID:** 283164511

**Site:** 47710

**Patient:** 3025

**Visit:** DAY 1

**Visit Date:**

**CRF:** PAGE\_25

**Section:** EOD\_SNUS

**Qualifying Value:** 25

**Field:** Date

**Row:** 1

**Value Text:** 20101208

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** This Date/Time occurs befosre any SNUS was dispensed. Please confirm if the date should be 09DEC2010.

**Internal Comment:** date put in freezer is 09DEC2010, however we were told to use date dispensed, which is 08DEC2010

**Resolution Type:** No Action Required

**Resolution Text:**

**Document #: R346798013**

**Discrepancy ID:** 279587611

**Site:** 47710

**Patient:** 3025

**Visit:** DAY 1

**Visit Date:**

**CRF:** PAGE\_32

**Section:** EOD

**Qualifying Value:** 32

**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 #: R346804713**

**Discrepancy ID:** 294290611                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 2                      **Visit Date:**  
**CRF:** PAGE\_36                      **Section:** SNUS\_DISP                      **Qualifying Value:** 36  
**Field:** Amount Dispensed                      **Row:** 1  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Amount Dispensed has not been supplied  
**Internal Comment:** no snus dispensed  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Discrepancy ID:** 294290711                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 2                      **Visit Date:**  
**CRF:** PAGE\_36                      **Section:** SNUS\_DISP                      **Qualifying Value:** 36  
**Field:** Flavor Dispensed                      **Row:** 1  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Flavor Dispensed has not been supplied  
**Internal Comment:** no snus dispensed  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Discrepancy ID:** 294290811                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 2                      **Visit Date:**  
**CRF:** PAGE\_36                      **Section:** SNUS\_DISP                      **Qualifying Value:** 36  
**Field:** Time Returned                      **Row:** 1  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Time Returned has not been supplied  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

## R346804713

Discrepancy ID: 283166311 Site: 47710 Patient: 3025

Visit: DAY 2

Visit Date:

CRF: PAGE\_36

Section: SNUS\_DISP

Qualifying Value: 36

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per conversation with DM on 12Jan11, please add date, time = ND and close queries stating no Snus was dispensed

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Discrepancy ID: 294302411 Site: 47710 Patient: 3025

Visit: DAY 2

Visit Date:

CRF: PAGE\_36

Section: SNUS\_DISP

Qualifying Value: 36

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

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

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

**Document #: R346805513**

**Discrepancy ID:** 319917211                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 2                      **Visit Date:**  
**CRF:** PAGE\_37                      **Section:** EOD\_SNUS                      **Qualifying Value:** 37  
**Field:** Time of Day Frozen (-70C)                      **Row:** 1  
**Value Text:** 2338  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please remove NA and report 'UNK' if the time is unknown.  
**Internal Comment:** corrected  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Discrepancy ID:** 330070611                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 2                      **Visit Date:**  
**CRF:** PAGE\_37                      **Section:** EOD\_SNUS                      **Qualifying Value:** 37  
**Field:**                      **Row:**  
**Value Text:**  
**Type:** MANUAL HEADER                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** The source data indicates that the empty vial (no SNUS were used) was frozen at 2338.  
Please verify if this time should be used instead of "UNK"  
**Internal Comment:** time added  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Discrepancy ID:** 330070711                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 2                      **Visit Date:**  
**CRF:** PAGE\_37                      **Section:** EOD\_SNUS                      **Qualifying Value:** 37  
**Field:**                      **Row:**  
**Value Text:**  
**Type:** MANUAL HEADER                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** For consistency, please see other entries for subject 3025. The study date was listed  
and 0 SNUS were given. Please verify if 09Dec2010 should be entered instead of "ND"  
**Internal Comment:** added date and time  
**Resolution Type:** Confirmed  
**Resolution Text:**

## R346805513

**Discrepancy ID:** 283165511

**Site:** 47710

**Patient:** 3025

**Visit:** DAY 2

**Visit Date:**

**CRF:** PAGE\_37

**Section:** EOD\_SNUS

**Qualifying Value:** 37

**Field:**

**Row:**

**Value Text:**

**Type:** MANUAL HEADER

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** please enter date, total of 0, time of day will be NA, count agrees YES.

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R346814513**

**Discrepancy ID:** 296834311                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 4                      **Visit Date:**  
**CRF:** PAGE\_58                      **Section:** SNUS\_DISP                      **Qualifying Value:** 58  
**Field:** Amount Dispensed                      **Row:** 1  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Amount Dispensed has not been supplied  
**Internal Comment:** DID NOT USE ANY SNUS ON DAY 4  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Discrepancy ID:** 296834411                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 4                      **Visit Date:**  
**CRF:** PAGE\_58                      **Section:** SNUS\_DISP                      **Qualifying Value:** 58  
**Field:** Flavor Dispensed                      **Row:** 1  
**Value Text:**  
**Type:** UNIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Value for Flavor Dispensed has not been supplied  
**Internal Comment:** DID NOT USE ANY SNUS ON DAY 4  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Discrepancy ID:** 296834511                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 4                      **Visit Date:**  
**CRF:** PAGE\_58                      **Section:** SNUS\_DISP                      **Qualifying Value:** 58  
**Field:**                      **Row:**  
**Value Text:**  
**Type:** MULTIVARIATE                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** 'NA, Not SNUS or Dual Use Group' is not ticked, but details have not been recorded.  
Please reconcile.  
**Internal Comment:** DID NOT USE ANY SNUS ON DAY 4  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R346814813**

**Discrepancy ID:** 283371911                      **Site:** 47710                      **Patient:** 3025  
**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:** If time is removed, perhaps the date should = day 4  
**Internal Comment:** Day 4 = 11dec2010  
CORRECTED DATE  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Discrepancy ID:** 283371711                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 4                      **Visit Date:**  
**CRF:** PAGE\_59                      **Section:** EOD\_SNUS                      **Qualifying Value:** 59  
**Field:** Time of Day Frozen (-70C)                      **Row:** 1  
**Value Text:** 0014  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please remove NA and report 'UNK' if the time is unknown.  
**Internal Comment:** corrected  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Discrepancy ID:** 330054711                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 4                      **Visit Date:**  
**CRF:** PAGE\_59                      **Section:** EOD\_SNUS                      **Qualifying Value:** 59  
**Field:**                      **Row:**  
**Value Text:**  
**Type:** MANUAL HEADER                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Per source data, there is a freeze time of 0014 (not Unknown). There were no SNUS used by the subject, but it appears the empty bottle was still frozen. Please verify if this entry should be 0014 instead of "UNK"  
**Internal Comment:** time added  
**Resolution Type:** Confirmed  
**Resolution Text:**



**Document #: R346822513**

**Discrepancy ID:** 279607711

**Site:** 47710

**Patient:** 3025

**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 #: R346825213**

**Discrepancy ID:** 279617111                      **Site:** 47710                      **Patient:** 3025  
**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 #: R346827813**

**Discrepancy ID:** 279623211                      **Site:** 47710                      **Patient:** 3025  
    **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 #: R346831313**

**Discrepancy ID:** 283398511                      **Site:** 47710                      **Patient:** 3025  
**Visit:** DAY 5/EARLY TER    **Visit Date:**  
**CRF:** PAGE\_80                      **Section:** LB                      **Qualifying Value:** 80  
**Field:** Requisition Number 2 (if applicable):                      **Row:** 1  
**Value Text:** 1111163770  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** please add req # for EOS hematology report (12dec2010 @12:22)  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R346835013**

**Discrepancy ID:** 283419611                      **Site:** 47710                      **Patient:** 3025  
**Visit:** PCM.1                      **Visit Date:**  
**CRF:** PAGE\_84                      **Section:** PCM                      **Qualifying Value:** 84  
**Field:** Indication                      **Row:** 1  
**Value Text:** DYSMENORRHEA  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** please add AE or med Hx for menstrual cramps as conmed was used.  
**Internal Comment:** Source update requested.  
                         AE ADDED  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R346836113**

**Discrepancy ID:** 320362211                      **Site:** 47710                      **Patient:** 3025  
**Visit:** AE                      **Visit Date:**  
**CRF:** PAGE\_85                      **Section:** AE                      **Qualifying Value:** 85  
**Field:** Action Taken with Study Treatment                      **Row:** 1  
**Value Text:** NA  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Since the AE occurred before any product was used, would this be better identified as  
                    'Not Applicable'?  
**Internal Comment:** changed to NA  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Document #: R346891513**

**Discrepancy ID:** 320362311                      **Site:** 47710                      **Patient:** 3025  
**Visit:** AE.1                      **Visit Date:**  
**CRF:** PAGE\_85                      **Section:** AE                      **Qualifying Value:** 85  
**Field:** Action Taken with Study Treatment                      **Row:** 1  
**Value Text:** NA  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Since the AE occurred before any product was used, would this be better identified as  
                    'Not Applicable'?  
**Internal Comment:** entry error  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Document #: R350732913**

<b>Discrepancy ID:</b> 296257811	<b>Site:</b> 47710	<b>Patient:</b> 3025
<b>Visit:</b> AE.4	<b>Visit Date:</b>	
<b>CRF:</b> PAGE_85	<b>Section:</b> AE	<b>Qualifying Value:</b> 85
<b>Field:</b> Severity		<b>Row:</b> 1
<b>Value Text:</b>		
<b>Type:</b> UNIVARIATE	<b>Status:</b> CURRENT	
<b>Review Status:</b> Resolved-Response Edited		
<b>Discrepancy:</b> Value for Severity has not been supplied		
<b>Internal Comment:</b> SEVERITY UNKNOWN		
<b>Resolution Type:</b> Confirmed		
<b>Resolution Text:</b>		

  

<b>Discrepancy ID:</b> 296257911	<b>Site:</b> 47710	<b>Patient:</b> 3025
<b>Visit:</b> AE.4	<b>Visit Date:</b>	
<b>CRF:</b> PAGE_85	<b>Section:</b> AE	<b>Qualifying Value:</b> 85
<b>Field:</b>		<b>Row:</b>
<b>Value Text:</b>		
<b>Type:</b> MULTIVARIATE	<b>Status:</b> CURRENT	
<b>Review Status:</b> Resolved-Response Edited		
<b>Discrepancy:</b> Did the subject experience any adverse events?' has been answered Yes, but details are missing. Please reconcile.		
<b>Internal Comment:</b> SEVERITY UNKNOWN		
<b>Resolution Type:</b> Confirmed		
<b>Resolution Text:</b>		

  

<b>Discrepancy ID:</b> 296258011	<b>Site:</b> 47710	<b>Patient:</b> 3025
<b>Visit:</b> AE.4	<b>Visit Date:</b>	
<b>CRF:</b> PAGE_85	<b>Section:</b> AE	<b>Qualifying Value:</b> 85
<b>Field:</b>		<b>Row:</b>
<b>Value Text:</b>		
<b>Type:</b> MULTIVARIATE	<b>Status:</b> CURRENT	
<b>Review Status:</b> Resolved-Response Edited		
<b>Discrepancy:</b> The Subject has had an Adverse Event of DYSMENORRHEA with a Onset Date of 11-DEC-2010 but the Resolved Time is missing and Ongoing is not ticked. Please provide the Resolved Time of the AE or clarify if Ongoing.		
<b>Internal Comment:</b> RESOLVE TIME UNKNOWN		
<b>Resolution Type:</b> Confirmed		
<b>Resolution Text:</b>		



# Deleted CRFs Report