

CRF Report for Study E8230249

Report run by Tamara Fisher at 13-AUG-2014 15:05:14

Report Parameters

Site: M01

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: 1018

Ending patient: 1018

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:

1018

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 R335814813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1018

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.

Verified

☒

Approved

☒

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

Document Number

R337858613

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:

1018

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.

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

Document Number R337858713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1018

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 R337858813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Subject Eligibility

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

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

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

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Tobacco Abstinence Question

Was Tobacco Abstinence Question asked? ☒ Yes ☐ No

Date

DD/MMM/YYYY

29-SEP-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

29-SEP-2010

Score

6

Comments

Urine Cotinine Screen

Date

DD/MMM/YYYY

29-SEP-2010

Actual Time
24-hour clock

11:24

NicCheck I
Results

☒ Positive
☐ Negative

Not Done

☐

Comments

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

Document Number R337859013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

MSFT Taste Test

Was MSFT Taste Test administered? ☒ Yes ☐ No

Date

DD/MMM/YYYY

29-SEP-2010

Product

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

SNUS Frost

☒ Yes ☐ No

SNUS Mellow

☒ Yes ☐ No

Preferred SNUS Type

☒ Frost ☐ Mellow ☐ None

Sticks

☒ Yes ☐ No

Strips

☒ Yes ☐ No

Orbs

☒ Yes ☐ No

Demographics

Date

DD/MMM/YYYY

29-SEP-2010

Date of Birth

DD/MMM/YYYY

(b) (6)

Gender

☐ Male

☒ Female

Ethnicity

☐ Hispanic or Latino

☒ Not Hispanic or Latino

Race

☒ White

☐ Black or African American

☐ Asian

☐ Native Hawaiian or Other Pacific Islander

☐ American Indian/Alaskan Native

☐ Other:

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☒ Frozen

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

Document Number

R337859113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

29-SEP-2010

Actual Time
24-hour clock

09:29

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

98

Diastolic Blood Pressure

mmHg

63

Pulse

beats/minute

70

Respiratory Rate

breaths/minute

18

Oral Temperature

°C

36.6

Body Measurements

Were Body Measurements Collected? ☒ Yes ☐ No

Date

DD/MMM/YYYY

29-SEP-2010

Parameter

Unit

Result

Height

cm

158.5

Weight

kg

76.3

BMI

kg/m²

30.4

Note: Body Mass Index will be derived.

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

Document Number R337859213

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:

1018

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

29-SEP-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:

Y244987

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

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

Document Number

R335942913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number: 1018

Subject Initials: (b) (6)

Is Blank

Urine Drug Screen

Was Urine Drug Screen Performed? ☒ Yes ☐ No

Date

DD/MMM/YYYY

29-SEP-2010

Urine Drug Screen Result

☐ Positive ☒ Negative

Urine Pregnancy Test

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

Date

DD/MMM/YYYY

29-SEP-2010

Urine Pregnancy Test Result

☐ Positive ☒ Negative

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

Document Number R337087213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 1

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Supine 12-Lead Electrocardiogram Report

| | | |
|---|-------------|---------------|
| Was ECG performed? | Date | Actual Time |
| <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | DD/MMM/YYYY | 24-hour clock |
| | 29-SEP-2010 | 13:30 |

| | | |
|------------------------|--------------|--------|
| Parameter | Unit | Result |
| Ventricular Heart Rate | beats/minute | 59 |
| PR Interval | milliseconds | 160 |
| QRS Duration | milliseconds | 82 |
| QT Interval | milliseconds | 412 |
| QTc Interval | milliseconds | 407 |

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 R335941413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Complete Physical Examination

Does the subject have any relevant findings?

☐ Yes ☒ No

Date

DD/MMM/YYYY

07-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

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

Document Number

R337859413

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 MENTHOL"/> (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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

1018

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? |
|---------------------|--|--|---|
| 07-OCT-2010 | 12:41 | 13:19 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |

| Parameter | Unit | Result |
|--------------------------|--------------|--------|
| Systolic Blood Pressure | mmHg | 113 |
| Diastolic Blood Pressure | mmHg | 67 |
| Pulse | beats/minute | 89 |
| ECO | ppm | 14 |

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"/> | |

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

Document Number R337859613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

SCREEN 2

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Randomization

Date

DD/MMM/YYYY

Randomization Number

Randomized Group

14-OCT-2010

1018

☒ SNUS

☐ Strips

☐ Dual Use of UB Cigarettes and SNUS

☐ Sticks

☐ Tobacco Abstinence

☐ Orbs

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

Document Number R337859713

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

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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: 1018

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

20-OCT-2010

Actual Time
24-hour clock

08:34

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

106

Diastolic Blood Pressure

mmHg

65

Pulse

beats/minute

81

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.7

Blood Collection for COHb

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

Not

Done

Comments

20-OCT-2010

22:00

22:37

☐

Expired Carbon Monoxide

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

ECO Level

(ppm)

% COHb

Not Done

Comments

20-OCT-2010

07:00

07:40

10

2.2

☐

20-OCT-2010

12:00

12:38

24

4.5

☐

20-OCT-2010

22:00

22:39

23

4.3

☐

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

Document Number R335953613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 1018

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 | 20-OCT-2010 | 07:43 | 07:51 | 35 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 2 | 20-OCT-2010 | 09:42 | 09:48 | 38 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 3 | 20-OCT-2010 | 10:36 | 10:41 | 34 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 4 | 20-OCT-2010 | 11:31 | 11:36 | 35 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 5 | 20-OCT-2010 | 12:04 | 12:10 | 32 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 6 | 20-OCT-2010 | 12:40 | 12:45 | 34 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 7 | 20-OCT-2010 | 13:48 | 13:54 | 34 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 8 | 20-OCT-2010 | 15:48 | 16:01 | 31 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 9 | 20-OCT-2010 | 18:01 | 18:04 | 50 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 10 | 20-OCT-2010 | 18:51 | 18:59 | 31 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 11 | 20-OCT-2010 | 19:36 | 19:42 | 33 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 12 | 20-OCT-2010 | 20:55 | 21:01 | 32 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 13 | 20-OCT-2010 | 22:04 | 22:10 | 30 | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 14 | 20-OCT-2010 | 22:43 | 22:49 | 32 | <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 |
|---------------------|-------------------------------|---|--|
| 20-OCT-2010 | 14 | 23:24 | YES |

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

Document Number R337859813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 1018

Subject Initials: (b) (6)

Is Blank

Urine Collection

| Scheduled Timepoint | Start Date/Time | Stop Date/Time | Total | Not | Comments |
|---------------------|------------------------------|------------------------------|--------------|--------------------------|----------|
| | DD/MMM/YYYY 24-hour clock | DD/MMM/YYYY 24-hour clock | Volume mL | | |
| -24 HOURS TO 0 HOUR | 20-OCT-2010 07:14 | 21-OCT-2010 07:34 | 4000 | <input type="checkbox"/> | |

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

| Date | Scheduled Timepoint | Actual Time | Not | Comments |
|-------------|---------------------|---------------|--------------------------|----------|
| DD/MMM/YYYY | | 24-hour clock | Done | |
| 20-OCT-2010 | 07:00 | 07:35 | <input type="checkbox"/> | |
| 20-OCT-2010 | 12:00 | 12:34 | <input type="checkbox"/> | |
| 20-OCT-2010 | 22:00 | 22:37 | <input type="checkbox"/> | |

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

Document Number R337483313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Fecal Collection

Not Applicable

| Scheduled Timepoint | Collection Date/Time | Weight g | Not Done | Comments |
|-------------------------------------|--|------------------------------------|--------------------------|----------------------|
| | DD/MMM/YYYY 24-hour clock | | | |
| <input type="text" value="DAY -1"/> | <input type="text" value="20-OCT-2010"/> <input type="text" value="10:34"/> | <input type="text" value="78.1"/> | <input type="checkbox"/> | <input type="text"/> |
| <input type="text" value="DAY -1"/> | <input type="text" value="20-OCT-2010"/> <input type="text" value="14:02"/> | <input type="text" value="91.7"/> | <input type="checkbox"/> | <input type="text"/> |
| <input type="text" value="DAY -1"/> | <input type="text" value="20-OCT-2010"/> <input type="text" value="15:47"/> | <input type="text" value="164.6"/> | <input type="checkbox"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> |

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name BASELINE, DAY -1

Subject Number: 1018

Subject Initials: (b) (6)

Is Blank

Questionnaires

Date of Assessment

DD/MMM/YYYY

20-OCT-2010

Scheduled Timepoint

19:00

Questionnaire

B-QSU

MNWS

Was Questionnaire Administered?

☒ Yes ☐ No

☒ Yes ☐ No

Maximum Use Level

Date

DD/MMM/YYYY

20-OCT-2010

Maximum Product Use

Allowed Per Day:

9

40% UB for Dual Use subjects:

☒ NA, Not Dual Use group

Comments

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R337860113

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Actual Time
24-hour clock

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

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="21-OCT-2010"/> | <input type="text" value="07:56"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="08:04"/> |
| <input type="text" value="2"/> | <input type="text" value="21-OCT-2010"/> | <input type="text" value="09:43"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="10:50"/> |
| <input type="text" value="3"/> | <input type="text" value="21-OCT-2010"/> | <input type="text" value="12:04"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="12:54"/> |
| <input type="text" value="4"/> | <input type="text" value="21-OCT-2010"/> | <input type="text" value="13:47"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="14:17"/> |
| <input type="text" value="5"/> | <input type="text" value="21-OCT-2010"/> | <input type="text" value="15:17"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="17:20"/> |
| <input type="text" value="6"/> | <input type="text" value="21-OCT-2010"/> | <input type="text" value="18:57"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="19:51"/> |
| <input type="text" value="7"/> | <input type="text" value="21-OCT-2010"/> | <input type="text" value="21:44"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="21:58"/> |
| <input type="text" value="8"/> | <input type="text" value="21-OCT-2010"/> | <input type="text" value="22:04"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="22:52"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text"/> |

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1018

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 |
|---------------------|--------------------------------|---|--|
| 21-OCT-2010 | 8 | 23:35 | YES |

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R337860313

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection

NA, Not Sticks group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_26 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R337860513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

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

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

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

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Page Version No. PAGE_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 ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

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

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Page Version No. PAGE_32.1 (v1, 18-NOV-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Urine Collection

| Scheduled Timepoint | Start Date/Time | Stop Date/Time | Total | Not | Comments |
|---------------------|------------------------------|------------------------------|--------------|--------------------------|----------|
| | DD/MMM/YYYY 24-hour clock | DD/MMM/YYYY 24-hour clock | Volume mL | | |
| 0 HOUR TO 24 HOURS | 21-OCT-2010 | 22-OCT-2010 | 3725 | <input type="checkbox"/> | |
| | 07:34 | 07:34 | | | |

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

| Date | Scheduled Timepoint | Actual Time | Not | Comments |
|-------------|---------------------|---------------|--------------------------|----------|
| DD/MMM/YYYY | | 24-hour clock | Done | |
| 21-OCT-2010 | 07:00 | 07:45 | <input type="checkbox"/> | |
| 21-OCT-2010 | 12:00 | 12:34 | <input type="checkbox"/> | |
| 21-OCT-2010 | 22:00 | 22:38 | <input type="checkbox"/> | |

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

Document Number R337453713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 1

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Blood Collection for COHb

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

Not

Done

Comments

21-OCT-2010

22:00

22:38

☐

Expired Carbon Monoxide

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

ECO Level

(ppm)

% COHb

Not Done

Comments

21-OCT-2010

07:00

07:51

9

2.1

☐

21-OCT-2010

12:00

12:37

5

1.3

☐

21-OCT-2010

22:00

22:39

4

1.3

☐

Questionnaires

Date of Assessment

DD/MMM/YYYY

Scheduled Timepoint

21-OCT-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

R337861113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

22-OCT-2010

Actual Time
24-hour clock

08:34

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

111

Diastolic Blood Pressure

mmHg

70

Pulse

beats/minute

79

Respiratory Rate

breaths/minute

12

Oral Temperature

°C

37.0

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

22-OCT-2010

If Yes, Specify Daily Amount

02

12-ounce serving of Ultralight Beer

00

6-ounce serving of White or Rose Wine

Verified



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Frozen



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

Document Number

R335945813

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 2

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

SNUS Dispensation/Collection

NA, Not SNUS or Dual Use group

NOTCHECK

| Seq. | Date DD/MM/YYYY | Time Dispensed 24-hour clock | Amount Dispensed | Flavor Dispensed | Time Returned 24-hour clock |
|------|--------------------|---------------------------------|---|--|--------------------------------|
| 1 | 22-OCT-2010 | 07:23 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 08:51 |
| 2 | 22-OCT-2010 | 09:43 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 10:46 |
| 3 | 22-OCT-2010 | 13:37 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 15:10 |
| 4 | 22-OCT-2010 | 17:22 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 17:31 |
| 5 | 22-OCT-2010 | 17:32 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 17:51 |
| 6 | 22-OCT-2010 | 19:05 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 19:38 |
| 7 | 22-OCT-2010 | 19:56 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 20:32 |
| 8 | 22-OCT-2010 | 21:25 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 22:16 |
| 9 | 22-OCT-2010 | 22:17 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 22:50 |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="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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Frozen



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

Document Number

R337861213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

1018

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 |
|---------------------|--------------------------------|---|--|
| 22-OCT-2010 | 9 | 23:20 | YES |

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

Document Number

R337861313

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 2

Subject Number:

1018

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

R337861413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 2

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R337861513

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"/> |

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_41 (v1, 15-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

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

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

Actual Time
24-hour clock

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

Diastolic Blood Pressure

mmHg

Pulse

beats/minute

Respiratory Rate

breaths/minute

Oral Temperature

°C

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

If Yes, Specify Daily Amount

12-ounce serving of Ultralight Beer

6-ounce serving of White or Rose Wine

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

Page Version No. PAGE_45 (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 3

Subject Number:

1018

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 | 23-OCT-2010 | 07:52 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 08:38 |
| 2 | 23-OCT-2010 | 09:23 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 09:51 |
| 3 | 23-OCT-2010 | 09:56 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 11:12 |
| 4 | 23-OCT-2010 | 12:04 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 12:38 |
| 5 | 23-OCT-2010 | 13:45 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 14:22 |
| 6 | 23-OCT-2010 | 15:21 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 16:13 |
| 7 | 23-OCT-2010 | 17:13 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 18:00 |
| 8 | 23-OCT-2010 | 19:15 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 21:00 |
| 9 | 23-OCT-2010 | 22:04 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 22:58 |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="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_46 (v1, 21-OCT-2010)

Document Number

R337862113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

SNUS Dispensation/Collection (Continued)

NA, Not SNUS or Dual Use group

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

End-of-Day Daily Composited SNUS Use

NA, Not SNUS or Dual Use group

| Date DD/MMM/YYYY | End-of-Day Total SNUS Count | Time of Day Frozen (-70C) 24-hour clock | Does Count Agree with Usage Log-Comment |
|--|--------------------------------|---|--|
| <input type="text" value="23-OCT-2010"/> | <input type="text" value="9"/> | <input type="text" value="23:15"/> | <input type="text" value="YES"/> |

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Page Version No. PAGE_47 (v1, 21-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 3

Subject Number:

1018

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_48 (v1, 15-OCT-2010)

Document Number R337862313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

CHECKED

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

Verified



Approved



Locked



Frozen



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

Document Number

R337862413

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"/> |

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

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

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

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

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

Document Number

R340093113

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="23-OCT-2010"/> | <input type="text" value="24-OCT-2010"/> | <input type="text" value="2900"/> | <input type="checkbox"/> | <input type="text"/> |
| | <input type="text" value="07:14"/> | <input type="text" value="07:34"/> | | | |

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="23-OCT-2010"/> | <input type="text" value="07:00"/> | <input type="text" value="07:34"/> | <input type="checkbox"/> | <input type="text"/> |
| <input type="text" value="23-OCT-2010"/> | <input type="text" value="12:00"/> | <input type="text" value="12:34"/> | <input type="checkbox"/> | <input type="text"/> |
| <input type="text" value="23-OCT-2010"/> | <input type="text" value="22:00"/> | <input type="text" value="22:34"/> | <input type="checkbox"/> | <input type="text"/> |

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 3

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Blood Collection for COHb

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

Not

Done

Comments

23-OCT-2010

22:00

22:34

☐

Expired Carbon Monoxide

Date

DD/MMM/YYYY

Scheduled Timepoint

Actual Time

24-hour clock

ECO Level

(ppm)

% COHb

Not Done

Comments

23-OCT-2010

07:00

07:41

3

1.1

☐

23-OCT-2010

12:00

12:36

1

0.8

☐

23-OCT-2010

22:00

22:35

2

1.0

☐

Questionnaires

Date of Assessment

DD/MMM/YYYY

Scheduled Timepoint

23-OCT-2010

19:00

Questionnaire

Was Questionnaire Administered?

B-QSU

☒ Yes ☐ No

MNWS

☒ Yes ☐ No

Verified

☒

Approved

☒

Locked

☒

Frozen

☒

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

Document Number

R337863013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

24-OCT-2010

Actual Time
24-hour clock

08:34

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

112

Diastolic Blood Pressure

mmHg

66

Pulse

beats/minute

92

Respiratory Rate

breaths/minute

14

Oral Temperature

°C

36.9

Assessment of Daily Alcohol Consumption

Was Daily Alcohol Consumption Rate Assessed?

☒ Yes ☐ No ☐ NA, Not a Drinker

Date of Assessment
DD/MMM/YYYY

24-OCT-2010

If Yes, Specify Daily Amount

00

12-ounce serving of Ultralight Beer

02

6-ounce serving of White or Rose Wine

Verified

☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R335953813

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

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="24-OCT-2010"/> | <input type="text" value="07:20"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="08:36"/> |
| <input type="text" value="2"/> | <input type="text" value="24-OCT-2010"/> | <input type="text" value="09:37"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="10:56"/> |
| <input type="text" value="3"/> | <input type="text" value="24-OCT-2010"/> | <input type="text" value="11:37"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="12:53"/> |
| <input type="text" value="4"/> | <input type="text" value="24-OCT-2010"/> | <input type="text" value="13:33"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="14:07"/> |
| <input type="text" value="5"/> | <input type="text" value="24-OCT-2010"/> | <input type="text" value="15:55"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="17:02"/> |
| <input type="text" value="6"/> | <input type="text" value="24-OCT-2010"/> | <input type="text" value="18:48"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="19:41"/> |
| <input type="text" value="7"/> | <input type="text" value="24-OCT-2010"/> | <input type="text" value="19:41"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="20:39"/> |
| <input type="text" value="8"/> | <input type="text" value="24-OCT-2010"/> | <input type="text" value="20:39"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="21:42"/> |
| <input type="text" value="9"/> | <input type="text" value="24-OCT-2010"/> | <input type="text" value="21:42"/> | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | <input type="text" value="22:38"/> |
| <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_58 (v1, 21-OCT-2010)

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

DAY 4

Subject Number:

1018

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 |
|---------------------|--------------------------------|---|--|
| 24-OCT-2010 | 9 | 23:21 | YES |

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

Document Number

R337863213

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:

1018

Subject Initials:

(b) (6)

Is Blank

Sticks Dispensation/Collection

NA, Not Sticks group

CHECKED

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

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

Document Number R337863313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Sticks Dispensation/Collection (Continued)

NA, Not Sticks group

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection

NA, Not Strips group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Strips Dispensation/Collection (Continued)

NA, Not Strips group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection

NA, Not Orbs Group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

UB Cigarette Dispensation/Collection

NA, Not Dual Use group

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

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group

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

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

25-OCT-2010

Actual Time
24-hour clock

08:36

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

110

Diastolic Blood Pressure

mmHg

67

Pulse

beats/minute

86

Respiratory Rate

breaths/minute

12

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

25-OCT-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 R337464213

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

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 | 25-OCT-2010 | 07:52 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 09:44 |
| 2 | 25-OCT-2010 | 12:04 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 13:05 |
| 3 | 25-OCT-2010 | 13:47 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 15:03 |
| 4 | 25-OCT-2010 | 15:05 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 16:09 |
| 5 | 25-OCT-2010 | 16:10 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 17:20 |
| 6 | 25-OCT-2010 | 17:20 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 18:09 |
| 7 | 25-OCT-2010 | 19:21 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 20:32 |
| 8 | 25-OCT-2010 | 21:15 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 22:03 |
| 9 | 25-OCT-2010 | 22:04 | <input checked="" type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input checked="" type="checkbox"/> Frost <input type="checkbox"/> Mellow | 23:02 |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="checkbox"/> Frost <input type="checkbox"/> Mellow | |
| | | | <input type="checkbox"/> 1 SNUS <input type="checkbox"/> 2 SNUS | <input type="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 R337864013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

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 |
|---------------------|--------------------------------|---|--|
| 25-OCT-2010 | 9 | 23:14 | YES |

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

Document Number R337864113

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: 1018

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 R337864313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

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 R337864413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

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 | |

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R337864513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

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 R337864613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

Subject Initials: (b) (6)

Is Blank

Orbs Dispensation/Collection (Continued)

NA, Not Orbs Group CHECKED

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R337864713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

Subject Initials: (b) (6)

Is Blank

UB Cigarette Dispensation/Collection

NA, Not Dual Use group CHECKED

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

End-of-Day Daily Composited YIU Filter Tip Disposition

NA, Not Dual Use group CHECKED

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

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

Document Number R337864813

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

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 | 25-OCT-2010 07:14 | 26-OCT-2010 07:34 | 1720 | <input type="checkbox"/> | |

Plasma Nicotine/Cotinine and Thiocyanate Analytical Sample

| Date | Scheduled Timepoint | Actual Time | Not | Comments |
|-------------|---------------------|---------------|--------------------------|----------|
| DD/MMM/YYYY | | 24-hour clock | Done | |
| 25-OCT-2010 | 07:00 | 07:37 | <input type="checkbox"/> | |
| 25-OCT-2010 | 12:00 | 12:34 | <input type="checkbox"/> | |
| 25-OCT-2010 | 22:00 | 22:34 | <input type="checkbox"/> | |

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

Document Number R337480313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

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 R337864913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

Subject Initials: (b) (6)

Is Blank

Blood Collection for COHb

| Date DD/MMM/YYYY | Scheduled Timepoint | Actual Time 24-hour clock | Not Done | Comments |
|---------------------|---------------------|------------------------------|--------------------------|----------|
| 25-OCT-2010 | 22:00 | 22:34 | <input type="checkbox"/> | |

Expired Carbon Monoxide

| Date DD/MMM/YYYY | Scheduled Timepoint | Actual Time 24-hour clock | ECO Level (ppm) | % COHb | Not Done | Comments |
|---------------------|---------------------|------------------------------|--------------------|--------|--------------------------|----------|
| 25-OCT-2010 | 07:00 | 07:43 | 2 | 1.0 | <input type="checkbox"/> | |
| 25-OCT-2010 | 12:00 | 12:36 | 1 | 0.8 | <input type="checkbox"/> | |
| 25-OCT-2010 | 22:00 | 22:36 | 2 | 1.0 | <input type="checkbox"/> | |

Questionnaires

Date of Assessment

DD/MMM/YYYY

25-OCT-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 R337865013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

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

25-OCT-2010

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

Requisition Number 1:

Y245689

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Requisition Number 4 (if applicable):

Requisition Number 5 (if applicable):

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

Requisition Number

Test Name

Test Code ID

| | | |
|--|--|--|
| | | |
| | | |
| | | |
| | | |
| | | |

Urine Pregnancy Test

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

Date

DD/MMM/YYYY

Urine Pregnancy Test Result

☐ Positive ☐ Negative

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R337865113

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

Subject Initials: (b) (6)

Is Blank

Abbreviated Physical Examination

Does the subject have any relevant findings?

☐ Yes ☒ No

Date

DD/MMM/YYYY

25-OCT-2010

Consider the following systems when performing the assessment:

01 General Appearance

06 Chest

02 Skin

07 Cardiovascular

05 Pulmonary

08 Abdomen and Liver/Spleen

Code

Findings

| | |
|--|--|
| | |
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Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R337865213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DAY 5/EARLY TERM

Subject Number: 1018

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 | 25-OCT-2010 | 08:30 |

| Parameter | Unit | Result |
|------------------------|--------------|--------|
| Ventricular Heart Rate | beats/minute | 72 |
| PR Interval | milliseconds | 162 |
| QRS Duration | milliseconds | 84 |
| QT Interval | milliseconds | 374 |
| QTc Interval | milliseconds | 409 |

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

25-OCT-2010

Exam Determination

Result

If Yes, Please Describe

Evidence of Leukoplakia?

☐ Yes ☒ No

Evidence of Other Oral Keratosis?

☐ Yes ☒ No

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

Document Number R337633213

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name DISCHARGE, DAY 6

Subject Number: 1018

Subject Initials: (b) (6)

Is Blank

Seated Vital Signs and HDYF? Inquiry

Were vital signs collected? ☒ Yes ☐ No

Date
DD/MMM/YYYY

26-OCT-2010

Actual Time
24-hour clock

07:29

Was HDYF?
question asked?

☒ Yes ☐ No

Parameter

Unit

Result

Systolic Blood Pressure

mmHg

116

Diastolic Blood Pressure

mmHg

73

Pulse

beats/minute

82

Respiratory Rate

breaths/minute

16

Oral Temperature

°C

36.5

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R337865313

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

PCM

Subject Number:

1018

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: MULTIVITAMIN/MINERAL

Indication: HEALTH

Dose:

2

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

12-SEP-2010

Stop Date

DD/MMM/YYYY

☒ Ongoing

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

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

Document Number

R339150713

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Previous and Concomitant Medications

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

☒ Yes, list below. ☐ No

Drug Name:

Indication:

Dose:

Unit: Select only one

☐ grams

☐ micrograms

☒ milligrams

☐ milliliter

☐ tablet

☐ other, specify:

Frequency: Select only one

☐ one time

☐ whenever necessary

☐ every morning

☐ at bedtime

☒ every day

☐ twice daily

☐ three times daily

☐ four times daily

☐ every four hours

☐ every other day

☐ every week

☐ other, specify:

Route: Select only one

☒ Oral

☐ Topical

☐ Subcutaneous

☐ Intravenous

☐ Intramuscular

☐ Intradermal

☐ Ocular, Left

☐ Ocular, Right

☐ Ocular, Both

☐ Sublingual

☐ Other, specify:

Start Date

DD/MMM/YYYY

Stop Date

DD/MMM/YYYY

☒ Ongoing

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

PCM

Subject Number:

1018

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: B COMPLEX

Indication: HEALTH

Dose:

2

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

12-SEP-2010

Stop Date

DD/MMM/YYYY

☒ Ongoing

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

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

Document Number

R339151913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Previous and Concomitant Medications

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

☒ Yes, list below. ☐ No

Drug Name:

Indication:

Dose:

Unit: Select only one

☐ grams

☐ micrograms

☒ milligrams

☐ milliliter

☐ tablet

☐ other, specify:

Frequency: Select only one

☒ one time

☐ whenever necessary

☐ every morning

☐ at bedtime

☐ every day

☐ twice daily

☐ three times daily

☐ four times daily

☐ every four hours

☐ every other day

☐ every week

☐ other, specify:

Route: Select only one

☒ Oral

☐ Topical

☐ Subcutaneous

☐ Intravenous

☐ Intramuscular

☐ Intradermal

☐ Ocular, Left

☐ Ocular, Right

☐ Ocular, Both

☐ Sublingual

☐ Other, specify:

Start Date

DD/MMM/YYYY

Stop Date

DD/MMM/YYYY

☐ Ongoing

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

Links to Discrepancy and Audit Sections

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R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

Subject Number:

Subject Initials:

Is Blank ☐

Previous and Concomitant Medications

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

☒ Yes, list below. ☐ No

Drug Name:

Indication:

Dose:

Unit: Select only one

☐ grams

☐ micrograms

☐ milligrams

☐ milliliter

☒ tablet

☐ other, specify:

Frequency: Select only one

☒ one time

☐ whenever necessary

☐ every morning

☐ at bedtime

☐ every day

☐ twice daily

☐ three times daily

☐ four times daily

☐ every four hours

☐ every other day

☐ every week

☐ other, specify:

Route: Select only one

☒ Oral

☐ Topical

☐ Subcutaneous

☐ Intravenous

☐ Intramuscular

☐ Intradermal

☐ Ocular, Left

☐ Ocular, Right

☐ Ocular, Both

☐ Sublingual

☐ Other, specify:

Start Date

DD/MMM/YYYY

Stop Date

DD/MMM/YYYY

☐ Ongoing

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

Links to Discrepancy and Audit Sections

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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

AE

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

1

Adverse Event:

EXCESSIVE FLATULENCE

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

20-OCT-2010

18:30

21-OCT-2010

14:20

☐ 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

R337865513

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

AE

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

2

Adverse Event:

NAUSEA

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

21-OCT-2010

08:04

21-OCT-2010

08:21

☐ 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

R337865613

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

AE

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

3

Adverse Event:

INDIGESTION

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

21-OCT-2010

10:20

21-OCT-2010

14:20

☐ 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

R337865713

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:

1018

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

4

Adverse Event:

ABDOMINAL PAIN

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

21-OCT-2010

13:50

21-OCT-2010

14:20

☐ 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

R337865813

Links to Discrepancy and Audit Sections

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

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

AE

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

5

Adverse Event:

LOOSE STOOL

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

21-OCT-2010

14:15

21-OCT-2010

16:00

☐ 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

R337865913

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:

1018

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

6

Adverse Event:

ANXIOUS FEELING

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

21-OCT-2010

19:45

21-OCT-2010

20:30

☐ Ongoing

Severity: Select only one

☒ Mild

☐ Moderate

☐ Severe

Action Taken Select only one

with Study

☐ Dose increased

☐ Treatment interrupted

Treatment:

☒ Dose not changed

☐ Treatment withdrawn

☐ Dose reduced

☐ Not applicable

Other Action Select all that apply

Taken with ☐ None

Subject: ☐ Required concomitant medication

☐ Required withdrawal from study

☒ Other, Specify: VITALS TAKEN

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

R337866013

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:

1018

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

7

Adverse Event:

RAW MOUTH

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

22-OCT-2010

15:30

24-OCT-2010

10:00

☐ 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

R337866113

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

AE

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

8

Adverse Event:

BLOOD TINGED NASAL DRAINAGE

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

23-OCT-2010

07:15

23-OCT-2010

11:00

☐ 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

R337866213

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

AE

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

9

Adverse Event:

INCREASED FLATULENCE

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

24-OCT-2010

19:00

25-OCT-2010

06:30

☐ Ongoing

Severity: Select only one

☒ Mild

☐ Moderate

☐ Severe

Action Taken Select only one

with Study

☐ Dose increased

☐ Treatment interrupted

Treatment:

☒ Dose not changed

☐ Treatment withdrawn

☐ Dose reduced

☐ Not applicable

Other Action Select all that apply

Taken with ☐ None

Subject: ☒ Required concomitant medication

☐ Required withdrawal from study

☐ Other, Specify:

Relationship Select only one

to Study Treatment:

☐ Not Related

☒ Possible

☐ Probable

☐ Definite

Serious Event: Select only one

☐ Yes

☒ No

Outcome: Select only one

☒ Recovered/Resolved

☐ Recovered/Resolved with Sequelae

☐ Recovering/Resolving

☐ Fatal

☐ Not Recovered/Not Resolved

☐ Unknown

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

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

Document Number

R337866313

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:

1018

Subject Initials:

(b) (6)

Is Blank

Adverse Events

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

Event Number:

10

Adverse Event:

MENSTRUAL CRAMPS

Onset Date

Onset Time

Resolved Date

Resolved Time

DD/MMM/YYYY

24-hour clock

DD/MMM/YYYY

24-hour clock

24-OCT-2010

18:57

UNK

UNK

☐ Ongoing

Severity: Select only one

☐ Mild

☐ Moderate

☐ Severe

Action Taken Select only one

with Study ☐ Dose increased

☐ Treatment interrupted

Treatment: ☒ Dose not changed

☐ Treatment withdrawn

☐ Dose reduced

☐ Not applicable

Other Action Select all that apply

Taken with ☐ None

Subject: ☒ Required concomitant medication

☐ Required withdrawal from study

☐ Other, Specify:

Relationship Select only one

to Study Treatment: ☒ Not Related

☐ Possible

☐ Probable

☐ Definite

Serious Event: Select only one

☐ Yes

☒ No

Outcome: Select only one

☐ Recovered/Resolved

☐ Recovered/Resolved with Sequelae

☐ Recovering/Resolving

☐ Fatal

☐ Not Recovered/Not Resolved

☒ Unknown

Verified

☒ Approved

☒ Locked

☒ Frozen

☒

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

Document Number

R353457613

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: 1018

Subject Initials: (b) (6)

Is Blank

Additional Assessments - Vital Signs

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

Date DD/MMM/YYYY 19-OCT-2010
Actual Time 24-hour clock 12:39
Position
☐ Standing
☐ Supine
☒ Seated
☐ Other, Specify:

| Parameter | Unit | Result |
|--------------------------|----------------|--------|
| Systolic Blood Pressure | mmHg | ND |
| Diastolic Blood Pressure | mmHg | ND |
| Pulse | beats/minute | 90 |
| Respiratory Rate | breaths/minute | ND |
| Oral Temperature | °C | ND |

Date DD/MMM/YYYY 21-OCT-2010
Actual Time 24-hour clock 20:21
Position
☐ Standing
☐ Supine
☒ Seated
☐ Other, Specify:

| Parameter | Unit | Result |
|--------------------------|----------------|--------|
| Systolic Blood Pressure | mmHg | 114 |
| Diastolic Blood Pressure | mmHg | 67 |
| Pulse | beats/minute | 97 |
| Respiratory Rate | breaths/minute | 18 |
| Oral Temperature | °C | 36.7 |

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R337866413

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name

LB ADDITIONAL

Subject Number:

1018

Subject Initials:

(b) (6)

Is Blank

Additional Assessments - Laboratory Evaluations

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

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

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number

R346355013

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name EG ADDITIONAL

Subject Number: 1018

Subject Initials: (b) (6)

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

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

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

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

ECG Interpretation:

☐ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

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

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

ECG Interpretation:

☐ Normal ☐ Abnormal, NCS ☐ Abnormal, CS

Comments Regarding CS Findings:

Verified ☒ Approved ☒ Locked ☒ Frozen ☒

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

Document Number R337634913

R.J. Reynolds Tobacco Company

Protocol Number: CSD0901

Covance Study Number: 8230249

Visit Name **STUDY COMPLETION**

Subject Number: **1018**

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

Is Blank

Study Completion

Date the subject completed OR withdrew from the study: **26-OCT-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 **R337866513**

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 #: R337860113

| | | | |
|-----------------------------|--------------------------------|-----------------------------------|-----------------------|
| Patient Site | Visit Visit Date | CRF CRF Page | |
| 1018 | Baseline, Day -1 | Page_22 | |
| M01 | | 022 | |
| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
| Max | Page number | 22 | Baseline, Day -1 |
| Group # | Group Name | | |
| 1 | INDYN | | |
| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
| Date | 21-OCT-2010 | 16-NOV-2010 13:59:36 | Data Entry Error |
| 1 | 20-OCT-2010 | Dawn Winter | |

Document #: R335948613

| | | |
|----------------|-------------------|-----------------|
| Patient | Visit | CRF |
| Site | Visit Date | CRF Page |
| 1018 | 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 | | 22-DEC-2010 15:00:31 Matthew Mickelson | Data Entry Error |
| 6-ounce serving of White or Rose Wine (2) 1 | 00 | | 22-DEC-2010 15:00:31 Matthew Mickelson | Data Entry Error |

Document #: R337860313

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|-------------------------|---------------------|
| 1018 | Day 1 | Page_25 |
| M01 | | 025 |

| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Snus_Disb | Page number | 25 | Day 1 |

| Group # | Group Name |
|----------------|-------------------|
| 0 | Section Header |

| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
|------------------|--------------------------------|-----------------------------------|-----------------------|
| DCM Blank flag | N | 16-NOV-2010 13:18:36 | Data Entry Error |
| 1 | Y | Dawn Winter | |

Document #: R335945813

| | | | |
|---------------------|--------------------------|-------------------------|----------------------|
| Patient | Visit | CRF | |
| Site | Visit Date | CRF Page | |
| 1018 | 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 | | 22-DEC-2010 15:01:34 Matthew Mickelson | Data Entry Error |
| 6-ounce serving of White or Rose Wine (2) 1 | 00 | | 22-DEC-2010 15:01:34 Matthew Mickelson | Data Entry Error |

Document #: R337861313

| Patient Site | Visit Visit Date | CRF CRF Page |
|--------------|------------------|--------------|
| 1018 | Day 2 | Page_37 |
| M01 | | 037 |

| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
|----------------------|-------------------|------------------|---------------|
| Snus_Dis | Page number | 37 | Day 2 |

| Group # | Group Name |
|---------|----------------|
| 0 | Section Header |

| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
|----------------|-------------------------|----------------------------|------------------|
| DCM Blank flag | N | 01-FEB-2011 09:02:18 | Data Entry Error |
| 1 | Y | Dawn Winter | |

Document #: R335951813

| | | | |
|---------------------|--------------------------|-------------------------|----------------------|
| Patient | Visit | CRF | |
| Site | Visit Date | CRF Page | |
| 1018 | 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 | 00 | | 22-DEC-2010 15:02:47 Matthew Mickelson | Data Entry Error |
| 6-ounce serving of White or Rose Wine (2) 1 | 2 02 | | 22-DEC-2010 15:02:47 Matthew Mickelson | Data Entry Error |

Document #: R337862213

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|-------------------------|---------------------|
| 1018 | Day 3 | Page_47 |
| M01 | | 047 |

| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Snus_Disb | Page number | 47 | Day 3 |

| Group # | Group Name |
|----------------|-------------------|
| 0 | Section Header |

| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
|------------------|--------------------------------|-----------------------------------|-----------------------|
| DCM Blank flag | N | 01-FEB-2011 09:05:12 | Data Entry Error |
| 1 | Y | Dawn Winter | |

Document #: R335953813

| | | | |
|---------------------|--------------------------|-------------------------|----------------------|
| Patient | Visit | CRF | |
| Site | Visit Date | CRF Page | |
| 1018 | 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 | 00 | | 22-DEC-2010 15:03:20 Matthew Mickelson | Data Entry Error |
| 6-ounce serving of White or Rose Wine (2) 1 | 2 02 | | 22-DEC-2010 15:03:20 Matthew Mickelson | Data Entry Error |

Document #: R337863213

| Patient Site | Visit Visit Date | CRF CRF Page |
|---------------------|-------------------------|---------------------|
| 1018 | Day 4 | Page_59 |
| M01 | | 059 |

| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Snus_Disb | Page number | 59 | Day 4 |

| Group # | Group Name |
|----------------|-------------------|
| 0 | Section Header |

| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
|------------------|--------------------------------|-----------------------------------|-----------------------|
| DCM Blank flag | N | 01-FEB-2011 10:14:30 | Data Entry Error |
| 1 | Y | Dawn Winter | |

Document #: R337464213

| | | | |
|-----------------------------|--------------------------|-------------------------|----------------------|
| Patient Site | Visit Visit Date | CRF CRF Page | |
| 1018 | 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 | | |

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|--|--------------------------------|---|-----------------------|
| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
| 12-ounce serving of Ultralight Beer (1) 1 | 2 02 | 22-DEC-2010 15:03:49 Matthew Mickelson | Data Entry Error |
| 6-ounce serving of White or Rose Wine (2) 1 | 00 | 22-DEC-2010 15:03:49 Matthew Mickelson | Data Entry Error |

Document #: R337864113

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|-----------------------------|--------------------------------|-----------------------------------|-----------------------|
| Patient Site | Visit Visit Date | CRF CRF Page | |
| 1018 | Day 5/Early Term | Page_69 | |
| M01 | | 069 | |
| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
| Snus_Disb | Page number | 69 | Day 5/Early Term |
| Group # | Group Name | | |
| 0 | Section Header | | |
| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
| DCM Blank flag | N | 01-FEB-2011 10:18:27 | Data Entry Error |
| 1 | Y | Dawn Winter | |

Document #: R337865113

| | | | |
|---|--------------------------------|-----------------------------------|-----------------------|
| Patient Site | Visit Visit Date | CRF CRF Page | |
| 1018 | 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) | G798499 | 17-FEB-2011 14:18:19 Dawn Winter | Data Entry Error |
| 1 | | | |

Document #: R339152913

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|---------------------|-------------------------|---------------------|
| Patient Site | Visit Visit Date | CRF CRF Page |
| 1018 | Pcm.4 | Page_84 |
| M01 | | |

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|-----------------------------|--------------------------|-------------------------|----------------------|
| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
| Pcm | Page number | 84 | Pcm.4 |

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|----------------|-------------------|
| Group # | Group Name |
| 1 | CM |

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|--------------------------|--|--|-----------------------|
| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
| ATC1 1 | ALIMENTARY TRACT AND METABOLISM, A | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |
| ATC1 Code 1 | A | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |
| ATC2 1 | DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, A03 | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |
| ATC2 Code 1 | A03 | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |
| ATC3 1 | DRUGS FOR FUNCTIONAL BOWEL DISORDERS, A03A | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |
| ATC3 Code 1 | A03A | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |
| ATC4 1 | OTHER DRUGS FOR FUNCTIONAL BOWEL DISORDERS, A03AX | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |
| ATC4 Code 1 | A03AX | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |
| Dose 1 | 80/30 1 | 29-MAR-2011 13:14:27 Dawn Winter | Data Entry Error |
| Drug Name 1 | GAS-EX GAS-X | 27-SEP-2011 14:32:58 Michael Richardson | Data Entry Error |
| Preferred Term 1 | SIMETICONE | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |
| Preferred Term Code 1 | 06269601001 | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |
| Synonym 1 | GAS-X /06269601/ | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |
| Synonym Code 1 | 06269601017 | 04-OCT-2011 10:28:07 Carol Kraucyk | Data Change |

Document #: R339152913

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|----------------|-------------------|-----------------|
| Patient | Visit | CRF |
| Site | Visit Date | CRF Page |
| 1018 | Pcm.4 | Page_84 |
| M01 | | |

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|---------------------|--------------------------|-------------------------|----------------------|
| Section | Qualifying Prompt | Qualifying Value | Section Visit |
| Section Date | | | |
| Pcm | Page number | 84 | Pcm.4 |

| | |
|----------------|-------------------|
| Group # | Group Name |
| 1 | CM |

| | | | |
|------|------------|----------------------|------------------|
| Unit | MILLIGRAMS | 29-MAR-2011 13:14:27 | Data Entry Error |
| 1 | OTHER | Dawn Winter | |

| | | | |
|------|--------|----------------------|------------------|
| Unit | OTHER | 29-MAR-2011 13:24:28 | Data Entry Error |
| 1 | TABLET | Dawn Winter | |

| | | | |
|----------|--------|----------------------|-------------|
| Verbatim | GAS-EX | 03-OCT-2011 15:44:41 | Data Change |
| 1 | GAS-X | Carol Kraucyk | |

| | | | |
|-------------------------------|--------|----------------------|------------------|
| other, specify: (Unit) (1) | | 29-MAR-2011 13:14:27 | Data Entry Error |
| 1 | TABLET | Dawn Winter | |

| | | | |
|-------------------------------|--------|----------------------|------------------|
| other, specify: (Unit) (1) | TABLET | 29-MAR-2011 13:24:28 | Data Entry Error |
| 1 | | Dawn Winter | |

Document #: R337865713

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|---------|------------|----------|
| Patient | Visit | CRF |
| Site | Visit Date | CRF Page |
| 1018 | 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 | | 31-MAR-2011 09:54:18 | Data Entry Error |
| with Study | NOT CHANGED | | Michael Richardson | |
| Treatment | | | | |
| 1 | | | | |

Document #: R337865913

| | | |
|----------------|-------------------|-----------------|
| Patient | Visit | CRF |
| Site | Visit Date | CRF Page |
| 1018 | Ae.4 | Page_85 |
| M01 | | |

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|---------------------|--------------------------|-------------------------|----------------------|
| Section | Qualifying Prompt | Qualifying Value | Section Visit |
| Section Date | | | |
| Ae | Page number | 85 | Ae.4 |

| | |
|----------------|-------------------|
| Group # | Group Name |
| 1 | AE |

| | | | | |
|-----------------|---------------------|-------------------|----------------------|------------------|
| Field | Changed From | Impact on | On | Reason |
| Row | Changed To | resequence | By | Comment |
| Relationship to | PROBABLE | | 26-JAN-2011 08:20:13 | Data Entry Error |
| Study Treatment | POSSIBLE | | Dawn Winter | |
| 1 | | | | |

Document #: R337866013

| | | |
|---------|------------|----------|
| Patient | Visit | CRF |
| Site | Visit Date | CRF Page |
| 1018 | Ae.5 | Page_85 |
| M01 | | |

| | | | |
|--------------|-------------------|------------------|---------------|
| Section | Qualifying Prompt | Qualifying Value | Section Visit |
| Section Date | | | |
| Ae | Page number | 85 | Ae.5 |

| | |
|---------|------------|
| Group # | Group Name |
| 1 | AE |

| | | | | |
|-----------------|-----------------|-------------|----------|------------------|
| Field | Changed From | Impact on | On | Reason |
| Row | Changed To | resequence | By | Comment |
| Adverse Event | ANXIRUS FEELING | 26-JAN-2011 | 08:21:27 | Data Entry Error |
| 1 | ANXIOUS FEELING | Dawn Winter | | |
| Relationship to | PROBABLE | 26-JAN-2011 | 08:21:27 | Data Entry Error |
| Study Treatment | POSSIBLE | Dawn Winter | | |
| 1 | | | | |

Document #: R337866213

| | | |
|----------------|-------------------|-----------------|
| Patient | Visit | CRF |
| Site | Visit Date | CRF Page |
| 1018 | Ae.7 | Page_85 |
| M01 | | |

| | | | |
|---------------------|--------------------------|-------------------------|----------------------|
| Section | Qualifying Prompt | Qualifying Value | Section Visit |
| Section Date | | | |
| Ae | Page number | 85 | Ae.7 |

| | |
|----------------|-------------------|
| Group # | Group Name |
| 1 | AE |

| | | | | |
|---------------|---------------------|-------------------|----------------------|------------------|
| Field | Changed From | Impact on | On | Reason |
| Row | Changed To | resequence | By | Comment |
| Resolved Date | 13-OCT-2010 | | 27-DEC-2010 15:45:53 | Data Entry Error |
| 1 | 23-OCT-2010 | | Dawn Winter | |

Document #: R337866313

| | | |
|----------------|-------------------|-----------------|
| Patient | Visit | CRF |
| Site | Visit Date | CRF Page |
| 1018 | Ae.8 | Page_85 |
| M01 | | |

| | | | |
|---------------------|--------------------------|-------------------------|----------------------|
| Section | Qualifying Prompt | Qualifying Value | Section Visit |
| Section Date | | | |
| Ae | Page number | 85 | Ae.8 |

| | |
|----------------|-------------------|
| Group # | Group Name |
| 1 | AE |

| | | | | |
|-----------------|---------------------|-------------------|----------------------|------------------|
| Field | Changed From | Impact on | On | Reason |
| Row | Changed To | resequence | By | Comment |
| Relationship to | PROBABLE | | 26-JAN-2011 08:22:56 | Data Entry Error |
| Study Treatment | POSSIBLE | | Dawn Winter | |
| 1 | | | | |

Document #: R353457613

| Patient Site | Visit Visit Date | CRF CRF Page |
|--------------|------------------|--------------|
| 1018 | Ae.9 | Page_85 |
| M01 | | |

| Section Section Date | Qualifying Prompt | Qualifying Value | Section Visit |
|----------------------|-------------------|------------------|---------------|
| Ae | Page number | 85 | Ae.9 |

| Group # | Group Name |
|---------|------------|
| 1 | AE |

| Field Row | Changed From Changed To | Impact on On resequence By | Reason Comment |
|------------|-------------------------|-------------------------------------|------------------|
| Severity 1 | MILD | 25-FEB-2011 07:41:43 Dawn Winter | Data Entry Error |

Discrepancy Detail Report

Document #: R337858613

Discrepancy ID: 244263711

Site: M01

Patient: 1018

Visit: SCREEN 1

Visit Date:

CRF: PAGE_02

Section: IC

Qualifying Value: 2

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Inclusion Criterion #5 is Yes, but Expired-Air CO (ECO) level is less than 15 ppm at Screening. Please verify inclusion criterion response and Expired-Air CO (ECO) level response and update as appropriate.

Internal Comment:

Resolution Type: Confirmed

Resolution Text: was done at screen visit 2

Document #: R337859213

Discrepancy ID: 244258511

Site: M01

Patient: 1018

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 30.4 is less than 18.0 or greater than 30.0 kg/m2. Please reconcile.

Internal Comment:

Resolution Type: No Action Required

Resolution Text:

Document #: R339152513

Discrepancy ID: 292767911

Site: M01

Patient: 1018

Visit: PCM.3

Visit Date:

CRF: PAGE_84

Section: PCM

Qualifying Value: 84

Field: Stop Date

Row: 1

Value Text: 20101024

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: review new AE entry and update dates as appropriate.

Internal Comment: It appears an AE needs to be generated, but the dispensation of tylenol ceased on 24Oct2010, so this page is confirmed.

Resolution Type: Confirmed

Resolution Text:

Document #: R339152913

Discrepancy ID: 320367211 **Site:** M01 **Patient:** 1018
Visit: PCM.4 **Visit Date:**
CRF: PAGE_84 **Section:** PCM **Qualifying Value:** 84
Field: Dose **Row:** 1
Value Text: 1
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per the completion guidelines, please report the Dose/Unit as "1 Tablet".
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 413667611 **Site:** M01 **Patient:** 1018
Visit: PCM.4 **Visit Date:**
CRF: PAGE_84 **Section:** PCM **Qualifying Value:** 84
Field: Drug Name **Row:** 1
Value Text: GAS-X
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please correct the spelling error.
Internal Comment: Gas-Ex was changed to Gas-x
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R337865713

Discrepancy ID: 320349711 **Site:** M01 **Patient:** 1018
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:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R337865813

Discrepancy ID: 292779311 **Site:** M01 **Patient:** 1018
Visit: AE.3 **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: Dose not changed vs Na for Action taken Regarding Study Drug.
Internal Comment: should be dose not changed
Resolution Type: Confirmed
Resolution Text:

Document #: R337865913

Discrepancy ID: 292783011 **Site:** M01 **Patient:** 1018
Visit: AE.4 **Visit Date:**
CRF: PAGE_85 **Section:** AE **Qualifying Value:** 85
Field: Relationship to Study Treatment **Row:** 1
Value Text: POSSIBLE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: per source data, entry should be "possibly related". Please update.
Internal Comment: updated
Resolution Type: Confirmed
Resolution Text:

Document #: R337866013

Discrepancy ID: 292817911 **Site:** M01 **Patient:** 1018
Visit: AE.5 **Visit Date:**
CRF: PAGE_85 **Section:** AE **Qualifying Value:** 85
Field: Adverse Event **Row:** 1
Value Text: ANXIOUS FEELING
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Spelling error - "Anxious"
Internal Comment: spelling corrected
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 292818011 **Site:** M01 **Patient:** 1018
Visit: AE.5 **Visit Date:**
CRF: PAGE_85 **Section:** AE **Qualifying Value:** 85
Field: Relationship to Study Treatment **Row:** 1
Value Text: POSSIBLE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Source data indicates "Possibly related". Please review and update CRF.
Internal Comment: corrected
Resolution Type: Confirmed
Resolution Text:

Document #: R337866313

Discrepancy ID: 292820711 **Site:** M01 **Patient:** 1018
Visit: AE.8 **Visit Date:**
CRF: PAGE_85 **Section:** AE **Qualifying Value:** 85
Field: Relationship to Study Treatment **Row:** 1
Value Text: POSSIBLE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Source data indicates "Possibly Related". Please review and update CRF as appropriate.
Internal Comment: updated
Resolution Type: Confirmed
Resolution Text:

Document #: R353457613

Discrepancy ID: 303222811 Site: M01 Patient: 1018
Visit: AE.9 Visit Date:
CRF: PAGE_85 Section: AE Qualifying Value: 85
Field: Severity Row: 1
Value Text:
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify to source if this can be determined. Will the CRF allow this entry to be blank?

Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 303479111 Site: M01 Patient: 1018
Visit: AE.9 Visit Date:
CRF: PAGE_85 Section: AE Qualifying Value: 85
Field: Severity Row: 1
Value Text:
Type: UNIVARIATE Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value for Severity has not been supplied

Internal Comment:
Resolution Type: Due Diligence
Resolution Text:

Discrepancy ID: 303222011 Site: M01 Patient: 1018
Visit: AE.9 Visit Date:
CRF: PAGE_85 Section: AE Qualifying Value: 85
Field:
Value Text:
Type: MULTIVARIATE Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: The Subject has had an Adverse Event of MENSTRUAL CRAMPS with a Onset Date of 24-OCT-2010 but the Resolved Date is missing and Ongoing is not ticked. Please provide the Resolved Date of the AE or clarify if Ongoing.

Internal Comment:
Resolution Type: Confirmed
Resolution Text:

R353457613

Discrepancy ID: 303479211 **Site:** M01 **Patient:** 1018

Visit: AE.9

Visit Date:

CRF: PAGE_85

Section: AE

Qualifying Value: 85

Field:

Row:

Value Text:

Type: MULTIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Did the subject experience any adverse events?' has been answered Yes, but details are missing. Please reconcile.

Internal Comment: An AE was not created at the time of concomitant medication dispensation, so AE details cannot be verified. Attempts to contact the subject have been made, with no response.

Resolution Type: Confirmed

Resolution Text:

Discrepancy ID: 303222111 **Site:** M01 **Patient:** 1018

Visit: AE.9

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 MENSTRUAL CRAMPS with a Onset Date of 24-OCT-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:

Deleted CRFs Report