NCT05553600

Statistical Analysis Plan

[redacted]

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Document History

Version	Date	Author	Description
1.0	15NOV2022	[redacted]	Final SAP
1.1	03MAR2023	[redacted]	Final SAP with Amendment: 1) Updated table 14.2.2.1 by adding number of tampons remaining white and any flow. 2) Updated table 14.2.2.2 by adding reasons why subjects were not able to insert the tampon using the applicator. 3) Added listing 16.2.6.2.3 for reasons why subjects were not able to insert the tampon using the applicator 4) Updated section 8.2 and 13.4 for the updates specified above. 5) Added hypothesis testing for significant difference between treatment groups to section 8.1 and 8.2 6) Added block of difference between test and reference articles for elongation and proportion of subject who were able to insert each tampon to Table 14.2.1 and 14.2.2.2 7) Added definition of Ns to table shells.

[redacted]

Table of Contents

[redacted]

List of Tables

List of Figures

[redacted]

List of Abbreviations

Abbreviation	Definition
AE	adverse event
ASA	American Statistical Association
ATC	anatomical therapeutic chemical
CI	confidence interval
CRF	case report form
CSR	clinical study report
EMA	European Medicines Agency
FDA	Food and Drug Administration
ICH	International Conference on Harmonization
ITT	intent-to-treat
MedDRA	medical dictionary for regulatory activities
SAE	serious adverse event
SAP	statistical analysis plan
SD	standard deviation
SOC	system organ class
TSS	toxic shock syndrome
WHO-DD	World Health Organization drug dictionary

1. Overview

This statistical analysis plan (SAP) describes the planned analysis and reporting for Kimberly-Clark Corporation protocol number AFC-21-001 (An Open-Label Clinical Validation Study of an Applicator Tampon), dated 24-Aug-2022, Version 2.0. Reference materials for this statistical plan include the protocol and the accompanying sample data collection documents. Operational aspects related to collection and timing of planned clinical assessments are not repeated in this SAP unless relevant to the planned analysis.

The structure and content of this SAP provides sufficient detail to meet the requirements identified by the Food and Drug Administration (FDA), European Medicines Agency (EMA), and International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guidance on Statistical Principles in Clinical Trials (ICH, 1998). All work planned and reported for this SAP will follow internationally accepted guidelines, published by the American Statistical Association (ASA, 2018) and the Royal Statistical Society (RSS, 2014), for statistical practice.

The planned analyses identified in this SAP may be included in clinical study reports (CSRs), regulatory submissions, or future manuscripts. Also, post-hoc exploratory analyses not necessarily identified in this SAP may be performed to further examine study data. Any post-hoc or unplanned, exploratory analysis performed will be clearly identified as such in the final CSR.

The statistical plan described hereafter is an *a priori* plan. It will be approved before any inferential or descriptive analysis of data pertaining to Kimberly-Clark Corporation's study AFC-21-001.

2. Study Objectives and Endpoints

2.1. Study Objective

2.1.1. Primary Objective

The primary objective of this study is to validate that changes in the design of the [redacted] tampons meet defined user needs. The primary objective will have been met if the following criteria are met:

- Test tampon elongation rate is the same as or better than the reference tampon for each absorbency, where same is defined as test tampon elongation rate ≤ reference tampon elongation rate.
- Product tolerability is deemed to be acceptable based on review of the results.
- Diary responses have ≥ 96% response rates consistent with each user need for each absorbency. If the rate is lower than 96%, the response rate consistent with the user need related to the test tampon must be the same as or better than the response rate of the reference tampon, where same is defined as test tampon response rate ≥ reference tampon response rate.

- Interview responses demonstrate that 95% of users are able to identify key information on the package and insert, and able to distinguish between absorbency levels on the wrappers.

2.2. Study Endpoints

2.2.1. Validation Criteria Endpoints

2.2.1.1. Primary Endpoint

The proportion of used tampons that have elongated will be used to assess the following user need:

- User can remove product from the vagina after use

2.2.1.2. Key Secondary Endpoints

The key secondary endpoints of this study include the following:

- Diary responses will be used to assess the following user needs:
  - Product to remain clean prior to use
  - Product to remain in working condition prior to use
  - User can access the product
  - User can vaginally insert and place the tampon
  - User can remove product from the vagina after use
  - Product absorbs fluid
- Interview responses will be used to assess the following user needs:
  - User is able to distinguish between absorbency levels
  - Packaging is labeled properly
- Product tolerability will be evaluated through the following measures:
  - Gynecological exam findings
  - Frequency and severity of adverse events

2.2.2. Safety Endpoints

The safety endpoints for this study, gynecological exam findings and frequency and severity of adverse events, are included as key secondary endpoints.

3. Overall Study Design and Plan

3.1. Overall Design

This study is an open-label, randomized, crossover study designed to validate that changes to the design of [redacted] tampons meet defined user needs. Subjects will be assigned to either a regular absorbency arm or super absorbency arm. Subjects will test a new tampon design (test tampon) and a commercially available tampon design (reference tampon).

Each tampon type will be used over the course of one menstrual cycle. Within each absorbency arm, subjects will be randomized to the order in which to use the test tampon and the reference tampon. Subject participation in the study will last over the course of 2 menstrual cycles, or approximately 2 months.

A subset of 120 subjects (60 subjects within each absorbency arm) will undergo gynecological examinations prior to and following tampon use. For the subset of subjects undergoing gynecological exams, the study will include a total of 4 visits, 2 visits for each menstrual cycle. The first visit will be the screening visit and the first pre-use visit. The next visit will be the first post-use visit, followed by the second pre-use visit and the second post-use visit. Pre-use visits will be conducted within 72 hours prior to expected menstruation and post-use visits will be conducted within 72 hours following the last tampon use for that menstrual cycle. Gynecological examinations will be performed at each visit. This subset of subjects will also complete a packaging and labeling interview at the first visit to assess whether subjects can identify and distinguish key information on the product packaging.

For the remainder of subjects who will not undergo gynecological examinations, the study will include 3 visits: a screening/pre-use visit and 2 post-use visits. Post-use visits will be conducted within 72 hours following the last tampon use for that menstrual cycle.

All subjects will keep a diary during menstruation with entries for each tampon used and will collect each used tampon to be returned to the site. At each post-use visit, site personnel will review subject diaries for completeness and accuracy, record the number of used and unused tampons returned, and evaluate used tampons to assess tampon integrity. Subjects will be considered to have completed the study after they complete the second post-use visit. Refer to the Schedule of Events (Table 1) for more details.

3.2. Sample Size and Power

The sample size was calculated for a single absorbency and is based on the assumption that 0.7% of reference tampons elongate (>10 mm) upon removal and 0.2% of test tampons elongate upon removal. An estimated yield of 43.75% was used, where yield is the number of usable tampons for the elongation analysis divided by the total number of products given to the subjects (i.e., yield means the percentage of tampons given to each subject that were used and can be included in the elongation analysis). It is assumed that subjects are given 16 reference tampons and 16 test tampons and use 7 tampons in each cycle.

With a power of 80% and a 2-sided alpha of 0.05, assuming 2 tampon types tested (reference and test) and each subject receiving 16 products per cycle, a total of 369 subjects will need to be enrolled in the study for each absorbency. Since there are 2 absorbencies, the study will enroll 738 subjects.

For each absorbency this translates into needing a total of 5,166 used tampons (2,538 used tampons for each tampon type (reference and test)).

3.3. Study Population

The study population consists of female subjects, ages 18-49, in good general health, in the

United States who normally use tampons for menstrual protection, menstruate regularly, and do not have a history of Toxic Shock Syndrome (TSS).

3.4. Test Articles Administered

Subjects will be assigned to one of two arms in the study based on the absorbency of tampon the subject uses most often: a regular absorbency arm or a super absorbency arm. Within each arm, subjects will be randomly assigned to the order in which to test a new, modified tampon design (test tampon) and a currently marketed, commercial tampon (reference tampon). Each tampon, test or reference, will be administered for use over the course of one menstrual cycle. Subjects will be administered a box with 16 tampons per menstrual cycle. The test article codes are listed below.

Test Article Description	Test Article Code
Modified [redacted] Tampons (test tampons) – regular absorbency	BR
Commercial [redacted] Tampons (reference tampons) – regular absorbency	CR
Modified [redacted] Tampons (test tampons) – super absorbency	BS
Commercial [redacted] Tampons (reference tampons) – super absorbency	CS

3.5. Method of Assigning Subjects to Treatment Groups

Subjects will be assigned a unique subject identification number by the site at screening. Following completion of screening procedures, eligible subjects will be assigned to either the regular or super absorbency arm, based on the tampon absorbency the subject uses most often. Within each arm, the order in which the test and reference tampons will be used will be randomized.

A randomization schedule that was created by a biostatistician at [redacted] will be provided to each site. Blinding was not required as this is an open-label study. Unique subject randomization numbers will be assigned by the site according to the site-specific randomization schedule. Randomization numbers should be assigned sequentially within each arm.

3.6. Blinding and Unblinding

Not applicable as this is an open-label study.

3.7. Schedule of Events

A detailed schedule of events for the study is provided in Table 1.

[redacted]

Table 1: Schedule of Events

Event	Visit 1 Screening/Baseline	Visit 2 Post-Use Visit	Visit 3 Pre-Use Visit	Visit 4 Post-Use Visit	Unscheduled Visit
Informed Consent	X				
Inclusion/Exclusion	X				
Demographics	X				
Medical History	X				
Concomitant Medications	X	X	X	X	X
Gynecological Symptom Assessment	X	X	X	X	X
Gynecological Exam (Visual inspection, infection assessment, vaginal discharge, and vaginal pH)	X	X	X	X	X
Packaging/Labeling Interview	X				
Randomization	X				
Test Article and Diary Dispensation	X	X*	X*		
Diary Training	X	X*	X*		
Test Article Collection (Used and unused products)		X		X	
Diary Review		X		X	
Tampon Integrity Assessment		X		X	
Adverse Event Collection		X	X	X	X
Study Completion				X	

*As needed

Key:

X	Conducted for all subjects
X	Conducted for a subset of 120 subjects (Note, visit 3 is only required for this subset of subjects)

[redacted]

4. Statistical Analysis and Reporting

4.1. Introduction

Data processing and tabulation of descriptive statistics described in this SAP will primarily use SAS (release 9.4 or higher). If the use of other software is warranted, the final statistical methodology report will detail what software was used for what purposes.

Continuous (quantitative) variable summaries will include the number of subjects (n) with non-missing values, mean, standard deviation (SD), median, minimum, and maximum.

Categorical (qualitative) variable summaries will include the frequency and percentage of subjects who are in the particular category or each possible value. Summaries may include 95% confidence intervals (CIs) if appropriate. In general, the denominator for the percentage calculation will be based upon the total number of subjects in the study population, either overall or within each absorbency arm, unless otherwise specified.

The minimum and maximum will be reported with the same degree of precision (i.e., the same number of decimal places) as the observed data. Measures of location (mean and median) will be reported to 1 degree of precision more than the observed data. Measures of spread (SD, 95% CI) will be reported to 2 degrees of precision more than the observed data.

Percentages will be presented to 1 decimal place, unless otherwise specified. General exceptions to this rule are values of 100% which will be displayed without any decimal places and zero counts which will not display percentages.

No inferential statistical hypothesis testing will be performed to assess whether the validation criteria have been met. All the analyses described in this SAP to assess whether validation criteria have been met are descriptive.

4.2. Interim Analysis and Data Monitoring

No interim analyses are planned.

5. Analysis Populations

The following analysis populations are planned for this study:

- **Intent-To-Treat Population (ITT):** The ITT population includes all subjects randomized into the study.
- **Safety Population:** The Safety Population includes all ITT subjects who insert at least 1 tampon.
- **Modified Intent-To-Treat Population (MITT):** The MITT population includes all safety subjects who have no major protocol deviations and return at least 1 tampon that can be assessed for elongation.

Assignment of subjects to populations will be determined at a data review meeting prior to database lock.

6. General Issues for Statistical Analysis

6.1. Statistical Definitions and Algorithms

6.1.1. Handling of Dropouts or Missing Data

In general, missing data will not be imputed unless otherwise stated.

6.1.2. Analysis Visit Windows

Analysis visits will be assigned based on the nominal visit recorded in the study database.

6.1.3. Pooling of Sites

Data will be pooled across sites for analysis.

6.1.4. Derived Variables

- Elongated = Any used tampon with a measurement of elongation >10 mm will be considered elongated.

6.1.5. Data Adjustments/Handling/Conventions

All collected data will be presented in listings. Data not subject to analysis according to this plan will not appear in any tables or graphs but will be included only in the data listings.

Adverse events will be coded using the Medical Dictionary for Regulatory Activities (MedDRA; version 25.1) thesaurus. Concomitant medications will be coded using the World Health Organization Drug Dictionary (WHO-DD) Enhanced B3 (September 2022).

The first article insertion date will be the date of the first tampon insertion, that the subject reported, but only for a tampon that has both the date of the tampon`s insertion and the date of the tampon`s removal documented in the diary. The last article's removal date will be defined in the same manner. The first insertion and last removal dates within each menstrual cycle will be identified using a similar logic but using the data from each menstrual cycle.

In case the subject didn`t report the tampon`s insertion and removal dates for the 1st menstrual period in the diary but returned at least 1 used tampon from 1st menstrual cycle and has available diary data for the 2nd menstrual cycle, then the first article insertion date and last article removal date for the 1st menstrual cycle will be calculated from the date of post-use visit 2 with the

assumption, that number of days between first tampon`s insertion and post-use visits are the same for both menstrual cycles.

If partial adverse event onset dates or partial medication dates occur, the convention for replacing missing dates for the purpose of statistical analysis is as follows: if just day is missing then the day assigned is the first day of the month or the date of first test article insertion (if in the same month), whichever is later; if just month is missing then the month assigned is the month of the first test article insertion, unless that results in a date before the first test article insertion in which case the month after the first test article insertion is used; and if both month and day are missing then the month assigned is the month of the first test article insertion and the day assigned is either the first day of the month or the first test article insertion date, whichever is later.

If partial adverse event onset times occur, the convention is as follows: if the missing time occurs on the day of the first test article insertion and both the hour and minute are missing then the time assigned is the time of the first test article insertion, otherwise if both the hour and minute are missing and the date is not the date of first test article insertion the time assigned is 12:00; if the date is the same as the date of the first test article insertion and only hour is missing the hour assigned is 12 or the hour of first test article insertion, whichever is later, and if the date is the same as the date of first test article insertion and only the minute is missing the minute assigned is 30 or the minute of first test article insertion, whichever is later. Otherwise the hour assigned is 12 if the hour is missing and the date is not the same as the date of first test article insertion and the minute assigned is 30 if the the date is not the same as the date of first test article insertion.

The following precatution will be considered when applying these conventions to adverse event onset dates and times: if the missing date and time reflect the date and time of onset of an adverse event, the modified date and time will be constructed to match the first documented date/time post test article administration while preserving the order in which the adverse event (AE) was reported in the CRF.

7. Study Subjects and Demographics

7.1. Disposition of Subjects and Withdrawals

The number of subjects randomized, the number of subjects completing, the number of subjects who withdraw early (including tabulated reasons for discontinuation from the study), and the number of subjects in each analysis population will be tabulated by absorbency arm and overall.

7.2. Protocol Violations and Deviations

Protocol deviations will be classified as minor or major and will be presented in a data listing.

7.3. Demographics and Other Baseline Characteristics

Demographic variables such as age, sex, race, and ethnicity will be summarized overall and by absorbency arm. Baseline characteristics such as the number of tampons typically used during period and the tampon absorbency used most often will also be summarized.

Demographic and baseline characteristic data will be summarized by absorbency arm and overall for the ITT population.

7.4. Exposure and Compliance

The number of used and unused tampons returned and the frequency and percentage of diaries returned with an entry present for each used tampon will be summarized by absorbency arm and overall for the Safety population.

Test article and diary dispensation information and diary review information will be listed.

8. Validation Criteria Analysis

All the analyses performed to assess whether validation criteria have been met will be performed separately for each absorbency arm, with the exception of the analysis of the packaging and labeling interview responses which will be analyzed for both absorbencies combined.

8.1. Elongation

Descriptive statistics will be reported for the length of elongation of used tampons within each test article type (test or reference tampon), and separately for each absorbency arm, in the MITT population. The number and percentage of used tampons that have elongated will be reported for test tampons and reference tampons. Determination of whether a tampon is considered to have elongated is described in Section 6.1.4. The denominator for the percentage calculation will be based upon the number of used tampons returned within each test article type (test or reference tampon) and within each absorbency arm (regular or super). The 95% CIs for the percentage elongated estimates will be computed using the exact method (Clopper & Pearson, 1934).

In addition, the testing of equality of proportions of elongation between test and reference article types within each absorbency arm will be performed. For this purpose, the difference between proportions will be calculated along with 95% Wald CIs. Pearson chi-square test will be computed in support of hypothesis testing. The samples for comparison will be considered independent.

The following hypothesis will be tested:

H0: p1-p2=0. There is no significant difference in the tampon`s elongation rate between the test and reference article types within each absorbency arm.

H1: p1-p2≠0. There is a significant difference in the tampon`s elongation rate between the test and reference article types within each absorbency arm.

[redacted]

8.2. Diary Responses

The number and percentage of diary responses will be reported for test tampon diary entries and reference tampon diary entries in the Safety population, and separately for each absorbency arm. Diary responses for individual tampon entries will be summarized separately from diary responses following last tampon use. Diary responses for individual tampon entries were reported specific to each tampon used and were recorded repeatedly for each used tampon throughout a given menstrual cycle. The denominator for the percentage calculation for individual tampon entry diary responses will be based upon the total number of used tampon diary entries within each question and within each test article type and within each absorbency arm. The number of tampons remaining white and when the subject reported having any flow when using the tampon will be summarized within each test article type and within each absorbency arm as well. The denominator for the percentage calculation will be the total number of used tampon diary entries within each question and within each test article type and within each absorbency arm. Diary responses recorded following last tampon use were reported only once per menstrual cycle. The reasons for not inserting the tampon using the applicator will be summarized. The denominator for the percentage calculation for diary responses following last tampon use will be based on the total number of diary entries within each question and within each test article type and within each absorbency arm. Individual diary responses and diary responses recorded following the last tampon will be listed. And additionally, the reasons for not inserting the tampon using the applicator will be presented in a separate listing. The 95% CIs for the percentage of patients who are able to insert each tampon will be computed using the exact method (Clopper & Pearson, 1934).

In addition, the testing of equality of proportions of patients who are able to insert each tampon between test and reference article types within each absorbency arm will be performed. For this purpose, the difference between proportions will be calculated along with 95% Wald CIs. Pearson chi-square test will be computed in support of hypothesis testing. The samples for comparison will be considered independent.

The following hypothesis will be tested:

H0: p1-p2=0. There is no significant difference in proportions of patients who are able to insert each tampon between the test and reference article types within each absorbency arm.

H1: p1-p2≠0. There is a significant difference in proportions of patients who are able to insert each tampon between the test and reference article types within each absorbency arm.

8.3. Packaging and Labeling Interview Responses

The packaging and labeling interview will be administered at the Screening/Baseline Visit (Visit 1) to the subset of subjects who were selected to undergo gynecological exams prior to and following tampon use. The number and percentage of subjects that were able to correctly identify and distinguish key product information will be reported for the subset of subjects in the ITT population who undergo gynecological examinations and complete the packaging and labeling interview. A subject will be considered to have correctly identified the information if they: 1)

correctly identify the key product information in their first response, or 2) correctly identify the information after a follow-up question from the interviewer. The summary will be presented for the subset of subjects in the ITT population overall, not by absorbency arm. The denominator for the percentage calculation will be based upon the total number of subjects in the ITT population who belong to the subset of subjects that were selected to undergo gynecological exams and complete the packaging and labeling interview.

8.4. Product Tolerability

Product tolerability will be evaluated through gynecological exam findings and frequency and severity of adverse events. The analysis of adverse events is presented in Section 9.1 and the analysis of gynecological exam findings is presented in Section 9.5.

9. Safety and Tolerability Analysis

Safety and tolerability will be evaluated from reported adverse events (AEs) and gynecological exam findings. All safety analyses will be performed on the Safety population. Analyses will be performed separately for each absorbency arm.

9.1. Adverse Events

All AEs and serious adverse events (SAEs) will be coded using the MedDRA v. 25.1.

All AE data will be summarized for 3 periods: before any test article use, during and following test tampon use, during and following reference tampon use. AEs will be assigned to an analysis period based on the below criteria. The criteria for assigning AEs to an analysis period will differ depending on the type of test article (reference or test tampon) first used by the subject.

Test article order	**Criteria for assigning AEs to analysis periods**
Reference tampon → Test tampon	If the start date of the adverse event was before the date of first insertion of a reference tampon, then the AE will be assigned to the "before any test article use" period. If the start date of the adverse event was on or after the date of first insertion of a reference tampon, but before the date of first insertion of a test tampon, then the adverse event will be assigned to the "during and following reference tampon use" period. If the start date of the adverse event was on or after the date of first insertion of a test tampon, then the adverse event will be assigned to the "during and following test tampon use" period.

Test tampon → Reference tampon	If the start date of the adverse event was before the date of first insertion of a test tampon, then the AE will be assigned to the "before any test article use" period. If the start date of the adverse event was on or after the date of first insertion of a test tampon, but before the date of first insertion of a reference tampon, then the adverse event will be assigned to the "during and following test tampon use" period. If the start date of the adverse event was on or after the date of first insertion of a reference tampon, then the adverse event will be assigned to the "during and following reference tampon use" period.

An overall summary of AEs will be provided; this will present number and percentage of subjects who reported at least 1 of the following: any AE, AEs by maximum severity, AEs by maximum relationship to study product, AEs by maximum frequency, and SAEs.

In addition to the overall summary, summaries of the number and percentage of subjects with AEs will be displayed for each absorbency arm, grouped by MedDRA system organ class and preferred term (coded using MedDRA v. 25.1). Summaries of AEs by severity, relationship to study product, and frequency will also be provided. In the case of multiple occurrences of the same AE within the same subject, each subject will only be counted once for each preferred term.

In the summaries showing severity, relationship to study product, and frequency, the event with the maximum severity, strongest relationship, and highest frequency, respectively, will be reported. If a particular event is missing the severity, relationship, or frequency then the strongest possible severity, relationship, or frequency will be assumed for analysis (severity = severe, relationship = definitely related, frequency = continuous).

A data listing of all AEs will be provided, displaying details of the event(s) captured on the CRF.

9.1.1. Serious Adverse Events

All SAEs that occur during the study will be listed by absorbency arm and also tabulated by system organ class and preferred term and presented by absorbency arm.

9.2. Clinical Laboratory Evaluations

No clinical laboratory evaluations are planned to be collected for this study.

9.3. Vital Signs

No vital signs are planned to be collected for this study.

9.4. Electrocardiograms

No electrocardiograms are planned to be performed for this study.

9.5. Gynecological Examination

A subset of subjects will undergo a gynecological examination at each study visit prior to and following tampon use. Vaginal pH, and the number and percentage of subjects with any lesions, a suspected infection, other abnormal findings, and a clinically significant result will be summarized separately for each absorbency arm using the subset of subjects in the Safety population who underwent gynecological examinations. Complete gynecological examination information will be listed.

9.6. Concomitant Medication

Medications will be coded using World Health Organization Drug Dictionary (WHO-DD) Enhanced B3 (September 2022).

All medication data will be listed. The listing will indicate whether the medication is considered a prior medication, concomitant medication, or both. Medications that started before first test article insertion date will be considered prior medications whether or not they were stopped before first test article insertion date. Any medications continuing or starting after first test article insertion date will be considered to be concomitant. If a medication starts before first test article insertion date and continues after first test article insertion date it will be considered both prior and concomitant.

9.7. Product Complaints

Information on product complaints that were not captured in the subject diaries or as adverse events will be provided in a separate listing.

10. Changes from Planned Analysis

Not applicable.

11. Other Planned Analysis

Not applicable.

11.1. Coronavirus 2019 (COVID-19) Impact

Should a study visit be affected by COVID-19, study staff will record how the visit was affected. This information will be presented in a listing.

12. References

ASA. (2018) Ethical Guidelines for Statistical Practice. Prepared by the Committee on Professional Ethics, April 2018. http://www.amstat.org/about/ethicalguidelines.cfm

Clopper, C. J., & Pearson, E. S. (1934). The use of confidence or fiducial limits illustrated in the case of the binomial. *Biometrika*, *26*(4), 404-413.

ICH (1998). ICH Harmonised Tripartite Guideline. Statistical Principles for Clinical Trials E9; 1998. https://database.ich.org/sites/default/files/E9_Guideline.pdf

RSS. (2014) The Royal Statistical Society: Code of Conduct, 2014. https://rss.org.uk/about/policy-and-guidelines/code-of-conduct/.

[redacted]

13. Tables, Listings, and Figures

All listings, tables, and graphs will have a header showing the sponsor company name and protocol and a footer showing the version of SAS, the file name and path, and the source of the data (e.g., listing number).

The following are planned summary tables for protocol number AFC-21-001. The table numbers and page numbers are place holders only and will be determined when the tables are produced.

13.1. Demographic Data Summary Tables and Figures

Table 2: Demographic Data Summary Tables and Figures

Table Number	Population	Table Title / Summary
Table 14.1.1	All subjects	Subject Disposition
Table 14.1.2	ITT	Demographics and Baseline Characteristics
Table 14.1.3	Safety	Exposure to Study Product

13.2. Validation Criteria Data

Table 3: Validation Criteria Data

Table Number	Population	Table Title / Summary
Table 14.2.1	MITT	Summary of Elongated Tampons
Table 14.2.2.1	Safety	Summary of Individual Tampon Entry Diary Reponses
Table 14.2.2.2	Safety	Summary of Diary Responses Following Last Tampon Use
Table 14.2.3	ITT, Gynecological Exam Subset	Summary of Packaging and Labeling Interview Responses

13.3. Safety and Tolerability Data

Table 4: Safety and Tolerability Data

Table Number	Population	Table Title / Summary
14.3.1 Displays of Adverse Events		
Table 14.3.1.1	Safety	Overall Summary of Adverse Events
Table 14.3.1.2	Safety	Adverse Events by System Organ Class and Preferred Term
Table 14.3.1.3	Safety	Adverse Events by System Organ Class, Preferred Term, and Maximum Severity

Table Number	Population	Table Title / Summary
Table 14.3.1.4	Safety	Adverse Events by System Organ Class, Preferred Term, and Maximum Relationship to Study Product
Table 14.3.1.5	Safety	Adverse Events by System Organ Class, Preferred Term, and Maximum Frequency
14.3.2 Summary of Deaths, Other Serious and Significant Adverse Events		
Table 14.3.2.1	Safety	Serious Adverse Events by System Organ Class and Preferred Term
14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events		
Table 14.3.3.1	Safety	Listing of Serious Adverse Events
14.3.6 Other Safety Data Summary Tables		
Table 14.3.6.1.1	Safety, Gynecological Exam Subset	Gynecological Examination – Visual Assessment Details
Table 14.3.6.1.2	Safety, Gynecological Exam Subset	Gynecological Examination – Additional Findings

[redacted]

13.4. Planned Listing Descriptions

The following are planned data and subject data listings for protocol number AFC-21-001.

In general, one listing will be produced per CRF domain. All listings will be sorted by absorbency arm, site, and subject number. All calculated variables will be included in the listings.

In all listings a blank line will be placed between each subject. Within a data listing, if an item appears line after line (e.g., repetition of subject number), then only the first occurrence will be displayed. Screen failures will only be presented in Listings 16.2.1.1, 16.2.2.1, and 16.2.2.3; otherwise, only enrolled subjects will be listed.

In data listings, the information for one subject will be kept on one page if at all possible, rather than splitting a subject's information across pages.

Table 5: Planned Listings

Listing Number	Population	Listing Title / Summary
16.2 Subject Data Listings		
16.2.1 Subject Discontinuations/Completions		
Listing 16.2.1.1	All Subjects	Subject Disposition
16.2.2 Protocol Deviations		
Listing 16.2.2.1	All Subjects	Inclusion and Exclusion Criteria
Listing 16.2.2.2	All Subjects	Protocol Deviations
Listing 16.2.2.3	Screen Failures	Reason for Screen Failures
16.2.3 Patients/Subjects Excluded from the Validation Criteria Analyses		
Listing 16.2.3.1	All Subjects	Analysis Populations
16.2.4 Demographic Data and Other Baseline Characteristics		
Listing 16.2.4.1	All Subjects	Subject Consent and Demographics
Listing 16.2.4.2	All Subjects	Medical History
Listing 16.2.4.3	All Subjects	Tampon Use Questionnaire
16.2.5 Compliance Data		
Listing 16.2.5.1	All Subjects	Test Article and Diary Dispensation and Diary Training
Listing 16.2.5.2	Safety Population	Diary Review
16.2.6 Individual Validation Criteria Data		
Listing 16.2.6.1	Safety Population	Tampon Integrity Assessment
Listing 16.2.6.2.1	Safety Population	Individual Tampon Entry Diary Responses
Listing 16.2.6.2.2	Safety Population	Diary Responses Following Last Tampon Use

Listing Number	Population	Listing Title / Summary
16.2 Subject Data Listings		
Listing 16.2.6.2.3	Safety Population	Reason for Not Inserting the Tampon Using the Applicator
Listing 16.2.6.3	Gynecological Exam Subset	Packaging and Labeling Interview
16.2.7 Adverse Event Listings (by Subject)		
Listing 16.2.7.1	All Subjects	Adverse Events
16.2.9 Other Clinical Observations and Measurements (by Subject)		
Listing 16.2.9.1.1	Gynecological Exam Subset	Gynecological Examination – Visual Assessment Details
Listing 16.2.9.1.2	Gynecological Exam Subset	Gynecological Examination – Additional Findings
Listing 16.2.9.2	All Subjects	Prior and Concomitant Medications
Listing 16.2.9.3	All Subjects	Product Complaints
16.2.10 Other Study Measurements or Assessments (by Subject)		
Listing 16.2.10.1	All Subjects	COVID-19 Impact Assessment

[redacted]

14. Tables and Listings Shells

14.1. Standard Layout for all Tables and Listings

The following standard layout will be applied to all Tables and Listings in support of this study. Note that programming notes may be added if appropriate after each shell.

[redacted]

Figure 1: Standardized Layout

Kimberly-Clark Corporation — Page xx of xx

Protocol: AFC-21-001 — Version

<Table, Listing, Figure> xx.x.x

<Title of Table, Listing, or Figure>

<Study Population and if applicable subgroup Description>

Body of Table, Listing or Figure

<Note: If directly Applicable>

Footnote 1 *<if applicable>* Recommendation is to keep footnotes to a minimum

Footnote 2 *<if applicable>*

Footnote n *<if applicable>*

Footnote n+1 *<pgm path and name>, <date>*

[redacted]

14.2. Planned Table Shells

See Figure 2 below.

[redacted]

Figure 2: Planned Table Shells

Table 14.1.1
Subject Disposition
All Subjects

Status Category	Regular Absorbency (N=XX)	Super Absorbency (N=XX)	Overall (N=XX)
Screened for Eligibility			xx
Screen Failure			xx
Enrolled	xx	xx	xx
Randomized	xx	xx	xx
ITT Population [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gynecological Exam Subset [2]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Safety Population [3]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Gynecological Exam Subset [2]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
MITT Population [4]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Completed Study	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Discontinued Early	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrew Consent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Violation / Non-Compliance	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Investigator / Sponsor Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Abbreviations: ITT = intent-to-treat; MITT = modified intent-to-treat.
Note: Percentages are n/Number of subjects in the ITT Population within absorbency arm and overall subjects *100. .
[1] The ITT Population includes all subjects randomized into the study.
[2] A subset of subjects was selected to undergo gynecological exams prior to and following tampon use. In addition, only the subjects in this subset completed the packaging and labeling interview.
[3] The Safety Population includes all ITT subjects who insert at least 1 tampon.
[4] The MITT Population includes all subjects in the Safety population who have no major protocol deviations and return at least 1 tampon that can be assessed for elongation.
n is the number of subjects within each category. N is the number of subjects within absorbency arm.
Reference Listing: 16.2.1.1

[redacted]

Table 14.1.2
Demographics and Baseline Characteristics
ITT Population

Variable Statistic or Category	Regular Absorbency (N=XX)	Super Absorbency (N=XX)	Overall (N=XX)
Age (years) [1]			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Gender			
Female	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Undifferentiated	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Unknown	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Race			
American Indian or Alaska Native	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Asian	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Black or African American	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Native Hawaiian or Other Pacific Islander	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
White	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
More than One Race	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not Reported	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Ethnicity			
Hispanic or Latino	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not Hispanic or Latino	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not Reported	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Unknown	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: ITT = intent-to-treat; SD = standard deviation.
Note: Percentages are n/Number of subjects in the ITT Population within absorbency arm and overall subjects * 100. Demographic information including age, gender, race, and ethnicity was collected at the Screening/Baseline Visit (Visit 1). Baseline characteristics including typical tampon use were obtained at the Screening/Baseline Visit (Visit 1) from the Tampon Use Questionnaire.
[1] Age was calculated as the integer difference in years between the subject's date of informed consent and date of birth.
n is the number of subjects within each category. N is the number of subjects within absorbency arm.
Reference Listings: 16.2.4.1; 16.2.4.3

[redacted]

Table 14.1.2 (cont'd.)
Demographics and Baseline Characteristics
ITT Population

Variable Statistic or Category	Regular Absorbency (N=XX)	Super Absorbency (N=XX)	Overall (N=XX)
Total tampons typically used during period			
Five or less	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Six or more	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Tampon Absorbency Used Most Often			
Light	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Regular	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Super	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Super Plus	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Ultra	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Equal numbers of two or more absorbencies	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: ITT = intent-to-treat; SD = standard deviation.
Note: Percentages are n/Number of subjects in the ITT Population within absorbency arm and overall subjects * 100. Demographic information including age, gender, race, and ethnicity was collected at the Screening/Baseline Visit (Visit 1). Baseline characteristics including typical tampon use were obtained at the Screening/Baseline Visit (Visit 1) from the Tampon Use Questionnaire.
[1] Age was calculated as the integer difference in years between the subject's date of informed consent and date of birth.
Reference Listings: 16.2.4.1; 16.2.4.3

[redacted]

Table 14.1.3
Exposure to Study Product
Safety Population

Test Article Type Variable Statistic or Category	Regular Absorbency (N=XX)	Super Absorbency (N=XX)	Overall (N=XX)
Reference Tampon			
Number of unused tampons returned			
n [1]	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Number of used tampons returned			
n [1]	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Diary entry present for each tampon used [2]	XX	XX	XX
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviation: SD = standard deviation.
Note: Percentages are n/Number of subjects, who responded to the question, in the Safety Population within absorbency arm and overall*100. Diary review and assessment of the number of unused and used tampons returned was performed at the post-use visits which were conducted within 72 hours following the last tampon use for that menstrual cycle. Subjects used each test article type (reference or test tampon) over the course of one menstrual cycle. N is the number of subjects within each article and within absorbency arm.
[1] n is the number of tampons.
[2] n is the number of subjects, who responded to the question.
Reference Listings: 16.2.5.2; 16.2.6.1

[redacted]

Table 14.1.3 (cont'd.)
Exposure to Study Product
Safety Population

Test Article Type Variable Statistic or Category	Regular Absorbency (N=XX)	Super Absorbency (N=XX)	Overall (N=XX)
Test Tampon			
Number of unused tampons returned			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Number of used tampons returned			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
Diary entry present for each tampon used			
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviation: SD = standard deviation.
Note: Percentages are n/Number of subjects in the Safety Population within absorbency arm and overall*100. Diary review and assessment of the number of unused and used tampons returned was performed at the post-use visits which were conducted within 72 hours following the last tampon use for that menstrual cycle. Subjects used each test article type (reference or test tampon) over the course of one menstrual cycle.
Reference Listings: 16.2.5.2; 16.2.6.1

[redacted]

Table 14.2.1
Summary of Elongated Tampons
MITT Population

Absorbency Arm: Regular

Variable Statistic	Test Tampon (N=XX)	Reference Tampon (N=XX)
Length of Elongation		
n [1]	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X
Min, Max	XX, XX	XX, XX
Elongated [2]		
n [1]	XX	XX
Percentage	XX.XX%	XX.XX%
95% CI for the Percentage [3]	XX.XXX%, XX.XXX%	XX.XXX%, XX.XXX%
Difference in Percentage	XX.XX%	
95% CI for the Difference in Percentage [4]	XX.XXX%, XX.XXX%	
Chi-Square	XX.X	
P-Value	X.XXX	

Abbreviations: CI = confidence interval; MITT = modified intent-to-treat; SD = standard deviation.
Note: Percentages are n/Number of used tampons returned by subjects in the MITT Population within tampon type*100. Length is measured in millimeters (mm). Tampon integrity assessments were performed at the post-use visits which were conducted within 72 hours following the last tampon use for that menstrual cycle. Subjects used each test article type (reference or test tampon) over the course of one menstrual cycle. N is the number of subjects within each article and within absorbency arm.
[1] n is the number of tampons.
[2] Any used tampon with a measurement of elongation >10 mm was considered elongated.
[3] The 95% CIs for the percentage elongated estimates were computed using the exact method.
[4] The 95% CIs for the difference in percentage elongated estimates were computed using Wald method
Reference Listing: 16.2.6.1

Programming Note: *Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.2.2.1
Summary of Individual Tampon Entry Diary Responses
Safety Population

Absorbency Arm: Regular

Variable Category	Test Tampon (N=XX)	Reference Tampon (N=XX)
Able to remove the tampon	XX	XX
Yes	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)
White area remaining on tampon	XX	XX
No areas on the tampon remained white	XX (XX.X%)	XX (XX.X%)
Less than half of the tampon remained white	XX (XX.X%)	XX (XX.X%)
About half of the tampon remained white	XX (XX.X%)	XX (XX.X%)
More than half of the tampon remained white	XX (XX.X%)	XX (XX.X%)
Whole product remained white	XX (XX.X%)	XX (XX.X%)
Flow when using the tampon	XX	XX
No flow	XX (XX.X%)	XX (XX.X%)
Spotting only	XX (XX.X%)	XX (XX.X%)
Light	XX (XX.X%)	XX (XX.X%)
Medium	XX (XX.X%)	XX (XX.X%)
Heavy	XX (XX.X%)	XX (XX.X%)
Tampons remaining white and where subject reported having any flow when using the tampon*	XX (XX.X%)	XX (XX.X%)

Note: Percentages are n/Number of used tampon diary entries recorded by subjects in the Safety Population within each question and within tampon type*100. Subject diaries were returned at the post-use visits which were conducted within 72 hours following the last tampon use for that menstrual cycle. Diary responses for individual tampon entries were reported specific to each tampon used and were recorded repeatedly for each used tampon throughout a given menstrual cycle. Subjects used each test article type (reference or test tampon) over the course of one menstrual cycle.
*Subjects must have reported both the whole product remained white and reported anything other than “No flow”. Percentages are n/Number of used tampon diary entries recorded by subjects in the Safety Population that indicate anything other than “No Flow” within tampon type*100.
n is the total number of diary entries for each section of the table. N is the number of subjects within each article and within absorbency arm.

Reference Listing: 16.2.6.2.1

Programming Note: *Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.2.2.2
Summary of Diary Responses Following Last Tampon Use
Safety Population

Absorbency Arm: Regular

Variable Category	Test Tampon (N=XX)	Reference Tampon (N=XX)
Able to open the box to retrieve wrapped tampons	XX	XX
Yes	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)
Able to open each tampon wrapper	XX	XX
Yes	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)
Tampons were clean prior to use	XX	XX
Yes	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)
Able to insert each tampon using the applicator	XX	XX
Yes	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)
Percentage of patients who are able to insert each tampon using the applicator	XX.XX%	XX.XX%
95% CI for the Percentage [1]	XX.XXX%, XX.XXX%	XX.XXX%, XX.XXX%
Difference in Percentage	XX.XX%	
95% CI for the Difference in Percentage [1]	XX.XXX%, XX.XXX%	
Chi-Square	XX.X	
P-Value	X.XXX	
Able to insert each tampon using the applicator (diary #1)	XX	XX
Yes	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)
Able to insert each tampon using the applicator (diary #2)	XX	XX
Yes	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)
Reason why was not able to insert tampon using the applicator	XX	XX
Not able to fully extend the applicator	XX (XX.X%)	XX (XX.X%)
Too hard to push the tampon out of the applicator	XX (XX.X%)	XX (XX.X%)

No tampon in the applicator	XX (XX.X%)	XX (XX.X%)
Applicator was damaged	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)

Note: Percentages are n/Number of recorded diary entries by subjects in the Safety Population within each question and within tampon type*100. Subject diaries were returned at the post-use visits which were conducted within 72 hours following the last tampon use for that menstrual cycle. Diary responses recorded following last tampon use were reported only once per menstrual cycle. Subjects used each test article type (reference or test tampon) over the course of one menstrual cycle.
n is the total number of diary entries for each section of the table. N is the number of subjects within each article and within absorbency arm.
[1] The 95% CIs for the percentage of patients who are able to insert each tampon using the applicator and for the difference in percentage of patients who are able to insert each tampon using the applicator were computed using the exact method.

Reference Listing: 16.2.6.2.2

Programming Note: *Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.2.3
Summary of Packaging and Labeling Interview Responses
ITT Population
Gynecological Exam Subset

Variable Category	Overall (N=XX)
Able to correctly identify tampon absorbency provided in the regular absorbency box	XX
Yes	XX (XX.X%)
No	XX (XX.X%)
Able to correctly identify the tampon absorbency ranges for the entire line of products on the box	XX
Yes	XX (XX.X%)
No	XX (XX.X%)
Able to correctly identify the Toxic Shock Syndrome warning on the box	XX
Yes	XX (XX.X%)
No	XX (XX.X%)
Able to correctly identify the information that states how long you should use a tampon on the box	XX
Yes	XX (XX.X%)
No	XX (XX.X%)
Able to correctly identify tampon absorbency provided in the super absorbency box	XX
Yes	XX (XX.X%)
No	XX (XX.X%)
Able to correctly identify tampon absorbency provided in the super plus absorbency box	XX
Yes	XX (XX.X%)
No	XX (XX.X%)

Abbreviation: ITT = intent-to-treat.
Note: Only the subset of subjects who were selected to undergo gynecological exams prior to and following tampon use completed the packaging and labeling interview. The packaging and labeling interview was conducted at the Screening/Baseline Visit (Visit 1). Percentages are n/Number of subjects in the ITT Population who belong to the subset of subjects that were selected to undergo gynecological exams
and responded to the respective question *100.
n is the total number of diary entries for each section of the table. N is the number of subjects within each article and within absorbency arm.
Reference Listing: 16.2.6.3

[redacted]

Table 14.2.3 (cont'd.)
Summary of Packaging and Labeling Interview Responses
ITT Population
Gynecological Exam Subset

Variable Category	Overall (N=XX)
Able to correctly identify tampon absorbencies provided in the multipack box	XX
Yes	XX (XX.X%)
No	XX (XX.X%)
Able to correctly identify a regular absorbency wrapped tampon	XX
Yes	XX (XX.X%)
No	XX (XX.X%)
Able to correctly identify a super absorbency wrapped tampon	XX
Yes	XX (XX.X%)
No	XX (XX.X%)
Able to correctly identify a super plus absorbency wrapped tampon	XX
Yes	XX (XX.X%)
No	XX (XX.X%)
Able to correctly identify the instructions for use from the product insert	XX
Yes	XX (XX.X%)
No	XX (XX.X%)
Able to correctly identify the Toxic Shock Syndrome warning from the product insert	XX
Yes	XX (XX.X%)
No	XX (XX.X%)

Abbreviation: ITT = intent-to-treat.
Note: Only the subset of subjects who were selected to undergo gynecological exams prior to and following tampon use completed the packaging and labeling interview. The packaging and labeling interview was conducted at the Screening/Baseline Visit (Visit 1). Percentages are n/Number of subjects in the ITT Population who belong to the subset of subjects that were selected to undergo gynecological exams and responded to the given question*100.
Reference Listing: 16.2.6.3

[redacted]

Table 14.3.1.1
Overall Summary of Adverse Events
Safety Population

Absorbency Arm: Regular

Category	Before Any Test Article Use (N=XX)	During and Following Test Tampon Use (N=XX)	During and Following Reference Tampon Use (N=XX)
Subjects with at least 1 AE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Subjects with at least 1 AE by Severity [1]			
Mild	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Moderate	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Severe	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Subjects with at least 1 AE by Relationship [2]			
Not Related	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Unlikely	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Possible	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Probable	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Definite	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Subjects with at least 1 AE by Frequency [3]			
Single	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Intermittent	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Continuous	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Subjects with at least 1 SAE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Abbreviations: AE = adverse event; SAE = serious adverse event.
Note: Percentages are n/Number of subjects in the Safety Population within absorbency group*100. AEs that began prior to insertion of any test article are summarized under Before Any Test Article Use. For subjects randomized to use the test tampon first, AEs that began on or after the date of insertion of first test tampon and prior to date of insertion of first reference tampon are summarized under During and Following Test Tampon Use, and AEs that began on or after the date of insertion of first reference tampon are summarized under During and Following Reference Tampon Use. For subjects randomized to use the reference tampon first, AEs that began on or after the date of insertion of first reference tampon and prior to date of insertion of first test tampon are summarized under During and Following Reference Tampon Use, and AEs that began on or after the date of insertion of first test tampon are summarized under During and Following Test Tampon Use. N is the number of subjects within each period and within absorbency arm.
[1] Subjects are counted only once at the worst severity. If a severity designation is missing, it will be considered as Severe.
[2] Subjects are counted only once at the strongest possible relationship. If a relationship designation is missing, it will be considered as Definite.
[3] Subjects are counted only once at the highest possible frequency. If a frequency designation is missing, it will be considered as Continuous.
Reference Listing: 16.2.7.1

Programming Note: *Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.3.1.2
Adverse Events by System Organ Class and Preferred Term
Safety Population

Absorbency Arm: Regular

System Organ Class Preferred Term	Before Any Test Article Use (N=XX)	During and Following Test Tampon Use (N=XX)	During and Following Reference Tampon Use (N=XX)
Subjects with at least 1 AE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
System Organ Class 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 3	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
…			
System Organ Class 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 3	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
…			

Abbreviations: AE = adverse event; MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term; SOC = system organ class.
Note: Percentages are n/Number of subjects in the Safety Population within absorbency group*100. AEs were coded using MedDRA version 25.1. AEs that began prior to insertion of any test article are summarized under Before Any Test Article Use. For subjects randomized to use the test tampon first, AEs that began on or after the date of insertion of first test tampon and prior to date of insertion of first reference tampon are summarized under During and Following Test Tampon Use, and AEs that began on or after the date of insertion of first reference tampon are summarized under During and Following Reference Tampon Use. For subjects randomized to use the reference tampon first, AEs that began on or after the date of insertion of first reference tampon and prior to date of insertion of first test tampon are summarized under During and Following Reference Tampon Use, and AEs that began on or after the date of insertion of first test tampon are summarized under During and Following Test Tampon Use. Subjects are counted once for each SOC and once for each PT. AEs are displayed by descending frequency of SOC, then PT within SOC, and then alphabetically by PT. N is the number of subjects within each article and within absorbency arm.
Reference Listing: 16.2.7.1

Programming Note: *Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.3.1.3
Adverse Events by System Organ Class, Preferred Term, and Maximum Severity
Safety Population

Absorbency Arm: Regular

System Organ Class Preferred Term Severity	Before Any Test Article Use (N=XX)	During and Following Test Tampon Use (N=XX)	During and Following Reference Tampon Use (N=XX)
Subjects with at least 1 AE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mild	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Moderate	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Severe	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
System Organ Class 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mild	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Moderate	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Severe	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mild	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Moderate	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Severe	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mild	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Moderate	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Severe	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
…			

Abbreviations: AE = adverse event; MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term; SOC = system organ class.
Note: Percentages are n/Number of subjects in the Safety Population within absorbency group*100. AEs were coded using MedDRA version 25.1. AEs that began prior to insertion of any test article are summarized under Before Any Test Article Use. For subjects randomized to use the test tampon first, AEs that began on or after the date of insertion of first test tampon and prior to date of insertion of first reference tampon are summarized under During and Following Test Tampon Use, and AEs that began on or after the date of insertion of first reference tampon are summarized under During and Following Reference Tampon Use. For subjects randomized to use the reference tampon first, AEs that began on or after the date of insertion of first reference tampon and prior to date of insertion of first test tampon are summarized under During and Following Reference Tampon Use, and AEs that began on or after the date of insertion of first test tampon are summarized under During and Following Test Tampon Use. Subjects are counted once for each SOC and once for each PT. The severity shown is the greatest severity reported for a particular subject (Severe > Moderate > Mild). AEs with a missing severity were counted as Severe. AEs are displayed by descending frequency of SOC, then PT within SOC, and then alphabetically by PT. N is the number of subjects within each article and within absorbency arm.
Reference Listing: 16.2.7.1

Programming Note: *Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.3.1.4
Adverse Events by System Organ Class, Preferred Term, and Maximum Relationship to Study Product
Safety Population

Absorbency Arm: Regular

System Organ Class Preferred Term Relationship	Before Any Test Article Use (N=XX)	During and Following Test Tampon Use (N=XX)	During and Following Reference Tampon Use (N=XX)
Subjects with at least 1 AE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not Related	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Unlikely	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Possible	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Probable	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Definite	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
System Organ Class 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not Related	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Unlikely	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Possible	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Probable	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Definite	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1			
Not Related	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Unlikely	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Possible	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Probable	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Definite	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
…			

Abbreviations: AE = adverse event; MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term; SOC = system organ class.
Note: Percentages are n/Number of subjects in the Safety Population within absorbency group*100. AEs were coded using MedDRA version 25.1. AEs that began prior to insertion of any test article are summarized under Before Any Test Article Use. For subjects randomized to use the test tampon first, AEs that began on or after the date of insertion of first test tampon and prior to date of insertion of first reference tampon are summarized under During and Following Test Tampon Use, and AEs that began on or after the date of insertion of first reference tampon are summarized under During and Following Reference Tampon Use. For subjects randomized to use the reference tampon first, AEs that began on or after the date of insertion of first reference tampon and prior to date of insertion of first test tampon are summarized under During and Following Reference Tampon Use, and AEs that began on or after the date of insertion of first test tampon are summarized under During and Following Test Tampon Use. Subjects are counted once for each SOC and once for each PT. The relationship shown is the greatest relationship reported for a particular subject (Definite > Probable > Possible > Unlikely > Not Related). AEs with a missing relationship were counted as Definite. AEs are displayed by descending frequency of SOC, then PT within SOC, and then alphabetically by PT. N is the number of subjects within each article and within absorbency arm.
Reference Listing: 16.2.7.1

Programming Note: *Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.3.1.5
Adverse Events by System Organ Class, Preferred Term, and Maximum Frequency
Safety Population

Absorbency Arm: Regular

System Organ Class Preferred Term Frequency	Before Any Test Article Use (N=XX)	During and Following Test Tampon Use (N=XX)	During and Following Reference Tampon Use (N=XX)
Subjects with at least 1 AE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Single	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Intermittent	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Continuous	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
System Organ Class 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Single	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Intermittent	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Continuous	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 1	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Single	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Intermittent	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Continuous	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Preferred Term 2	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Single	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Intermittent	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Continuous	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
…			

Abbreviations: AE = adverse event; MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term; SOC = system organ class.
Note: Percentages are n/Number of subjects in the Safety Population within absorbency group*100. AEs were coded using MedDRA version 25.1. AEs that began prior to insertion of any test article are summarized under Before Any Test Article Use. For subjects randomized to use the test tampon first, AEs that began on or after the date of insertion of first test tampon and prior to date of insertion of first reference tampon are summarized under During and Following Test Tampon Use, and AEs that began on or after the date of insertion of first reference tampon are summarized under During and Following Reference Tampon Use. For subjects randomized to use the reference tampon first, AEs that began on or after the date of insertion of first reference tampon and prior to date of insertion of first test tampon are summarized under During and Following Reference Tampon Use, and AEs that began on or after the date of insertion of first test tampon are summarized under During and Following Test Tampon Use. Subjects are counted once for each SOC and once for each PT. The frequency shown is the greatest frequency reported for a particular subject (Continuous > Intermittent > Single). AEs with a missing frequency were counted as Continuous. AEs are displayed by descending frequency of SOC, then PT within SOC, and then alphabetically by PT. N is the number of subjects within each article and within absorbency arm.
Reference Listing: 16.2.7.1

Programming Note: *Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.3.2.1
Serious Adverse Events by System Organ Class and Preferred Term
Safety Population

Same as shell 14.3.1.2; Programming Note: *Replace "Subjects with at least 1 AE" with "Subjects with at least 1 Serious AE".*

[redacted]

Table 14.3.3.1
Listing of Serious Adverse Events
Safety Population

Absorbency Arm: Regular

Subject ID	Study Period [1]	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ End Date (Study Day)	Severity/ Relationship/ Frequency	Serious?/ Criteria Met	Concomitant medication(s) given? [2]	Outcome/Study Product Action Taken	Study Product Interruption Start Date (Study Day) / End Date (Study Day)	Caused Discontinuation from Study?
XXXXXX	During and Following Test Tampon Use	XXXXXXXXXX XXXXXXXXXX/ XXXXXXXXX	DDMMMYYYY (XX)/ DDMMMYYYY (XX)	XXXXXXX/ XXXXXXXXX XXXXXXXXXX	Yes/ XXXXXXXX	XXX	XXXXXXX/ XXXXX	DDMMMYYYY (XX)/ DMMMYYYY (XX)	XX
	During and Following Reference Tampon Use	XXXXXXXXXX XXXXXXXXXX/ XXXXXXXXX	DDMMMYYYY (XX)/ Ongoing	XXXXXXX/ XXXXXXXXX XXXXXXXXXX	Yes/ XXXXXXXX	XXX	XXXXXXX/ XXXXX		XX
XXXXXX	Before Any Test Article Use	XXXXXXXXXX XXXXXXXXXX/ XXXXXXXXX	DDMMMYYYY (-XX)/ DDMMMYYYY (XX)	XXXXXXX/ XXXXXXXXX XXXXXXXXXX	Yes/ XXXXXXX	XXX	XXXXXXX/ XXXXX		XX

…

Abbreviations: AE = adverse event; MedDRA = Medical Dictionary for Regulatory Activities.
Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon). AEs were coded using MedDRA version 25.1.
[1] AEs that began prior to insertion of any test article are listed as the Before Any Test Article Use period. For subjects randomized to use the test tampon first, AEs that began on or after the date of insertion of first test tampon and prior to date of insertion of first reference tampon are listed under the During and Following Test Tampon Use period, and AEs that began on or after the date of insertion of first reference tampon are listed under the During and Following Reference Tampon Use period. For subjects randomized to use the reference tampon first, AEs that began on or after the date of insertion of first reference tampon and prior to date of insertion of first test tampon are listed under the During and Following Reference Tampon Use period, and AEs that began on or after the date of insertion of first test tampon are listed under the During and Following Test Tampon Use period.
[2] If a concomitant medication was given due to the AE, this will be identified in the prior and concomitant medications listing.

Programming Note: *Concatenate all serious criteria marked as Yes with a semicolon. Concatenate all actions taken marked as Yes with a semicolon. If Action Taken, Other is Yes, then concatenate 'Other:' with the text provided in If Other, specify. If no text is provided in If Other, specify, then list 'Other: Not specified'. If no events meet the criteria for display, present "No events are reported." All system organ class and preferred term text should be in proper case. Continue for Absorbency Arm: Super.*

[redacted]

Table 14.3.6.1.1
Gynecological Examination – Visual Assessment Details
Safety Population
Gynecological Exam Subset

Absorbency Arm: Regular Visit Area Examined Assessment Category	Test Tampon (N=XX)	Reference Tampon (N=XX)
Pre-Use Visit		
Perineum		
Any Lesions		
Yes	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)
Not Done	XX (XX.X%)	XX (XX.X%)
Type A Lesions [1]	XX (XX.X%)	XX (XX.X%)
Erythema	XX (XX.X%)	XX (XX.X%)
Edema	XX (XX.X%)	XX (XX.X%)
Coverage of Lesions [2]		
50% or less	XX (XX.X%)	XX (XX.X%)
Greater than 50%	XX (XX.X%)	XX (XX.X%)
Type B Lesions [1]	XX (XX.X%)	XX (XX.X%)
Petechia	XX (XX.X%)	XX (XX.X%)
Ecchymoses	XX (XX.X%)	XX (XX.X%)
Coverage of Lesions [2]		
50% or less	XX (XX.X%)	XX (XX.X%)
Greater than 50%	XX (XX.X%)	XX (XX.X%)

Note: Percentages are n/Number of subjects in the Safety Population who belong to the subset of subjects that were selected to undergo gynecological exams within tampon type*100. For the gynecological exam subset, exams were conducted at pre- and post-use visits for each tampon type. Subjects used each tampon type (reference or test) over the course of one menstrual cycle. Pre-use visits were conducted within 72 hours prior to expected menstruation and post-use visits were conducted within 72 hours following the last tampon use for that menstrual cycle. Not Done means that gynecological exam was not done. Subjects XXX,XXX have any lesions found.
[1] Subjects are counted only once for each type of lesion.
[2] Subjects are counted only once for the highest coverage lesion recorded for each lesion type.
n is the number of subjects within each category. N is the number of subjects within each article and within absorbency arm.
Reference Listing: 16.2.9.1.1

Programming Note: *There will be a pre-use visit and a post-use visit for each tampon type for each subject. Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.3.6.1.1 (cont'd.)
Gynecological Examination – Visual Assessment Details
Safety Population
Gynecological Exam Subset

Absorbency Arm: Regular Visit Area Examined Assessment Category	Test Tampon (N=XX)	Reference Tampon (N=XX)
Pre-Use Visit		
Perineum (cont'd.)		
Type C Lesions [1]	XX (XX.X%)	XX (XX.X%)
Epithelium: Disrupted, superficial	XX (XX.X%)	XX (XX.X%)
Epithelium: Disrupted, deep	XX (XX.X%)	XX (XX.X%)
Blood vessel: Intact	XX (XX.X%)	XX (XX.X%)
Blood vessel: Disrupted	XX (XX.X%)	XX (XX.X%)
Peeling	XX (XX.X%)	XX (XX.X%)
Abrasion	XX (XX.X%)	XX (XX.X%)
Ulceration	XX (XX.X%)	XX (XX.X%)
Laceration	XX (XX.X%)	XX (XX.X%)
Coverage of Lesions [2]		
50% or less	XX (XX.X%)	XX (XX.X%)
Greater than 50%	XX (XX.X%)	XX (XX.X%)
Type D Lesions [1]	XX (XX.X%)	XX (XX.X%)
Coverage of Lesions [2]		
50% or less	XX (XX.X%)	XX (XX.X%)
Greater than 50%	XX (XX.X%)	XX (XX.X%)

Repeat for the following areas examined: Vulva, Urethra, Vagina, Cervix; Repeat for the following visit: Post-Use Visit

Note: Percentages are n/Number of subjects in the Safety Population who belong to the subset of subjects that were selected to undergo gynecological exams within tampon type*100. For the gynecological exam subset, exams were conducted at pre- and post-use visits for each tampon type. Subjects used each tampon type (reference or test) over the course of one menstrual cycle. Pre-use visits were conducted within 72 hours prior to expected menstruation and post-use visits were conducted within 72 hours following the last tampon use for that menstrual cycle.
[1] Subjects are counted only once for each type of lesion.
[2] Subjects are counted only once for the highest coverage lesion recorded for each lesion type.
Reference Listing: 16.2.9.1.1

Programming Note: *There will be a pre-use visit and a post-use visit for each tampon type for each subject. Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.3.6.1.2
Gynecological Examination – Additional Findings
Safety Population
Gynecological Exam Subset

Absorbency Arm: Regular Visit Area Examined Statistic or Category	Test Tampon (N=XX)	Reference Tampon (N=XX)
Pre-Use Visit		
Vaginal Discharge – Quantity		
Scant	XX (XX.X%)	XX (XX.X%)
Small Amount	XX (XX.X%)	XX (XX.X%)
Moderate Amount	XX (XX.X%)	XX (XX.X%)
Profuse	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)
Vaginal Discharge – Odor		
Malodorous	XX (XX.X%)	XX (XX.X%)
Non-Malodorous	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)
Vaginal Discharge – Color		
Clear	XX (XX.X%)	XX (XX.X%)
White	XX (XX.X%)	XX (XX.X%)
Yellow	XX (XX.X%)	XX (XX.X%)
Green	XX (XX.X%)	XX (XX.X%)
Red (Bloody)	XX (XX.X%)	XX (XX.X%)
Gray	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)

Note: Percentages are n/Number of subjects in the Safety Population who belong to the subset of subjects that were selected to undergo gynecological exams within tampon type*100. For the gynecological exam subset, exams were conducted at pre- and post-use visits for each tampon type. Subjects used each tampon type (reference or test) over the course of one menstrual cycle. Pre-use visits were conducted within 72 hours prior to expected menstruation and post-use visits were conducted within 72 hours following the last tampon use for that menstrual cycle. n is the number of subjects within each category. N is the number of subjects within each article and within absorbency arm.
Subjects XXX,XXX had any abnormal gynecological findings. Subjects XXX,XXX reported any clinically significant gynecological exam result.
Reference Listing: 16.2.9.1.2

Programming Note: *There will be a pre-use visit and a post-use visit for each tampon type for each subject. Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.3.6.1.2 (cont'd.)
Gynecological Examination – Additional Findings
Safety Population
Gynecological Exam Subset

Absorbency Arm: Regular Visit Area Examined Statistic or Category	Test Tampon (N=XX)	Reference Tampon (N=XX)
Pre-Use Visit		
Vaginal Discharge – Consistency		
Thin	XX (XX.X%)	XX (XX.X%)
Thick	XX (XX.X%)	XX (XX.X%)
Variable	XX (XX.X%)	XX (XX.X%)
Cottage Cheese Like	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)
Vaginal pH		
n	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X
Min, Max	XX, XX	XX, XX
Suspected Infection		
Yes	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)

Note: Percentages are n/Number of subjects in the Safety Population who belong to the subset of subjects that were selected to undergo gynecological exam within tampon type*100. For the gynecological exam subset, exams were conducted at pre- and post-use visits for each tampon type. Subjects used each tampon type (reference or test) over the course of one menstrual cycle. Pre-use visits were conducted within 72 hours prior to expected menstruation and post-use visits were conducted within 72 hours following the last tampon use for that menstrual cycle.
Reference Listing: 16.2.9.1.2

Programming Note: *There will be a pre-use visit and a post-use visit for each tampon type for each subject. Repeat for Absorbency Arm: Super.*

[redacted]

Table 14.3.6.1.2 (cont'd.)
Gynecological Examination – Additional Findings
Safety Population
Gynecological Exam Subset

Absorbency Arm: Regular Visit Area Examined Statistic or Category	Test Tampon (N=XX)	Reference Tampon (N=XX)
Pre-Use Visit		
Other Abnormal Findings		
Yes	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)
Gynecological Exam Result Clinically Significant		
Yes	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)
Missing	XX (XX.X%)	XX (XX.X%)
Repeat for the following visit: Post-Use Visit		

Note: Percentages are n/Number of subjects in the Safety Population who belong to the subset of subjects that were selected to undergo gynecological exam within tampon type*100. For the gynecological exam subset, exams were conducted at pre- and post-use visits for each tampon type. Subjects used each tampon type (reference or test) over the course of one menstrual cycle. Pre-use visits were conducted within 72 hours prior to expected menstruation and post-use visits were conducted within 72 hours following the last tampon use for that menstrual cycle.
Reference Listing: 16.2.9.1.2

Programming Note: *There will be a pre-use visit and a post-use visit for each tampon type for each subject. Repeat for Absorbency Arm: Super.*

[redacted]

14.3. Planned Listing Shells

See Figure 3 below.

[redacted]

Figure 3: Planned Listing Shells

Listing 16.2.1.1
Subject Disposition
All Subjects

Absorbency Arm: XXX

Subject ID	Subject Status	Date of Completion / Discontinuation (Study Day)	Reason for Discontinuation	If Death, Date of Death (Study Day)/ Cause of Death	If Lost to Follow-Up, Date of Last Contact (Study Day)/ Comment
XXXXX	XXXXXXXXXXX	DDMMMYYYY (XX)			
XXXXX	XXXXXXXXXXX	DDMMMYYYY (XX)	XXXXXXXXXX		
XXXXX	XXXXXXX	DDMMMYYYY (XX)	XXXXXXXXX	DDMMMYYYY (XX)/ XXXXXXXXXXX	
XXXXX	XXXXXXX	DDMMMYYYY (XX)	XXXXXXXXX		DDMMMYYYY (XX)/ XXXXXXXXXXX

Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon).

Programming Note: *If reason for discontinuation is present, concatenate reason for discontinuation with specify text, e.g., "Adverse Event: XXXXX". If a secondary cause of death is listed, concatenate to the primary cause of death with a semicolon. Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.2.1
Inclusion and Exclusion Criteria
All Subjects

Absorbency Arm: XXX

Subject ID	Date Screened	Met All Eligibility Criteria?	Criteria Not Met/Reason Not Met
XXXXX	DDMMMYYYY	Yes	
XXXXX	DDMMMYYYY	Yes	
XXXXX	DDMMMYYYY	No	Inclusion #1/XXXXXXXXXXXXXXXXXX; Exclusion #9/XXXXXXXXXXXX
XXXXX	DDMMMYYYY	Yes	

Programming Note: *If there is no "Reason Not Met" included for the corresponding criteria not met, then concatenate the criteria not met with "Reason not given", e.g., "Inclusion #1/Reason not given". If there are multiple criteria met, please list each criteria/reason not met concatenated with a ";". Repeat for Absorbency Arm: Regular and Absorbency Arm: Super. Display screen failures at the end of the listing. For screen failures, the top row will read "Absorbency Arm: Not Assigned (Screen Failures)".*

[redacted]

Listing 16.2.2.2
Protocol Deviations
All Subjects

Absorbency Arm: XXX

Subject ID	Any Major Protocol Deviations?	Deviation Occurred During a Time Frame?	Deviation Start Date (Study Day)/ Deviation End Date (Study Day)	First Visit Impacted/ Last Visit Impacted	Protocol Deviation Category	Description
XXXXX	No					
XXXXX	Yes	Yes	DDMMMYYYY (XX)/ DDMMMYYYY (XX)	XXXXXXX/ XXXXXXX	XXXXXXXXXX	
		No	DDMMMYYYY (XX)/ DDMMMYYYY (XX)	XXXXXXX/ XXXXXXX	XXXXXXXXXX	
XXXXX	Yes	Yes	DDMMMYYYY (XX)/ DDMMMYYYY (XX)	XXXXXXX/ XXXXXXX	XXXXXXXXXX	

Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon).

Programming Note: *If "Deviation Occurred During a Time Frame?" is "No" then repeat Deviation Start Date (Study) for Deviation End Date (Study Day) and repeat First Visit Impacted for Last Visit Impacted. If there is text for "Additional Description (Other than "NA", "N/A" and similar)", then concatenate that text with the text for "Description", e.g., "DESCRIPTION TEXT XXX. ADDITIONAL TEXT." Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.2.3
Reason for Screen Failures
Screen Failures

Subject ID	Failed Date	Met All Eligibility Criteria?	Criteria Not Met/Reason Not Met
XXXXX	DDMMMYYYY	No	Inclusion #4/XXXXXXXXXXXXXXXXX; Exclusion #2/XXXXXXXXXXXX
XXXXX	DDMMMYYYY	No	Inclusion #1/XXXXXXXXXXXXXXXXX; Exclusion #9/XXXXXXXXXXXX
XXXXX	DDMMMYYYY	No	Inclusion #8/XXXXXXXXXXXXXXXXX; Exclusion #5/XXXXXXXXXXXX
XXXXX	DDMMMYYYY	No	Inclusion #6/XXXXXXXXXXXXXXXXX; Exclusion #12/XXXXXXXXXXXX

Programming Note: *If there is no "Reason Not Met" included for the corresponding criteria not met, then concatenate the criteria not met with "Reason not given", e.g., "Inclusion #1/Reason not given". If there are multiple criteria met, please list each criteria/reason not met concatenated with a ";".*

[redacted]

Listing 16.2.3.1
Analysis Populations
All Subjects

Absorbency Arm: XXX

	Randomization				Analysis Populations			
Subject ID	Date	Number	Tampon Used First	Part of Subset? [1]	ITT [2]	Safety [3]	MITT [4]	Primary Reason(s) for Exclusion
XXXXXX	DDMMMYYYY	XXXX	XXXXXXXX	XXXXXXXX	Yes	No	No	Safety: Subject did not insert any tampons.
XXXXXX	DDMMMYYYY	XXXX	XXXXX	XXXXX	Yes	Yes	Yes	
XXXXXX	DDMMMYYYY	XXXX	XXXXXXXX	XXXXXXXX	Yes	Yes	No	MITT: Subject did not return any tampons that could be assessed for elongation.
XXXXXX	DDMMMYYYY	XXXX	XXXXX	XXXXXXXX	No	No	No	ITT: Subject was not randomized.

Abbreviations: BR = regular absorbency test tampon; BS = super absorbency test tampon; CR = regular absorbency reference tampon; CS = super absorbency reference tampon; ITT = intent-to-treat; MITT = modified intent-to-treat.
[1] A subset of subjects were selected to undergo gynecological exams prior to and following tampon use. In addition, this subset of subjects completed the packaging and labeling interview at the Screening/Baseline Visit (Visit 1).
[2] The ITT Population includes all subjects randomized into the study.
[3] The Safety Population includes all ITT subjects who insert at least 1 tampon.
[4] The MITT Population includes all subjects in the Safety population who have no major protocol deviations and return at least 1 tampon that can be assessed for elongation.

Programming Note: *Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.4.1
Subject Consent and Demographics
All Subjects

Absorbency Arm: XXX

Subject ID	Date Informed Consent Signed/ Consent Version	Protocol Version	Date of Birth	Age (years)	Sex	Ethnicity	Race
XXXXXX	DDMMMYYYY/ XXXXXXXXXX	XXXXXXXXX	DDMMMYYYY	XX	Female	XXXXXX	XXXXXXX
XXXXXX	DDMMMYYYY/ XXXXXXXXXX	XXXXXXXXX	DDMMMYYYY	XX	Female	XXXXXX	XXXXXX
XXXXXX	DDMMMYYYY/ XXXXXXXXXX	XXXXXXXXX	DDMMMYYYY	XX	Unknown	XXXXXX	XXXXX
XXXXXX	DDMMMYYYY/ XXXXXXXXXX	XXXXXXXXX	DDMMMYYYY	XX	Female	XXXXXX	XXXXXX
XXXXXX	DDMMMYYYY/ XXXXXXXXXX	XXXXXXXXX	DDMMMYYYY	XX	Undifferentiated	XXXXXX	XXXXXX

Programming Note: *If multiple races are selected, then concatenate all selected races using a semicolon. Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.4.2
Medical History
All Subjects

Absorbency Arm: XXX

Subject ID	Any Medical History Reported?	Date Medical History Collected (Study Day)	Category/ Verbatim Term	Start Date (Study Day)/ End Date (Study Day)	Medical History Disease/Condition Under Control?
XXXXXX	Yes	DDMMMYYYY (XX)	XXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY (XX)/ DDMMMYYYY (XX)	Yes
			XXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX/ XXXXXXXXXXXXX	–MMMYYYY / Ongoing	No
XXXXXX	Yes	DDMMMYYYY (XX)	XXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX/ XXXXXXXXXXXXX	DDMMMYYYY (XX)/ DDMMMYYYY (XX)	Yes
			XXXXXXXXXXXXXXX/ XXXXXXXXXXXXXX/ XXXXXXXXXXXXX	–MMMYYYY / Ongoing	Yes

Abbreviation: MedDRA = Medical Dictionary for Regulatory Activities.
Note: At the Screening/Baseline Visit (Visit 1), subjects were asked to report any previously ongoing or current medical conditions or procedures that had occurred within 3 months prior to study entry. Medical history was coded using MedDRA version 25.1. Study day is calculated relative to the date of first insertion of study product (either test or reference tampon).

Programming Note: *If medical history is ongoing, denote with "Ongoing" rather than the end date. Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.4.3
Tampon Use Questionnaire
All Subjects

Absorbency Arm: XXX

Subject ID	Study Visit	Date Completed (Study Day)	Assessment	Result
XXXXX	XXXXXXXX	DDMMMYYYY (XX)	How many total tampons do you typically use during your period?	XXX
			What tampon absorbency do you use most often?	XXX
			Are you willing to use only regular absorbency tampons during your participation in the study, if needed and if you qualify?	XXX
			Are you willing to use only super absorbency tampons during your participation in the study, if needed and if you qualify?	XXX
XXXXX	XXXXXXXX	DDMMMYYYY (XX)	How many total tampons do you typically use during your period?	XXX
			What tampon absorbency do you use most often?	XXX
			Are you willing to use only regular absorbency tampons during your participation in the study, if needed and if you qualify?	XXX
			Are you willing to use only super absorbency tampons during your participation in the study, if needed and if you qualify?	XXX

Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon).

Programming Note: *If the response for "What tampon absorbency do you use the most?" is "I use approximately equal numbers of 2 or more absorbency tampons" then please concatenate the result with the tampons selected, e.g., "I use approximately equal numbers of 2 or more absorbency tampons: Light; Regular". Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.5.1
Test Article and Diary Dispensation and Diary Training
All Subjects

Absorbency Arm: XXX

Subject ID	Study Visit	Test Article and Diary Dispensation Completed?	Diary Training Performed?/ Reason Not Performed	Diary Number	Lot Number of Tampons Dispensed	Tampon Code Dispensed	Dispensation Date (Study Day)
XXXXX	XXXXXXXXX	Yes	Yes	XX	XX	XX	DDMMMYYYY (XX)
	XXXXXXXXX	Yes	No/ XXXXXXXXXXXXXX	XX	XX	XX	DDMMMYYYY (XX)
XXXXX	XXXXXXXXX	Yes	Yes	XX	XX	XX	DDMMMYYYY (XX)
	XXXXXXXXX	No	No/ XXXXXXXXXXXXXX	XX	XX	XX	DDMMMYYYY (XX)

Abbreviations: BR = regular absorbency test tampon; BS = super absorbency test tampon; CR = regular absorbency reference tampon; CS = super absorbency reference tampon.
Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon).

Programming Note: *Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.5.2
Diary Review
Safety Population

Absorbency Arm: XXX

Subject ID	Study Visit	Date Returned (Study Day)	Diary Number	Tampon Code	Diary Entry for Each Tampon Used?	Are All Diary Entries Accurate and Complete?	Were All Discrepancies Addressed and Corrected with Subject?
XXXXX	XXXXXXXXX	DDMMMYYYY (XX)	1	XX	Yes	Yes	
	XXXXXXXXX	DDMMMYYYY (XX)	2	XX	No	No	No; XXXXXXXXXXXXXXX
XXXXX	XXXXXXXXX	DDMMMYYYY (XX)	1	XX	Yes	No	Yes
	XXXXXXXXX	DDMMMYYYY (XX)	2	XX	Yes	Yes	

Abbreviations: BR = regular absorbency test tampon; BS = super absorbency test tampon; CR = regular absorbency reference tampon; CS = super absorbency reference tampon.
Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon).

Programming Note: *If the response for "Were all discrepancies addressed and corrected with the subject?" is "No", then concatenate the text for "If no, please explain", e.g., "No; XXXXXXXXXXXXX". Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.6.1
Tampon Integrity Assessment
Safety Population

Absorbency Arm: XXX

Subject ID	Study Visit	Assessment Performed?/ Reason Not Performed	Assessment Date (Study Day)	Number of Used Tampons Returned	Number of Unused Tampons Returned	Menstrual Cycle	Tampon Code Returned	Tampon Number	Length of Elongation (mm)	Elongated [1]?	Picture Taken of Tampon?
XXXXXX	XXXXXX	No/ XXXXXXXXXXX									
XXXXXX	XXXXXX	Yes	DDMMMYYYY (XX)	XX	XX	XX	XX	XX	XX	No	Yes
						XX	XX	XX	XX	No	Yes
						XX	XX	XX	XX	Yes	Yes
						XX	XX	XX	XX	XX	No
						XX	XX	XX	XX	XX	XX
						XX	XX	XX	XX	XX	XX
						XX	XX	XX	XX	XX	XX
						XX	XX	XX	XX	XX	XX
	XXXXXX	Yes	DDMMMYYYY (XX)	XX	XX	XX	XX	XX	XX	XX	XX
						XX	XX	XX	XX	XX	XX
						…	…	…	…	…	…

Abbreviations: BR = regular absorbency test tampon; BS = super absorbency test tampon; CR = regular absorbency reference tampon; CS = super absorbency reference tampon.
Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon).
[1] Any used tampon with a measurement of elongation >10 mm was considered elongated.

Programming Note: *Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.6.2.1
Individual Tampon Entry Diary Responses
Safety Population

Absorbency Arm: XXX

Subject ID	Study Visit	Diary Number	Tampon Code	Entry Number	Date/Time (Study Day) Tampon Inserted	Date/Time (Study Day) Tampon Removed	Able to Remove Tampon?	White Area Remaining on Tampon?	Flow When Using Tampon?	Comments
XXXXX	XXXXXXX	1	XX	XX	DDMMMYYYY/HH:MM (XX)	DDMMMYYYY/HH:MM (XX)	XX	XXXXXX	XXXX	
				XX	DDMMMYYYY/HH:MM (XX)	DDMMMYYYY/HH:MM (XX)	XX	XXXXXX	XXXX	XXXXXX
				XX	DDMMMYYYY/HH:MM (XX)	DDMMMYYYY/HH:MM (XX)	XX	XXXXXX	XXXX	
				XX	DDMMMYYYY/HH:MM (XX)	DDMMMYYYY/HH:MM (XX)	XX	XXXXXX	XXXX	XXXXXX
	XXXXXXX	2	XX	XX	DDMMMYYYY/HH:MM (XX)	DDMMMYYYY/HH:MM (XX)	XX	XXXXXX	XXXX	
				XX	DDMMMYYYY/HH:MM (XX)	DDMMMYYYY/HH:MM (XX)	XX	XXXXXX	XXXX	XXXXXX
				XX	DDMMMYYYY/HH:MM (XX)	DDMMMYYYY/HH:MM (XX)	XX	XXXXXX	XXXX	
XXXXX	XXXXXXX	1	XX	XX	DDMMMYYYY/HH:MM (XX)	DDMMMYYYY/HH:MM (XX)	XX	XXXXXX	XXXX	
				XX	DDMMMYYYY/HH:MM (XX)	DDMMMYYYY/HH:MM (XX)	XX	XXXXXX	XXXX	XXXXXX
				…	…	…	…	…	…	…

Abbreviations: BR = regular absorbency test tampon; BS = super absorbency test tampon; CR = regular absorbency reference tampon; CS = super absorbency reference tampon.
Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon).

Programming Note: *Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.6.2.2
Diary Responses Following Last Tampon Use
Safety Population

Absorbency Arm: XXX

Subject ID	Study Visit	Diary Number	Tampon Code	Assessment	Response
XXXXX	XXXXXXX	1	XX	Were you able to open the box to retrieve the wrapped tampons?	Yes
				Were you able to open each tampon wrapper?	Yes
				Were each of the tampons clean prior to using them?	Yes
				Were you able to insert each tampon using the applicator?	Yes
	XXXXXXX	2	XX	Were you able to open the box to retrieve the wrapped tampons?	Yes
				Were you able to open each tampon wrapper?	No; XXXXXXXXXX
				Were each of the tampons clean prior to using them?	Yes
				Were you able to insert each tampon using the applicator?	No
XXXXX	XXXXXXX	1	XX	Were you able to open the box to retrieve the wrapped tampons?	Yes
				Were you able to open each tampon wrapper?	Yes
				Were each of the tampons clean prior to using them?	Yes
				Were you able to insert each tampon using the applicator?	Yes
	XXXXXXX	…	…	…	…

Abbreviations: BR = regular absorbency test tampon; BS = super absorbency test tampon; CR = regular absorbency reference tampon; CS = super absorbency reference tampon.

Programming Note: *If the response for any of the assessments "Were you able to open the box to retrieve the wrapped tampons?", "Were you able to open each tampon wrapper?", or "Were each of the tampons clean prior to using them?" is "No" then concatenate the text from the corresponding "If no, please explain in detail", e.g., "No; XXXXXXXXX". If the response for the assessment "Were you able to insert each tampon using the applicator?" is "No", then keep it as 'No' without the details.*
Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.

[redacted]

Listing 16.2.6.2.3
Reason for Not Inserting the Tampon Using the Applicator
Safety Population

Absorbency Arm: XXX

Subject ID	Study Visit	Diary Number	Tampon Code	Reason	Explain in Detail, Why You Were Not Able to Insert Each Tampon Using the Applicator	Comments
XXXXX	XXXXXXX	1	XX	XXXX; XXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXX
	XXXXXXX	2	XX	XXXX; XXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXX
XXXXX	XXXXXXX	1	XX	XXXX; XXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXX
	XXXXXXX	…	…		…	…

Abbreviations: BR = regular absorbency test tampon; BS = super absorbency test tampon; CR = regular absorbency reference tampon; CS = super absorbency reference tampon.

Programming Note: *Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*
In case of several reasons, please concatenate them by ";".

[redacted]

Listing 16.2.6.3
Packaging and Labeling Interview
Gynecological Exam Subset

Absorbency Arm: XXX

Subject ID	Study Visit	Assessment Performed?/ Reason Not Done	Assessment Date (Study Day)	Interviewer Initials	Assessment	Response
XXXXX	XXXXXXX	No/XXXXXXXX				
XXXXX	XXXXXXX	Yes	DDMMMYYYY (XX)	XX	What tampon absorbency or absorbencies are provided in this box? / Was subject able to identify the correct information?	XXXX/Yes
					Show me where you found that information / Was subject able to identify the correct information?	NA
					Can you show me the tampon absorbency ranges for the entire line of products on the box?	XX
					Can you show me the Toxic Shock Syndrome warning on the box?	XX
					Can you show me on the bow where the information is that states how long you should use a tampon?	XX
					What tampon absorbency or absorbencies are provided in this box? / Was subject able to identify the correct information?	XXXX/No
					Show me where you found that information / Was subject able to identify the correct information?	XX/Yes
					What tampon absorbency or absorbencies are provided in this box? / Was subject able to identify the correct information?	XXXX/No
					Show me where you found that information / Was subject able to identify the correct information?	XX/Yes
					What tampon absorbency or absorbencies are provided in this box? / Was subject able to identify the correct information?	XXX/
					Show me where you found that information / Was subject able to identify the correct information?	
					Can you identify a regular absorbency wrapped tampon?	XX
					Can you identify a super absorbency wrapped tampon?	XX
					Can you identify a super plus absorbency wrapped tampon?	XX
					Can you show me the instructions for use on the product insert?	XX
					Can you show me the Toxic Shock Syndrome warning on the product insert?	XX

Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon).

Programming Note: *Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.7.1
Adverse Events
All Subjects

Absorbency Arm: XXX

Subject ID	Study Period [1]	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ End Date (Study Day)	Severity/ Relationship/ Frequency	Serious?/ Criteria Met	Concomitant medication(s) given? [2]	Outcome/Study Product Action Taken	Study Product Interruption Start Date (Study Day) / End Date (Study Day)	Caused Discontinuation from Study?
XXXXXX	During and Following Test Tampon Use	XXXXXXXXXX XXXXXXXXXX/ XXXXXXXXX	DDMMMYYYY (XX)/ DDMMMYYYY (XX)	XXXXXXX/ XXXXXXXXX XXXXXXXXXX	Yes/ XXXXXXXX	XXX	XXXXXXX/ XXXXX	DDMMMYYYY (XX)/ DMMMYYYY (XX)	XX
	During and Following Reference Tampon Use	XXXXXXXXXX XXXXXXXXXX/ XXXXXXXXX	DDMMMYYYY (XX)/ Ongoing	XXXXXXX/ XXXXXXXXX XXXXXXXXXX	No	XXX	XXXXXXX/ XXXXX		XX
XXXXXX	Before Any Test Article Use	XXXXXXXXXX XXXXXXXXXX/ XXXXXXXXX	DDMMMYYYY (-XX)/ DDMMMYYYY (XX)	XXXXXXX/ XXXXXXXXX XXXXXXXXXX	No	XXX	XXXXXXX/ XXXXX		XX

…

Abbreviations: AE = adverse event; MedDRA = Medical Dictionary for Regulatory Activities.
Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon). AEs were coded using MedDRA version 25.1.
[1] AEs that began prior to insertion of any test article are listed as the Before Any Test Article Use period. For subjects randomized to use the test tampon first, AEs that began on or after the date of insertion of first test tampon and prior to date of insertion of first reference tampon are listed under the During and Following Test Tampon Use period, and AEs that began on or after the date of insertion of first reference tampon are listed under the During and Following Reference Tampon Use period. For subjects randomized to use the reference tampon first, AEs that began on or after the date of insertion of first reference tampon and prior to date of insertion of first test tampon are listed under the During and Following Reference Tampon Use period, and AEs that began on or after the date of insertion of first test tampon are listed under the During and Following Test Tampon Use period.
[2] If a concomitant medication was given due to the AE, this will be identified in the prior and concomitant medications listing.

Programming Note: *Repeat for Absorbency Arm: Regular and Absorbency Arm: Super*

[redacted]

Listing 16.2.9.1.1
Gynecological Examination – Visual Assessment Details
Gynecological Exam Subset

Absorbency Arm: XXX

Subject ID	Study Visit	Exam Performed?/ Reason Not Performed	Exam Date (Study Day)	Clinically Significant Result?	Area Examined	Lesions?/ Type/ Coverage (%)	Comment
XXXXXX	XXXXXXXX	Yes	DDMMMYYYY (XX)	No	Perineum	No	
					Vulva	Yes/ Type A; Edema 50 or less	XXXXXXXXX
					Urethra	No	
					Vagina	Yes Type C; Disrupted, Deep; Intact; Peeling	
					Cervix	No	
	XXXXXXXX	No/ XXXXXXXXXXXXXXXX					

Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon). For the subset of subjects that were selected to undergo gynecological examinations prior to and following tampon use, gynecological exams were conducted at pre-use visits and post-use visits for each test article type. Subjects used each test article type (reference or test tampon) over the course of one menstrual cycle. Pre-use visits were conducted within 72 hours prior to expected menstruation and post-use visits were conducted within 72 hours following the last tampon use for that menstrual cycle.

Programming Note: *The study visits will include the following: "Pre-test tampon use visit", "Post-test tampon use visit", "Pre-reference tampon use visit", and "Post-reference tampon use visit". If "Were there any lesions?" is "Yes", then concatenate the lesion type with the corresponding description(s), e.g., "Type A; Erythema". Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.9.1.2
Gynecological Examination – Additional Findings
Gynecological Exam Subset

Absorbency Arm: XXX

Subject ID	Study Visit	Exam Performed?/ Reason Not Performed	Exam Date (Study Day)	Vaginal Discharge Quantity/ Odor/ Color/ Consistency	Vaginal pH	Suspected Infection?	Other Abnormal Findings?	Clinically Significant Result?
XXXXXX	XXXXXXXX	Yes	DDMMMYYYY (XX)	XXXXXXXX/ XXXXXX/ XXXXXXXX/ XXXXXXXXXXX	XX	No	No	No
	XXXXXXXX	Yes	DDMMMYYYY (XX)	XXXXXXXX/ XXXXXX/ XXXXXXXX/ XXXXXXXXXXX	XX	Yes	No	Yes
	XXXXXXXX	No/ XXXXXXXXXXXXXXXX						
	XXXXXXXX	Yes	DDMMMYYYY (XX)	XXXXXXXX/ XXXXXX/ XXXXXXXX/ XXXXXXXXXXX	XX	No	Yes; XXXXXX	No
XXXXXX	XXXXXXXX	No/ XXXXXXXXXXXXXXXX						

Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon). For the subset of subjects that were selected to undergo gynecological examinations prior to and following tampon use, gynecological exams were conducted at pre-use visits and post-use visits for each test article type. Subjects used each test article type (reference or test tampon) over the course of one menstrual cycle. Pre-use visits were conducted within 72 hours prior to expected menstruation and post-use visits were conducted within 72 hours following the last tampon use for that menstrual cycle.

Programming Note: *The study visits will include the following: "Pre-test tampon use visit", "Post-test tampon use visit", "Pre-reference tampon use visit", and "Post-reference tampon use visit". If "Other abnormal findings" is "Yes" then concatenate with text in "If yes, describe" using a semicolon (i.e., "Yes; XXXXXXXXX"). Repeat for Absorbency Arm: Regular and Absorbency Arm: Super.*

[redacted]

Listing 16.2.9.2
Prior and Concomitant Medications
All Subjects

Absorbency Arm: XXX

Subject ID	Any Medications Reported?	Prior or Concomitant [1]	ATC Class (Level 4)/ Preferred Term/ Medication or Therapy	Indication	Start Date (Study Day)/ End Date (Study Day)	Dose (Unit)	Route/ Frequency
XXXXXX	Yes	XXX	XXXXX/ XXXXXXXXX/ XXXXXXXXXX	XXXXX	DDMMMYYYY (XX)/ DDMMMYYYY (XX)	XXX (XXX)	XXXXXXXX/ XXXXXXX
		XXX; XXX	XXXXX/ XXXXXXXXX/ XXXXXXXXXX	XXXXX	–MMMYYYY/ Ongoing	XXX (XXX)	XXXXXXXX/ XXXXXXX
		XXX	XXXXX/ XXXXXXXXX/ XXXXXXXXXX	XXXXX	DDMMMYYYY (XX)/ DDMMMYYYY (XX)	XXX (XXX)	XXXXXXXX/ XXXXXXX
XXXXXX	No						

Abbreviations: ATC = Anatomical Therapeutic Chemical Classification System; WHO-DD = World Health Organization Drug Dictionary.
Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon). Medications were coded using WHO-DD Enhanced B3 (September 2022).
[1] Prior medications are all medications that were started before the first insertion of the test article. Concomitant medications are all medications that were started after the first insertion of the test article or were continuing after the first insertion of the test article. If a medication starts before the first insertion of the test article and continues after the first insertion of the test article it is considered both prior and concomitant.

Programming Note: *If Route, or Frequency is "Other", display "If Other, specify" text only (i.e., do not display "Other: XXXXXX" but just "XXXXXX"). Sort by subject, start date, end date, ATC Level 4 & Preferred Term. Repeat for Absorbency Arm: Regular and Absorbency Arm: Super*

[redacted]

Listing 16.2.9.3
Product Complaints
All Subjects

Absorbency Arm: XXX

Subject ID	Any Product Complaints Reported? [1]	Issue/Problem Date (Study Day)	Product Code	Complaint Description	Device Available to be Examined?
XXXXXX	Yes	DDMMMYYYY (XX)	XX	XXXXXXXXXXXXXXXX	No
		DDMMMYYYY (XX)	XX	XXXXXXXXXXXXXXXX	Yes
XXXXXX	No				
XXXXXX	Yes	DDMMMYYYY (XX)	XX	XXXXXXXXXXXXXXXX	Yes

Abbreviations: BR = regular absorbency test tampon; BS = super absorbency test tampon; CR = regular absorbency reference tampon; CS = super absorbency reference tampon.
Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon).
[1] Includes product complaints reported that were not previously captured in the subject diary or as an adverse event.

Programming Note: *Repeat for Absorbency Arm: Regular and Absorbency Arm: Super*

[redacted]

Listing 16.2.10.1
COVID-19 Impact Assessment
All Subjects

Absorbency Arm: XXX

Subject ID	Subject Affected by COVID-19?	Visit Impacted	Visit Type Adjustment	Visit Date (Study Day)	Efficacy Assessments Missed?	Safety Assessments Missed?	Early Termination Reason, if attributable to COVID-19	Comments
XXXXX	Yes	XXXXX	XXXX	DDMMMYYYY (XX)	XXX	XXX		XXXXXXX
XXXXX	Yes	XXXXX	XXXX; XXXX	DDMMMYYYY (XX)	XX	XXX	XXXXXXX	
XXXXX	No							

Abbreviation: COVID-19 = novel coronavirus disease-2019.
Note: Study day is calculated relative to the date of first insertion of study product (either test or reference tampon).

Programming Note: *If more than once visit type adjustment is selected, then concatenate all selected with a semicolon. If visit type adjustment "Other" is selected, or if "ET reason (if attributable to COVID-19)" is "Other", then display "Other, specify" text only (i.e., do not display "Other: XXXXXX" but just "XXXXXX"). Repeat for Absorbency Arm: Regular and Absorbency Arm: Super*