

CRF Report for Study E8230249

Report run by Tamara Fisher at 13-AUG-2014 16:46:57

Report Parameters

Site: M01

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: 1044

Ending patient: 1044

Legend: How different values appear in the report

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

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

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Investigator:

MANDARINO

Information Correct?

☒ Yes ☐ No

REMOTE DATA CAPTURE CASE REPORT FORM

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

Protocol No. CSD0901

Covance Study No. 8230249

for

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

by

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

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

Document Number R340815013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

☐

Inclusion Criteria

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

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

*If No, document on Subject Eligibility Page.

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

Document Number R340815113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

☐

Inclusion Criteria

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

Yes No*

12

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

13

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

R340815213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

☐

Exclusion Criteria

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

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

*If Yes, document on Subject Eligibility Page.

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

Document Number R340815313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

14-OCT-2010

DD/MMM/YYYY

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

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

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

Verified



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

Document Number

R340815413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Tobacco Abstinence Question

Was Tobacco Abstinence Question asked? ☒ Yes ☐ No

Date

DD/MMM/YYYY

14-OCT-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

14-OCT-2010

Score

4

Comments

Urine Cotinine Screen

Date

DD/MMM/YYYY

14-OCT-2010

Actual Time
24-hour clock

09:22

NicCheck I
Results

☒ Positive
☐ Negative

Not Done

☐

Comments

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

Document Number R340815513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

MSFT Taste Test

Was MSFT Taste Test administered? ☒ Yes ☐ No

Date

DD/MMM/YYYY

Product

SNUS Frost

SNUS Mellow

Preferred SNUS Type

Sticks

Strips

Orbs

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

☒ Yes ☐ No

☒ Yes ☐ No

☒ Frost ☐ Mellow ☐ None

☒ Yes ☐ No

☒ Yes ☐ No

☒ Yes ☐ No

Demographics

Date

DD/MMM/YYYY

Date of Birth

DD/MMM/YYYY

Gender

☐ Male

☒ Female

Ethnicity

☐ Hispanic or Latino

☒ Not Hispanic or Latino

Race

☒ White

☐ Black or African American

☐ Asian

☐ Native Hawaiian or Other Pacific Islander

☐ American Indian/Alaskan Native

☐ Other:

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date

DD/MMM/YYYY

14-OCT-2010

Actual Time

24-hour clock

08:50

Was HDYF?

question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

123

Diastolic Blood Pressure

mmHg

90

Pulse

beats/minute

73

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.7

Body Measurements

Were Body Measurements Collected? ☒ Yes ☐ No

Date

DD/MMM/YYYY

14-OCT-2010

Parameter

Unit

Result

Height

cm

163.1

Weight

kg

84.4

BMI

kg/m²

31.7

Note: Body Mass Index will be derived.

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

Document Number R340815813

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

SCREEN 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Laboratory Evaluations

Were the scheduled laboratory samples obtained?

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

Date

DD/MMM/YYYY

14-OCT-2010

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

Requisition Number 1:

Y245002

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

R340815913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Urine Drug Screen

Was Urine Drug Screen Performed? ☒ Yes ☐ No

Date

DD/MMM/YYYY

14-OCT-2010

Urine Drug Screen Result

☐ Positive ☒ Negative

Urine Pregnancy Test

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

Date

DD/MMM/YYYY

14-OCT-2010

Urine Pregnancy Test Result

☐ Positive ☒ Negative

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

Document Number

R340816213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Medical History

Does the subject have any relevant medical history?

☐ Yes ☒ No

Date

DD/MMM/YYYY

Consider the following systems when performing the assessment:

- | | | |
|------------------------------------|--------------------------|------------------|
| 01 Skin | 06 Lymphatic/Hematologic | 11 Neurological |
| 02 Ears, Eyes, Nose, Throat (EENT) | 07 Gastrointestinal | 12 Immunological |
| 03 Breasts | 08 Genitourinary | 13 Psychological |
| 04 Respiratory | 09 Musculoskeletal | 14 Allergies |
| 05 Cardiovascular | 10 Endocrine | |

Code	Diagnosis/Procedure	Date of Onset DD/MMM/YYYY	Date of Resolution DD/MMM/YYYY	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Ongoing
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Ongoing
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Ongoing
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Ongoing
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Ongoing
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Ongoing
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Ongoing
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Ongoing
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Ongoing
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Ongoing
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Ongoing

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Supine 12-Lead Electrocardiogram Report

Was ECG performed?	Date DD/MMM/YYYY	Actual Time 24-hour clock
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	14-OCT-2010	09:29

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	63
PR Interval	milliseconds	152
QRS Duration	milliseconds	84
QT Interval	milliseconds	394
QTc Interval	milliseconds	403

ECG Interpretation:

☐ Normal ☒ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

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

Document Number R340816713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Complete Physical Examination

Does the subject have any relevant findings?

☐ Yes ☒ No

Date

DD/MMM/YYYY

21-OCT-2010

Consider the following systems when performing the assessment:

01 General Appearance

05 Pulmonary

09 Lymphatic

02 Skin

06 Chest

10 Musculoskeletal

03 Ears, Eyes, Nose, Throat

07 Cardiovascular

11 Neurological

04 Head/Neck

08 Abdomen and Liver/Spleen

Code

Findings

Verified



Approved



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

Document Number

R340816913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Usual Brand Cigarette Pack Data

Date
DD/MMM/YYYY

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

Oral Health Examination

Was Oral Health Examination performed? ☒ Yes ☐ No

Date
DD/MMM/YYYY

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

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

Document Number

OverFlow Section For Document Number R340931913

1 MARLBORO GOLD PACK

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Did Subject Smoke Single Cigarette? ☒ Yes ☐ No

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

Date DD/MMM/YYYY	Actual Time Cigarette Smoked 24-hour clock	Actual Time Vitals Collected 24-hour clock	Was HDYF? question asked?
21-OCT-2010	12:40	13:17	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	128
Diastolic Blood Pressure	mmHg	91
Pulse	beats/minute	83
ECO	ppm	22

Urine Cotinine Screen

Not Applicable ☒

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R340933213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Randomization

Date

DD/MMM/YYYY

Randomization Number

Randomized Group

28-OCT-2010

1044

☐ SNUS

☐ Strips

☒ Dual Use of UB Cigarettes and SNUS

☐ Sticks

☐ Tobacco Abstinence

☐ Orbs

Verified



Approved



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

Document Number

R340933813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Actual Time
24-hour clock

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Urine Drug Screen

Was Urine Drug Screen Performed? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Urine Drug Screen Result

☐ Positive ☒ Negative

Urine Pregnancy Test

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

Date
DD/MMM/YYYY

Urine Pregnancy Test Result

☐ Positive ☒ Negative

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

03-NOV-2010

Actual Time
24-hour clock

08:12

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

119

Diastolic Blood Pressure

mmHg

82

Pulse

beats/minute

73

Respiratory Rate

breaths/minute

12

Oral Temperature

°C

36.6

Blood Collection for COHb

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

Not

Done

Comments

22:00

☒

UNABLE TO OBTAIN SAMPLE

Expired Carbon Monoxide

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

ECO Level

(ppm)

% COHb

Not Done

Comments

03-NOV-2010

07:00

07:13

7

1.8

☐

03-NOV-2010

12:00

12:14

19

3.7

☐

03-NOV-2010

22:00

22:21

23

4.3

☐

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R340934413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

UB Cigarette Dispensation/Collection

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?	If No, Comment
1	03-NOV-2010	07:18	07:27	34	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
2	03-NOV-2010	08:13	08:21	34	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
3	03-NOV-2010	09:28	09:34	35	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
4	03-NOV-2010	10:38	10:47	34	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
5	03-NOV-2010	11:42	11:49	33	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
6	03-NOV-2010	12:19	12:25	37	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
7	03-NOV-2010	14:09	14:19	35	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
8	03-NOV-2010	14:52	14:57	46	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
9	03-NOV-2010	16:33	16:39	37	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
10	03-NOV-2010	17:56	18:00	36	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
11	03-NOV-2010	18:46	18:52	37	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
12	03-NOV-2010	19:44	19:51	32	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
13	03-NOV-2010	21:14	21:19	40	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
14	03-NOV-2010	21:42	21:47	38	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

End-of-Day Daily Composited YIU Filter Tip Disposition

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
03-NOV-2010	16	23:10	YES

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R340934913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?	If No, Comment
15	03-NOV-2010	22:23	22:29	37	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
16	03-NOV-2010	22:43	22:48	41	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	
					<input type="checkbox"/> Yes <input type="checkbox"/> No	

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Urine Collection

Scheduled Timepoint	Start Date/Time	Stop Date/Time	Total	Not	Comments
	DD/MMM/YYYY	DD/MMM/YYYY	Volume		
-24 HOURS TO 0 HOUR	24-hour clock	24-hour clock	mL	Done	
	03-NOV-2010	04-NOV-2010	2650	<input type="checkbox"/>	
	06:52	07:12			

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
03-NOV-2010	07:00	07:12	<input type="checkbox"/>	
03-NOV-2010	12:00	12:12	<input type="checkbox"/>	
	22:00		<input checked="" type="checkbox"/>	UNABLE TO OBTAIN SAMPLE

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

Document Number R340936113

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: 1044

Subject Initials: (b) (6)

Is Blank

Questionnaires

Date of Assessment

DD/MMM/YYYY

03-NOV-2010

Scheduled Timepoint

19:00

Questionnaire

B-QSU

MNWS

Was Questionnaire Administered?

☒ Yes ☐ No

☒ Yes ☐ No

Maximum Use Level

Date

DD/MMM/YYYY

03-NOV-2010

Maximum Product Use

Allowed Per Day:

7

40% UB for Dual Use subjects:

6

☐ NA, Not Dual Use group

Comments

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

Document Number R340936713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

04-NOV-2010

Actual Time
24-hour clock

08:12

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

119

Diastolic Blood Pressure

mmHg

90

Pulse

beats/minute

76

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

04-NOV-2010

If Yes, Specify Daily Amount

02

12-ounce serving of Ultralight Beer

00

6-ounce serving of White or Rose Wine

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

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

Document Number

R341112913

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	04-NOV-2010	11:42	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow	11:47
2	04-NOV-2010	21:42	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow	21:48
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="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

R341113213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

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

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
04-NOV-2010	2	23:03	YES

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

Document Number

R341113713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

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

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Page Version No. PAGE_29 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_30 (v1, 19-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
1	04-NOV-2010	07:16	07:22	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	04-NOV-2010	11:12	11:18	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	04-NOV-2010	13:32	13:38	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	04-NOV-2010	15:48	15:55	34	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	04-NOV-2010	18:47	18:52	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	04-NOV-2010	22:19	22:24	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	
					<input type="checkbox"/> Yes	<input type="checkbox"/> No	

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
04-NOV-2010	6	23:03	YES

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Urine Collection

Scheduled Timepoint	Start Date/Time	Stop Date/Time	Total	Not	Comments
	DD/MMM/YYYY 24-hour clock	DD/MMM/YYYY 24-hour clock	Volume mL		
0 HOUR TO 24 HOURS	<input type="text" value="04-NOV-2010"/>	<input type="text" value="05-NOV-2010"/>	<input type="text" value="2400"/>	<input type="checkbox"/>	<input type="text"/>
	<input type="text" value="07:12"/>	<input type="text" value="07:12"/>			

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
<input type="text" value="04-NOV-2010"/>	<input type="text" value="07:00"/>	<input type="text" value="07:12"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text" value="04-NOV-2010"/>	<input type="text" value="12:00"/>	<input type="text" value="12:13"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text" value="04-NOV-2010"/>	<input type="text" value="22:00"/>	<input type="text" value="22:12"/>	<input type="checkbox"/>	<input type="text"/>

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Blood Collection for COHb

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

Not

Done

Comments

04-NOV-2010

22:00

22:12

☐

Expired Carbon Monoxide

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

ECO Level

(ppm)

% COHb

Not Done

Comments

04-NOV-2010

07:00

07:14

10

2.2

☐

04-NOV-2010

12:00

12:14

13

2.7

☐

04-NOV-2010

22:00

22:15

10

2.2

☐

Questionnaires

Date of Assessment

DD/MMM/YYYY

Scheduled Timepoint

04-NOV-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

R341116413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Actual Time
24-hour clock

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

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

Document Number

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

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="05-NOV-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"/>

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

Document Number

Links to Discrepancy and Audit Sections

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

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

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
05-NOV-2010	0	22:46	ND SUBJECT TOOK NO PRODUCT ON THIS DA

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

Document Number

R341128413

OverFlow Section For Document Number R341128413

1 ND SUBJECT TOOK NO PRODUCT ON THIS DAY

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group

CHECKED

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

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

Document Number

R341128513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

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

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

Document Number R341128613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?	If No, Comment
1	05-NOV-2010	08:15	08:21	37	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
2	05-NOV-2010	11:02	11:08	35	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
3	05-NOV-2010	13:29	13:34	38	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
4	05-NOV-2010	16:46	16:53	28	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
5	05-NOV-2010	20:38	20:44	36	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
6	05-NOV-2010	22:16	22:22	34	<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

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
05-NOV-2010	6	22:46	YES

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

06-NOV-2010

Actual Time
24-hour clock

08:12

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

122

Diastolic Blood Pressure

mmHg

87

Pulse

beats/minute

78

Respiratory Rate

breaths/minute

12

Oral Temperature

°C

36.4

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

06-NOV-2010

If Yes, Specify Daily Amount

02

12-ounce serving of Ultralight Beer

00

6-ounce serving of White or Rose Wine

Verified



Approved



Locked



Frozen



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

Document Number

R341136613

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 3

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	06-NOV-2010	11:42	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow	11:51
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

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

Document Number

R341136813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 3

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

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

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
06-NOV-2010	1	23:11	YES

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

Document Number R341136913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection

NA, Not Sticks group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

NOTCHECK

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
1	06-NOV-2010	07:24	07:28	44	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	06-NOV-2010	12:22	12:30	32	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	06-NOV-2010	14:34	14:41	33	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	06-NOV-2010	19:07	19:13	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	06-NOV-2010	21:42	21:47	33	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	06-NOV-2010	22:35	22:40	34	<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

NA, Not Dual Use group

NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
06-NOV-2010	6	23:13	YES

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

Document Number R341138013

Document Number R341139113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Urine Collection

Scheduled Timepoint	Start Date/Time	Stop Date/Time	Total	Not	Comments
	DD/MMM/YYYY 24-hour clock	DD/MMM/YYYY 24-hour clock	Volume mL		
48 HOURS TO 72 HOURS	<input type="text" value="06-NOV-2010"/>	<input type="text" value="07-NOV-2010"/>	<input type="text" value="2000"/>	<input type="checkbox"/>	<input type="text"/>
	<input type="text" value="06:52"/>	<input type="text" value="07:12"/>			

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
<input type="text" value="06-NOV-2010"/>	<input type="text" value="07:00"/>	<input type="text" value="07:15"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text" value="06-NOV-2010"/>	<input type="text" value="12:00"/>	<input type="text" value="12:12"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text" value="06-NOV-2010"/>	<input type="text" value="22:00"/>	<input type="text" value="22:12"/>	<input type="checkbox"/>	<input type="text"/>

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

Document Number

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Blood Collection for COHb

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

Expired Carbon Monoxide

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	ECO Level (ppm)	% COHb	Not Done	Comments
06-NOV-2010	07:00	07:18	7	1.8	<input type="checkbox"/>	
06-NOV-2010	12:00	12:15	7	1.8	<input type="checkbox"/>	
06-NOV-2010	22:00	22:14	15	3.0	<input type="checkbox"/>	

Questionnaires

Date of Assessment
DD/MMM/YYYY

Questionnaire

Was Questionnaire Administered?

B-QSU ☒ Yes ☐ No

MNWS ☒ Yes ☐ No

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Actual Time
24-hour clock

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

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 4

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	07-NOV-2010	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

R341164813

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

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

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
07-NOV-2010	0	23:31	YES

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

Document Number

R341165213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

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

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

Document Number R341165713

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"/>

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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	07-NOV-2010	09:35	09:42	39	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	07-NOV-2010	12:29	12:36	32	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	07-NOV-2010	18:42	18:50	28	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	07-NOV-2010	20:11	20:16	37	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	07-NOV-2010	21:19	21:24	33	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
6	07-NOV-2010	22:31	22:38	31	<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

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
07-NOV-2010	6	23:33	YES

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Page Version No. PAGE_66 (v1, 18-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 DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

08-NOV-2010

Actual Time
24-hour clock

08:15

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

113

Diastolic Blood Pressure

mmHg

81

Pulse

beats/minute

73

Respiratory Rate

breaths/minute

14

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-NOV-2010

If Yes, Specify Daily Amount

02

12-ounce serving of Ultralight Beer

00

6-ounce serving of White or Rose Wine

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

Document Number R341143213

Links to Discrepancy and Audit Sections

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group NOTCHECK

Seq.	Date DD/MMM/YYYY	Time Dispensed 24-hour clock	Amount Dispensed	Flavor Dispensed	Time Returned 24-hour clock
1	08-NOV-2010	11:42	<input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow	11:51
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	
			<input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS	<input type="checkbox"/> Frost <input type="checkbox"/> Mellow	

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

Document Number R341182413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

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

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total SNUS Count	Time of Day Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
08-NOV-2010	1	23:27	YES

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Document Number R341183113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 5/EARLY TERM

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group

CHECKED

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

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

Document Number

R341183513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 5/EARLY TERM

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

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

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

Document Number

R341183813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Strips Dispensation/Collection

NA, Not Strips group CHECKED

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

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

Document Number R341183913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Strips Dispensation/Collection (Continued)

NA, Not Strips group CHECKED

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

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

Document Number R341184013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Orbs Dispensation/Collection

NA, Not Orbs Group CHECKED

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

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

Document Number R341184613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group CHECKED

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

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

Document Number R341184813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

UB Cigarette Dispensation/Collection

NA, Not Dual Use group NOTCHECK

Seq	Date DD/MMM/YYYY	Time UB Dispensed 24-hour clock	Time UB Returned 24-hour clock	Cigarette Butt Length mm	Mouth-End Filter Cut for YIU?		If No, Comment
1	08-NOV-2010	10:22	10:29	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
2	08-NOV-2010	13:28	13:40	33	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
3	08-NOV-2010	15:11	15:19	36	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4	08-NOV-2010	16:55	17:02	35	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
5	08-NOV-2010	19:35	19:43	27	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	FILTER WAS BURNED
6	08-NOV-2010	21:42	21:46	32	<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

NA, Not Dual Use group NOTCHECK

Date DD/MMM/YYYY	End-of-Day Total Tip Count	Time of Day Daily YIU Frozen (-70C) 24-hour clock	Does Count Agree with Usage Log-Comment
08-NOV-2010	5	23:28	NO ONE NOT PROCESSED DUE TO BEING BU

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

Document Number R341184913

OverFlow Section For Document Number R341184913

1 NO ONE NOT PROCESSED DUE TO BEING BURNT

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Document Number R341185913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Urine Collection

Scheduled Timepoint	Start Date/Time	Stop Date/Time	Total	Not	Comments
	DD/MMM/YYYY 24-hour clock	DD/MMM/YYYY 24-hour clock	Volume mL		
96 HOURS TO 120 HOURS	08-NOV-2010 06:52	09-NOV-2010 07:12	1031	<input type="checkbox"/>	

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

Date	Scheduled Timepoint	Actual Time	Not	Comments
DD/MMM/YYYY		24-hour clock	Done	
08-NOV-2010	07:00	07:13	<input type="checkbox"/>	
08-NOV-2010	12:00	12:12	<input type="checkbox"/>	
08-NOV-2010	22:00	22:16	<input type="checkbox"/>	

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

Document Number R341186213

Links to Discrepancy and Audit Sections

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Fecal Collection

Not Applicable CHECKED

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

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

Document Number R341186513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Blood Collection for COHb

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

Expired Carbon Monoxide

Date DD/MMM/YYYY	Scheduled Timepoint	Actual Time 24-hour clock	ECO Level (ppm)	% COHb	Not Done	Comments
08-NOV-2010	07:00	07:15	7	1.8	<input type="checkbox"/>	
08-NOV-2010	12:00	12:14	8	1.9	<input type="checkbox"/>	
08-NOV-2010	22:00	22:18	17	3.4	<input type="checkbox"/>	

Questionnaires

Date of Assessment

DD/MMM/YYYY

08-NOV-2010

Scheduled Timepoint

19:00

Questionnaire

B-QSU

MNWS

Exit - Product Attributes

Was Questionnaire Administered?

☒ Yes ☐ No

☒ Yes ☐ No

☒ Yes ☐ No

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R341186713

Links to Discrepancy and Audit Sections

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

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Laboratory Evaluations

Were the scheduled laboratory samples obtained?

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

Date

DD/MMM/YYYY

08-NOV-2010

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

Requisition Number 1:

Y245625

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Requisition Number 4 (if applicable):

Requisition Number 5 (if applicable):

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

Requisition Number

Test Name

Test Code ID

Urine Pregnancy Test

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

Date

DD/MMM/YYYY

08-NOV-2010

Urine Pregnancy Test Result

☐ Positive ☒ Negative

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R341187213

Links to Discrepancy and Audit Sections

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

Document Number R341188313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Supine 12-Lead Electrocardiogram Report

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

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	61
PR Interval	milliseconds	158
QRS Duration	milliseconds	88
QT Interval	milliseconds	440
QTc Interval	milliseconds	433

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

08-NOV-2010

Exam Determination

Result

If Yes, Please Describe

Evidence of Leukoplakia?

☐ Yes ☒ No

Evidence of Other Oral Keratosis?

☐ Yes ☒ No

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R341188613

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DISCHARGE, DAY 6

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

09-NOV-2010

Actual Time
24-hour clock

07:07

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

119

Diastolic Blood Pressure

mmHg

87

Pulse

beats/minute

90

Respiratory Rate

breaths/minute

14

Oral Temperature

°C

36.5

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R341144213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

PCM

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Previous and Concomitant Medications

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

☐ Yes, list below. ☒ No

Drug Name:

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

R341225513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

AE

Subject Number:

1044

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

1

Adverse Event:

LIGHTHEADEDNESS

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

08-NOV-2010

07:12

08-NOV-2010

07:25

☐ 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

R341229413

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:

1044

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

2

Adverse Event:

ECCHYMOSIS AT LEFT ANTECUBITAL VENIPUNCTURE SITE

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

08-NOV-2010

10:04

17-NOV-2010

15:00

☐ 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

R341229713

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:

1044

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

3

Adverse Event:

ECCHYMOSIS RIGHT ANTECUBITAL VENIPUNCTURE SITE

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

08-NOV-2010

10:04

17-NOV-2010

15:00

☐ 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

R341230313

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:

1044

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

4

Adverse Event:

DIFFUSE T WAVE ABNORMALITIES

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

08-NOV-2010

08:09

09-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: ECG STRESS TEST

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

R353202213

Links to Discrepancy and Audit Sections

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

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name VS ADDITIONAL

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Additional Assessments - Vital Signs

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

Date DD/MM/YYYY 21-OCT-2010
Actual Time 24-hour clock 13:19
Position
☐ Standing
☐ Supine
☒ Seated
☐ Other, Specify:

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	120
Diastolic Blood Pressure	mmHg	86
Pulse	beats/minute	ND
Respiratory Rate	breaths/minute	ND
Oral Temperature	°C	ND

Date DD/MM/YYYY 02-NOV-2010
Actual Time 24-hour clock 12:26
Position
☐ Standing
☐ Supine
☒ Seated
☐ Other, Specify:

Parameter	Unit	Result
Systolic Blood Pressure	mmHg	118
Diastolic Blood Pressure	mmHg	82
Pulse	beats/minute	ND
Respiratory Rate	breaths/minute	ND
Oral Temperature	°C	ND

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R341239113

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 LB ADDITIONAL

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Additional Assessments - Laboratory Evaluations

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

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R341239813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name EG ADDITIONAL

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

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

Date DD/MMM/YYYY Actual Time 24-hour clock
02-NOV-2010 12:36

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	84
PR Interval	milliseconds	152
QRS Duration	milliseconds	86
QT Interval	milliseconds	384
QTc Interval	milliseconds	453

ECG Interpretation:

☒ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

Date DD/MMM/YYYY Actual Time 24-hour clock
08-NOV-2010 08:21

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	65
PR Interval	milliseconds	164
QRS Duration	milliseconds	90
QT Interval	milliseconds	390
QTc Interval	milliseconds	405

ECG Interpretation:

☐ Normal ☐ Abnormal, NCS ☒ Abnormal, CS

Comments Regarding CS Findings:

WIDESPREAD NON SPECIFIC T WAVE

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R341240113

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 EG ADDITIONAL

Subject Number: 1044

Subject Initials: (b) (6)

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

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

Date DD/MMM/YYYY Actual Time 24-hour clock
08-NOV-2010 11:23

Parameter	Unit	Result
Ventricular Heart Rate	beats/minute	85
PR Interval	milliseconds	132
QRS Duration	milliseconds	86
QT Interval	milliseconds	390
QTc Interval	milliseconds	464

ECG Interpretation:

☐ Normal ☐ Abnormal, NCS ☒ Abnormal, CS

Comments Regarding CS Findings:

DUE TO ABNORMAL T WAVE

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 R341240513

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 **STUDY COMPLETION**

Subject Number: **1044**

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

Is Blank

Study Completion

Date the subject completed OR withdrew from the study: **09-NOV-2010**
DD/MMM/YYYY

Reason for Withdrawal (check one):

☒ NA, Completed Study

☐ Adverse Event, specify:

☐ Terminated by Sponsor

☐ Consent Withdrawn

☐ Lost to Follow-up

☐ Other, specify:

Investigator Comments (if none, leave blank):

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number **R341240913**

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 #: R341112913

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
1044	Day 1	Page_23	
M01		023	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Alc	Page number	23	Day 1

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
12-ounce serving of Ultralight Beer (1) 1	2 02		23-DEC-2010 09:46:26 Luis Hernandez	Data Entry Error
6-ounce serving of White or Rose Wine (2) 1	00		23-DEC-2010 09:46:26 Luis Hernandez	Data Entry Error

Document #: R341127913

Patient	Visit	CRF
Site	Visit Date	CRF Page
1044	Day 2	Page_35
M01		035

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Vs	Page number	35	Day 2

Group #	Group Name
1	VS

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Oral Temperature	36.4		16-FEB-2011 15:28:06	Data Entry Error
(C)	36.8		Dawn Winter	
1				

Document #: R341127913

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
1044	Day 2	Page_35	
M01		035	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Alc	Page number	35	Day 2

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
12-ounce serving of Ultralight Beer (1) 1	2 02		23-DEC-2010 09:46:50 Luis Hernandez	Data Entry Error
6-ounce serving of White or Rose Wine (2) 1	00		23-DEC-2010 09:46:50 Luis Hernandez	Data Entry Error

Document #: R341128113

Patient	Visit	CRF
Site	Visit Date	CRF Page
1044	Day 2	Page_36
M01		036

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

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Amount Dispensed (1) 1			29-MAR-2011 10:17:58 Dawn Winter	Row Inserted
Date 1	05-NOV-2010		29-MAR-2011 10:17:58 Dawn Winter	Row Inserted
Flavor Dispensed (2) 1			29-MAR-2011 10:17:58 Dawn Winter	Row Inserted
Seq. 1	1		29-MAR-2011 10:17:58 Dawn Winter	Row Inserted
Time Dispensed (1) 1	ND		29-MAR-2011 10:17:58 Dawn Winter	Row Inserted
Time Returned (2) 1			29-MAR-2011 10:17:58 Dawn Winter	Row Inserted

Document #: R341128413

Patient Site	Visit Visit Date	CRF CRF Page
1044	Day 2	Page_37
M01		037

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eod_Snus	Page number	37	Day 2

Group #	Group Name
1	INDYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does Count Agree with Usage Log- Comment 1	NA ND SUBJECT TOOK NO PRODUCT ON THIS DAY	29-MAR-2011 10:20:24 Dawn Winter	Data Entry Error

Document #: R341136613

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
1044	Day 3	Page_45	
M01		045	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Alc	Page number	45	Day 3

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
12-ounce serving of Ultralight Beer (1) 1	2 02		23-DEC-2010 09:47:06 Luis Hernandez	Data Entry Error
6-ounce serving of White or Rose Wine (2) 1	00		23-DEC-2010 09:47:06 Luis Hernandez	Data Entry Error

Document #: R341139313

Patient Site	Visit Visit Date	CRF CRF Page	
1044	Day 3	Page_55	
M01		055	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcu	Page number	55	Day 3

Group #	Group Name
1	PCU

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Start Date 1	03-NOV-2010 06-NOV-2010	29-NOV-2010 09:12:05 Dawn Winter	Data Entry Error
Start Time 1	0712 0652	17-FEB-2011 08:43:35 Dawn Winter	Data Entry Error
Stop Date 1	04-NOV-2010 07-NOV-2010	29-NOV-2010 09:12:05 Dawn Winter	Data Entry Error

Document #: R341142313

Patient	Visit	CRF
Site	Visit Date	CRF Page
1044	Day 4	Page_57
M01		057

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Alc	Page number	57	Day 4

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
12-ounce serving of Ultralight Beer (1) 1	2 02		23-DEC-2010 09:47:23 Luis Hernandez	Data Entry Error
6-ounce serving of White or Rose Wine (2) 1	00		23-DEC-2010 09:47:23 Luis Hernandez	Data Entry Error

Document #: R341164813

Patient	Visit	CRF
Site	Visit Date	CRF Page
1044	Day 4	Page_58
M01		058

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Snus_Dis	Page number	58	Day 4

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Amount Dispensed (1) 1			29-MAR-2011 10:21:28 Dawn Winter	Row Inserted
Date 1	07-NOV-2010		29-MAR-2011 10:21:28 Dawn Winter	Row Inserted
Flavor Dispensed (2) 1			29-MAR-2011 10:21:28 Dawn Winter	Row Inserted
Seq. 1	1		29-MAR-2011 10:21:28 Dawn Winter	Row Inserted
Time Dispensed (1) 1	ND		29-MAR-2011 10:21:28 Dawn Winter	Row Inserted
Time Returned (2) 1			29-MAR-2011 10:21:28 Dawn Winter	Row Inserted

Document #: R341166513

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
1044	Day 4	Page_66	
M01		066	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Ub_Dis	Page number	66	Day 4

Group #	Group Name
1	SU

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
If No, Comment		29-NOV-2010	10:03:24	Row Inserted
1		Dawn Winter		
If No, Comment		29-NOV-2010	10:03:24	Row Inserted
2		Dawn Winter		
If No, Comment		29-NOV-2010	10:03:24	Row Inserted
3		Dawn Winter		
If No, Comment		29-NOV-2010	10:03:24	Row Inserted
4		Dawn Winter		
If No, Comment		29-NOV-2010	10:03:24	Row Inserted
5		Dawn Winter		
If No, Comment		29-NOV-2010	10:03:24	Row Inserted
6		Dawn Winter		
Mouth-End Filter	YES	29-NOV-2010	10:03:03	Pass1
Cut for YIU?		Dawn Winter		
7				
Mouth-End Filter		29-NOV-2010	10:03:24	Pass1
Cut for YIU?	<Row Deleted>	Dawn Winter		
7				

Document #: R341143213

Patient Site	Visit Visit Date	CRF CRF Page	
1044	Day 5/Early Term	Page_67	
M01		067	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Alc	Page number	67	Day 5/Early Term
Group #	Group Name		
1	SU		
Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
12-ounce serving of Ultralight Beer (1) 1	2 02	23-DEC-2010 09:51:08 Luis Hernandez	Data Entry Error
6-ounce serving of White or Rose Wine (2) 1	00	23-DEC-2010 09:51:08 Luis Hernandez	Data Entry Error

Document #: R341184913

Patient Site	Visit Visit Date	CRF CRF Page	
1044	Day 5/Early Term	Page_76	
M01		076	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eod	Page number	76	Day 5/Early Term
Group #	Group Name		
1	INDYN		
Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does Count Agree with Usage Log-Comment	NO	29-MAR-2011 10:22:55	Data Entry Error
1	NO ONE NOT PROCESSED DUE TO BEING BURNT	Dawn Winter	

Document #: R341186213

Patient Site	Visit Visit Date	CRF CRF Page	
1044	Day 5/Early Term	Page_77	
M01		077	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcu	Page number	77	Day 5/Early Term
Group #	Group Name		
1	PCU		
Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Start Time	0712	17-FEB-2011 08:44:55	Data Entry Error
1	0652	Dawn Winter	

Document #: R341186213

Patient Site	Visit Visit Date	CRF CRF Page	
1044	Day 5/Early Term	Page_77	
M01		077	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pnct	Page number	77	Day 5/Early Term
Group #	Group Name		
1	PCB		
Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments	DIFFICULT DRAW	17-FEB-2011 08:44:55	Data Entry Error
3		Dawn Winter	

Document #: R341186713

Patient Site	Visit Visit Date	CRF CRF Page	
1044	Day 5/Early Term	Page_79	
M01		079	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Cohb	Page number	79	Day 5/Early Term
Group #	Group Name		
1	PCB		
Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments	DIFFICULT DRAW	17-FEB-2011 08:45:54	Data Entry Error
1		Dawn Winter	

Document #: R341187213

Patient Site	Visit Visit Date	CRF CRF Page	
1044	Day 5/Early Term	Page_80	
M01		080	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	80	Day 5/Early Term
Group #	Group Name		
1	LB		
Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Requisition Number 2 (if applicable): (2)	G797935	17-FEB-2011 08:07:34 Dawn Winter	Data Entry Error
1			

Document #: R341229413

Patient Site	Visit Visit Date	CRF CRF Page
1044	Ae	Page_85
M01		085

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

Group #	Group Name
1	AE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Taken with Study Treatment 1	NA NOT CHANGED	29-MAR-2011 10:23:50 Dawn Winter	Data Entry Error

Document #: R341229713

Patient	Visit	CRF
Site	Visit Date	CRF Page
1044	Ae.1	Page_85
M01		

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

Group #	Group Name
1	AE

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Action Taken	NA		29-MAR-2011 10:25:03	Data Entry Error
with Study	NOT CHANGED		Dawn Winter	
Treatment				
1				

Document #: R341230313

Patient	Visit	CRF
Site	Visit Date	CRF Page
1044	Ae.2	Page_85
M01		

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Ae	Page number	85	Ae.2

Group #	Group Name
1	AE

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Action Taken	NA		29-MAR-2011 10:26:00	Data Entry Error
with Study	NOT CHANGED		Dawn Winter	
Treatment				
1				

Document #: R353202213

Patient Site	Visit Visit Date	CRF CRF Page
1044 M01	Ae.3	Page_85

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	85	Ae.3

Group #	Group Name
1	AE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Adverse Event 1	DIFFUGE T WAVE ABNORMALITIES DIFFUSE T WAVE ABNORMALITIES	23-FEB-2011 13:41:19 Dawn Winter	Data Entry Error

Document #: R341239113

Patient	Visit	CRF	
Site	Visit Date	CRF Page	
1044	Vs Additional	Page_86	
M01		086	
Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
Vs	Page number	86	Vs Additional

Group #	Group Name
1	VS

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
Oral Temperature (C) 1	NA ND		21-FEB-2011 10:08:55 Luis Hernandez	Data Entry Error
Pulse (beats/minute) 1	NA ND		21-FEB-2011 10:08:55 Luis Hernandez	Data Entry Error
Respiratory Rate (breaths/minute) (1) 1	NA ND		21-FEB-2011 10:08:55 Luis Hernandez	Data Entry Error
Oral Temperature (C) 2	NA ND		21-FEB-2011 10:08:55 Luis Hernandez	Data Entry Error
Pulse (beats/minute) 2	NA ND		21-FEB-2011 10:08:55 Luis Hernandez	Data Entry Error
Respiratory Rate (breaths/minute) (1) 2	NA ND		21-FEB-2011 10:08:55 Luis Hernandez	Data Entry Error

Document #: R341240113

Patient Site	Visit Visit Date	CRF CRF Page	
1044	Eg Additional	Page_88	
M01		088	

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eg	Page number	88	Eg Additional

Group #	Group Name
1	EG

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments Regarding CS Findings: 2	DUE TO T WAVE ABNORMAL	23-FEB-2011 07:57:01 Dawn Winter	Data Entry Error
Comments Regarding CS Findings: 2	DUE TO T WAVE ABNORMAL WIDESPREAD NON SPECIFIC T WAVE	23-FEB-2011 08:01:44 Dawn Winter	Data Entry Error
ECG Interpretation 2	ABNORMAL, NCS ABNORMAL, CS	23-FEB-2011 07:57:01 Dawn Winter	Data Entry Error

Document #: R341240513

Patient Site	Visit Visit Date	CRF CRF Page
1044 M01	Eg Additional.1	Page_88

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eg	Page number	88	Eg Additional.1

Group #	Group Name
1	EG

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments Regarding CS Findings: 1	DUE TO ABNORMAL T WAVE	23-FEB-2011 08:02:49 Dawn Winter	Data Entry Error
ECG Interpretation 1	ABNORMAL, NCS ABNORMAL, CS	23-FEB-2011 08:02:49 Dawn Winter	Data Entry Error

Discrepancy Detail Report

Document #: R340815813

Discrepancy ID: 257102811

Site: M01

Patient: 1044

Visit: SCREEN 1

Visit Date:

CRF: PAGE_08

Section: BM

Qualifying Value: 8

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Subject's BMI 31.7 is less than 18.0 or greater than 30.0 kg/m2. Please reconcile.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R341127913

Discrepancy ID: 299298011 **Site:** M01 **Patient:** 1044
Visit: DAY 2 **Visit Date:**
CRF: PAGE_35 **Section:** VS **Qualifying Value:** 35
Field: Oral Temperature (C) **Row:** 1
Value Text: 36.8
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per source documents the temperature reads 36.8 degrees. Please review source and reconcile.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R341128113

Discrepancy ID: 320724811 **Site:** M01 **Patient:** 1044
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:

Resolution Type: Confirmed

Resolution Text:

Discrepancy ID: 320724911 **Site:** M01 **Patient:** 1044
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:

Resolution Type: Confirmed

Resolution Text:

Discrepancy ID: 319795311 **Site:** M01 **Patient:** 1044
Visit: DAY 2 **Visit Date:**
CRF: PAGE_36 **Section:** SNUS_DISP **Qualifying Value:** 36
Field: NA, Not SNUS or Dual Use group **Row:** 1

Value Text: NOTCHECK

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please indicate if any SNUS was dispensed. If not, please report the sequence number, date, and report 'ND' in the time dispensed.

Internal Comment:

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

Resolution Text:

R341128113

Discrepancy ID: 320725011 Site: M01 Patient: 1044
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:

Discrepancy ID: 320725111 Site: M01 Patient: 1044
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 #: R341128413

Discrepancy ID: 319572811 **Site:** M01 **Patient:** 1044
Visit: DAY 2 **Visit Date:**
CRF: PAGE_37 **Section:** EOD_SNUS **Qualifying Value:** 37
Field: Does Count Agree with Usage Log-Comment **Row:** 1
Value Text: ND SUBJECT TOOK NO PRODUCT ON THIS DAY
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please report 'ND' instead of 'NA' and provide a comment.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R341139313

Discrepancy ID: 299324111

Site: M01

Patient: 1044

Visit: DAY 3

Visit Date:

CRF: PAGE_55

Section: PCU

Qualifying Value: 55

Field: Start Time

Row: 1

Value Text: 0652

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: The time entered in source documents is before the time entered into RDC. Please review the source and reconcile.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R341164813

Discrepancy ID: 320725811 **Site:** M01 **Patient:** 1044
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:

Resolution Type: No Action Required

Resolution Text:

Discrepancy ID: 320725911 **Site:** M01 **Patient:** 1044
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:

Resolution Type: No Action Required

Resolution Text:

Discrepancy ID: 319795511 **Site:** M01 **Patient:** 1044
Visit: DAY 4 **Visit Date:**
CRF: PAGE_58 **Section:** SNUS_DISP **Qualifying Value:** 58
Field: NA, Not SNUS or Dual Use group **Row:** 1

Value Text: NOTCHECK

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please indicate if any SNUS was dispensed. If not, please report the sequence number, date, and report 'ND' in the time dispensed.

Internal Comment:

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

Resolution Text:

R341164813

Discrepancy ID: 320726011 Site: M01 Patient: 1044
Visit: DAY 4 Visit Date:
CRF: PAGE_58 Section: SNUS_DISP Qualifying Value: 58
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: No Action Required

Resolution Text:

Discrepancy ID: 320726111 Site: M01 Patient: 1044
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:

Resolution Type: No Action Required

Resolution Text:

Document #: R341184913

Discrepancy ID: 319954611 **Site:** M01 **Patient:** 1044
Visit: DAY 5/EARLY TER **Visit Date:**
CRF: PAGE_76 **Section:** EOD **Qualifying Value:** 76
Field: Does Count Agree with Usage Log-Comment **Row:** 1
Value Text: NO ONE NOT PROCESSED DUE TO BEING BURNT
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please provide a comment as to why the count does not agree.
Internal Comment: comment added
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R341186213

Discrepancy ID: 299325611 **Site:** M01 **Patient:** 1044

Visit: DAY 5/EARLY TER **Visit Date:**

CRF: PAGE_77

Section: PCU

Qualifying Value: 77

Field: Start Time

Row: 1

Value Text: 0652

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per source documents the collection start time is prior to the time listed in RDC. Please review source and correct the time.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R341186213

Discrepancy ID: 299325711 **Site:** M01 **Patient:** 1044
Visit: DAY 5/EARLY TER **Visit Date:**
CRF: PAGE_77 **Section:** PNCT **Qualifying Value:** 77
Field: Comments **Row:** 3
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per eCRF completion guidelines the comment is not needed. Please remove.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R341186713

Discrepancy ID: 299326011 **Site:** M01 **Patient:** 1044
Visit: DAY 5/EARLY TER **Visit Date:**
CRF: PAGE_79 **Section:** COHB **Qualifying Value:** 79
Field: Comments **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per CRF completion guidelines the comment is not needed. Please remove.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R341188613

Discrepancy ID: 299326611 **Site:** M01 **Patient:** 1044
Visit: DAY 5/EARLY TER **Visit Date:**
CRF: PAGE_82 **Section:** EG **Qualifying Value:** 82
Field: Comments Regarding CS Findings: **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please complete this field, adding the comments listed on the ECG.
Internal Comment: finding is not cs comment not needed
Resolution Type: Confirmed
Resolution Text:

Document #: R341229413

Discrepancy ID: 320350211

Site: M01

Patient: 1044

Visit: AE

Visit Date:

CRF: PAGE_85

Section: AE

Qualifying Value: 85

Field: Action Taken with Study Treatment

Row: 1

Value Text: NOT CHANGED

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Since the AE occurred during the time when the product was being taken, would this be better identified as 'Dose Not Changed'?

Internal Comment: changed

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

Resolution Text:

Document #: R341229713

Discrepancy ID: 320350311

Site: M01

Patient: 1044

Visit: AE.1

Visit Date:

CRF: PAGE_85

Section: AE

Qualifying Value: 85

Field: Action Taken with Study Treatment

Row: 1

Value Text: NOT CHANGED

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Since the AE occurred during the time when the product was being taken, would this be better identified as 'Dose Not Changed'?

Internal Comment: changed

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

Resolution Text:

Document #: R341230313

Discrepancy ID: 320350411

Site: M01

Patient: 1044

Visit: AE.2

Visit Date:

CRF: PAGE_85

Section: AE

Qualifying Value: 85

Field: Action Taken with Study Treatment

Row: 1

Value Text: NOT CHANGED

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Since the AE occurred during the time when the product was being taken, would this be better identified as 'Dose Not Changed'?

Internal Comment: changed

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

Resolution Text:

Document #: R353202213

Discrepancy ID: 301691811 **Site:** M01 **Patient:** 1044
Visit: AE.3 **Visit Date:**
CRF: PAGE_85 **Section:** AE **Qualifying Value:** 85
Field: Adverse Event **Row:** 1

Value Text: DIFFUSE T WAVE ABNORMALITIES

Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify if "diffuge" should be "diffuse"

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Discrepancy ID: 302070611 **Site:** M01 **Patient:** 1044
Visit: AE.3 **Visit Date:**
CRF: PAGE_85 **Section:** AE **Qualifying Value:** 85
Field: **Row:**

Value Text:

Type: MULTIVARIATE **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: The Subject has had an Adverse Event of DIFFUSE T WAVE ABNORMALITIES with a Onset Date of 08-NOV-2010 but the Resolved Time is missing and Ongoing is not ticked. Please provide the Resolved Time of the AE or clarify if Ongoing.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R341240113

Discrepancy ID: 300619811 **Site:** M01 **Patient:** 1044
Visit: EG ADDITIONAL **Visit Date:**
CRF: PAGE_88 **Section:** EG **Qualifying Value:** 88
Field: ECG Interpretation **Row:** 2
Value Text: ABNORMAL, CS
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Monitor to verify upon assessment of significance by PI.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 258458711 **Site:** M01 **Patient:** 1044
Visit: EG ADDITIONAL **Visit Date:**
CRF: PAGE_88 **Section:** EG **Qualifying Value:** 88
Field: QTc Interval (milliseconds) **Row:** 1
Value Text: 453
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value of 453 for QTc Interval (milliseconds) above expected maximum of 450
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R341240513

Discrepancy ID: 300619611 **Site:** M01 **Patient:** 1044
Visit: EG ADDITIONAL.1 **Visit Date:**
CRF: PAGE_88 **Section:** EG **Qualifying Value:** 88
Field: ECG Interpretation **Row:** 1
Value Text: ABNORMAL, CS
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Monitor to verify upon significance assessment by PI.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 258458811 **Site:** M01 **Patient:** 1044
Visit: EG ADDITIONAL.1 **Visit Date:**
CRF: PAGE_88 **Section:** EG **Qualifying Value:** 88
Field: QTc Interval (milliseconds) **Row:** 1
Value Text: 464
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value of 464 for QTc Interval (milliseconds) above expected maximum of 450
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Deleted CRFs Report