Touch and Feel Evaluation of Two Foam Hand Sanitizers

Protocol Number MED-2022-DIV60-001

DATE (18-NOV-2022)
Version 3.0

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INVESTIGATOR ACKNOWLEDGMENT SIGNATURE

- I agree to conduct the study in accordance with the relevant, current protocol and will make changes in the protocol only after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of participants.

- I agree to personally conduct and supervise the investigation as described within.

- I agree to inform all participants that the device is being used for the purposes of an investigational study.

- I will ensure that requirements relating to obtaining informed consent in the guidelines for Good Clinical Practices (GCP), and 21 Code of Federal Regulations (CFR) Part 50 and Institutional Review Board (IRB) review and approval in 21 CFR Part 56 are met.

- I agree to report to the sponsor, IRB and/or Ethics Committee, according to the protocol, adverse experiences that occur during the course of the investigation in accordance with guidelines for GCP and 21 CFR 812.

- I have read and understood the information in the protocol, including the potential risks.

- I agree to maintain adequate and accurate records in accordance with guidelines for GCP and 21 CFR 812.140 and to make those records available for inspection.

- I will ensure that an IRB compliant with the requirements of guidelines for GCP and 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human participants or others.

- I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in the guidelines for GCP and the CFR.

I have received and reviewed this investigational plan. I will conduct the study as described.

Principal Investigator (Print name):
Principal Investigator (Signature):
Date (DD-MMM-YYYY):

DOCUMENT HISTORY

VERSION	DATE	DESCRIPTION
Version 1.0	12-SEP-2022	Initial Release
Version 2.0	19-OCT-2022	Protocol update to include the waiving of informed consent.
Version 3.0	18-NOV-2022	Update to Section 9.1.1.

1. PROTOCOL SUMMARY

1.1. Synopsis

Title:	Touch and Feel Evaluation of Two Foam Hand Sanitizers
Study Description:	Hand sanitizers are a standard of hygiene requirements. Hand sanitizers must be effective at reducing germ count on the hands while ideally providing emollients to moisturize the skin after use. To improve compliance with hand sanitizing protocols, hand sanitizers should provide a pleasant touch and feel experience for end users, especially for healthcare worker (HCW) users, who use these products frequently. The goal of this study is to evaluate the user experience of two foam hand sanitizers produced by Medline and GOJO when used by HCWs. The foam sanitizer products that will be evaluated in this study include: ➢ Spectrum™ Advanced Hand Sanitizer Foam (hereby referred to as the Spectrum product) ➢ PURELL® Advanced Foam Hand sanitizer (hereby referred to as the Purell product)
Phase:	Post-market.
Primary Objective:	To establish the non-inferiority of the Spectrum product to the Purell product by comparing the foam hand sanitizers with regard to the user touch and feel experience and overall acceptability.
Primary Endpoint:	The user touch and feel experience of the hand sanitizer products evaluated by visual analog scale assessments (VAS) of HCWs overall satisfaction and moisturization, and HCWs assessment of product preference.
Study Population:	Number of participants, N = 45. Inclusion criteria Individuals who meet the following criteria will participate in this study: ➢ HCWs ≥ 18 years of age. Exclusion criteria

	Individuals who meet any of the following criteria will not be allowed to participate in this study: ➢ Individual has a skin condition that might result in irritation from the hand sanitizers. ➢ Individual has a known allergy to the ingredients in the test products.
Power Analysis Methods:	The sample size of 90 (45 for the foam cohort and 45 for a gel cohort to be evaluated in a future study) was estimated to provide 80% power at the 95% level of confidence for the proportion of HCWs preferring one product over the competing product using the "Non-Inferiority Tests for the Difference Between Two Correlated Proportions" procedure in PASS 2021 Power Analysis and Sample Size Software (2021). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass. The estimated non-inferiority margins were .03 to .08 with estimated proportion differences of .1, .15 and .20. This study utilizes the sample of N=45 for the foam product cohort.
Description of Sites/Facilities Enrolling Participants:	The study will be conducted at Northshore Hospitals.
Description of Study design:	This will be a prospective, single-blinded randomized cohort study that will be conducted over the course of one study visit. Participants will be asked to wash and dry their hands and apply a sanitizer product. The order in which the two hand sanitizer products are applied will be randomized. The participants will be instructed to apply the product topically to their hands and rub the product until the product is absorbed. After product application, the participants will complete a VAS assessment of their touch and feel experience with the product. Participants will then repeat the process with the second product. In the time between evaluating each product, participants will be asked to wash and dry their hands with soap and water and wait an additional two minutes after their hands have dried. After applying both products, the participants will complete a product preference questionnaire.
Participant Duration:	Approximately one hour.

1.1. Schedule of Activities (SOA)

Required Study Activities and Assessments	Visit 1
Verification of Eligibility	**X**
Participant Washes Hands and Waits Minimum 2 Minutes	**X**
Study Staff Times Participant for 2 Minute Waiting Period After Hand Washing	**X**
Application of Hand Sanitizer A	**X**
User Touch and Feel VAS Assessment	**X**
Participant Washes Hands and Waits 2 Minutes	**X**
Study Staff Times Participant for 2 Minute Waiting Period After Hand Washing	**X**
Application of Hand Sanitizer B	**X**
User Touch and Feel VAS Assessment	**X**
Product Preference Questionnaire	**X**
Participant Dismissal	**X**
Adverse Events	**X**

2. INTRODUCTION

2.1. Background & Rationale

Hand sanitizers are a standard of hygiene requirements. Hand sanitizers are a standard tool frequently used in hospital settings by healthcare (HCWs) for hand disinfection. The Centers for Disease Control and Prevention (CDC) states that HCWs should use an alcohol-based hand rub, such as a hand sanitizer, or wash their hands with soap and water immediately before and after patient contact, during aseptic tasks, after contact with blood, bodily fluids, or contaminated surfaces, and immediately after glove removal. [1] Additionally, the World Health Organization (WHO) guidelines on hand hygiene state that alcohol-based handrubs rapidly and effectively inactivate a wide array of potentially harmful microorganisms on hands. [2] Hand sanitizers must be effective at reducing germ count on the hands while ideally providing emollients to moisturize the skin after use. To improve compliance with hand sanitizing protocols, hand sanitizers should provide a pleasant touch and feel experience for users, especially for healthcare worker (HCW) users.

The goal of this study is to evaluate the user touch and feel experience of two hand sanitizer foam products produced by Medline and GOJO when the products are used by HCWs.

2.2. Study Products

2.2.1. Spectrum™ Advanced Hand Sanitizer Foam

Spectrum Advanced Hand Sanitizer Foam is made with a 70% ethyl alcohol foaming formula that evaporates quickly on the hands and is effective at eliminating 99.99% of common germs harmful germs and bacteria. The formula includes added moisturizers to help reduce dry skin. The SKU number for Spectrum Advanced Hand Sanitizer Foam is HH70F1000 will be used with the X10 Medline Dispenser.

2.2.2. PURELL® Advanced Foam Hand sanitizer

The SKU number for PURELL® Advanced Foam Hand Sanitizer is GOJ190502 will be used with PURELL® LTX-12™ Dispenser SKU GOJ192004.

2.3. Risk/Benefit Profile

2.3.1. Potential Study Risks

This study entails minimal risk to the participants. All hand sanitizer products are commercially available and widely used in clinical settings. There is the possibility of minor skin irritation with the application of the hand sanitizer products; however, the magnitude of this should be no greater than what occurs through the normal use of the hand sanitizers. In addition, the study is designed such that the test products will be applied on the non-compromised skin of participants with no known skin conditions, which should impose less risk for study participants.

2.3.2. Potential Study Benefits

Direct benefit to the study participants is unlikely. However, the results from this study may better inform the user touch and feel experience of the study products among HCWs, which may translate into improved user experience and frequency of use of the study products by HCWs.

2.3.3. Assessment of Potential Risk/Benefit Profile

As this study entails minimal risk to the study participants and the results may further inform the user touch and feel experience of the study products by HCWs, the risk/benefit profile of this study is acceptable.

3. OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINT(S)
Primary		
1. To establish the non-inferiority of the Spectrum product to the Purell product by comparing the foam hand sanitizers with regard to the user touch and feel experience and overall acceptability.	1. The user touch and feel experience of the hand sanitizer products evaluated by VAS assessments of HCWs overall satisfaction and moisturization, and HCWs assessment of product preference.	1. To evaluate the HCW user touch and feel experience of the products and compare product preference between the foam hand sanitizer products.

4. STUDY DESIGN

4.1. Overall Design

This will be a prospective, double-blinded randomized cohort study that will be conducted over the course of one study visit. Participants will evaluate two foam hand sanitizer products.

The requirement to obtain informed consent will be waived for this clinical study. Following screening for eligibility, successfully enrolled participants will be asked to wash and dry their hands and apply one of two foam hand sanitizer products. The order in which each product is applied first will be randomized. The participants will be instructed to apply the first product (Hand Sanitizer A) topically to their hands and rub the product until the product is absorbed. The aliquot provided from the automated dispenser will be approximately 1 mL of each hand sanitizer product. After product

application, the participants will complete a VAS assessment of their touch and feel experience with Hand Sanitizer A. The participant will then be asked to wash and dry their hands with soap and water and wait an additional two minutes after their hands have dried. The participant will then repeat the described process with the second product (Hand Sanitizer B). After applying the two foam Hand Sanitizers A and B, the participant will complete a product preference questionnaire. At this point, the participant has completed the study and will be dismissed.

4.2. End of Study Definition

This study will be considered complete upon issuance of a Clinical Study Report that has been approved by the Clinical Affairs Director.

5. STUDY POPULATION

5.1. Inclusion Criteria

Individuals who meet the following criteria will participate in this study:

- HCWs ≥ 18 years of age.

5.2. Exclusion Criteria

Individuals who meet any of the following criteria will not be allowed to participate in this study:

- Individual has a skin condition that might result in irritation from the hand sanitizers.
- Individual has a known allergy to the ingredients in the test products.

5.3. Strategies for Recruitment and Retention

Participants will be recruited during staff meetings at Northshore hospitals.

6. STUDY PROCEDURES AND ASSESSMENTS

6.1. Visit 1

6.1.1. Informed consent and screening

6.1.1.1. Informed Consent

The requirement to obtain informed consent from the participant will be waived for this clinical study.

6.1.1.2. Verification and Eligibility

The PI or delegated study staff will verify the eligibility of the individual for the study, based on the inclusion and exclusion criteria that will be evaluated in the Participant Screening Form. The participant will receive a unique screening number that will be recorded in the Participant Screening Form. The participant responses will be included in the Participant Screening Form.

Successfully enrolled participants will be assigned a unique participant identification number based on the order in which they enroll. If the individual is considered eligible to participate in the study, the participant will proceed to the study activities detailed in sections 6.1.2, 6.1.3, 6.1.4, and 6.1.5.

6.1.2. Participant Cohort Randomization

Participants will be assigned to evaluate two foam hand sanitizers. The order in which the participants test a hand sanitizer product first or second will be randomly assigned. The participants, as well as on-site staff will be blinded to testing products. If a participant is unable to complete the study or has missing data, the participant will be replaced such that the new participant will be assigned to the randomization cohort of the replaced participant. Randomization schedule will be generated using SAS® software, Version 9.4 of the SAS System for Windows. Copyright © 2013 SAS Institute Inc.

6.1.3. Hand Sanitizer A Application and Touch and Feel Assessment

Study staff will be provided with hand sanitizers and dispensers to use prior to handling any items such as product bottles, pens, or paperwork, for the duration of the study activities.

Participants will first be asked to wash and dry their hands and wait an additional two minutes after their hands have dried before application of the hand sanitizer products. Study staff will use a stopwatch set for two minutes to ensure participant compliance to the two minute waiting period after hand washing. The participants will be instructed by study staff to apply one automatically dispensed amount, approximately 1 mL, of the first product (Hand Sanitizer A) topically to their hands and rub the product until the product is absorbed. The order in which each product is applied will be randomized. After product application, the participants will complete a VAS assessment of their touch and feel experience with Hand Sanitizer A, which will include questions regarding the participant's perceived moisturization and overall satisfaction with the hand sanitizer. Participant responses to the assessment will be recorded in the CRF by study staff.

6.1.4. Hand Sanitizer B Application and Touch and Feel Assessment

The participant will again be asked to wash their hands with soap and water and dry their hands and wait an additional two minutes after their hands have dried. Study staff will again time the two minute waiting period using a stopwatch. The participant will then repeat the described application process with the second product (Hand Sanitizer B), as the participants will be instructed by study staff to apply one automatically dispensed amount of approximately 1 mL of Hand Sanitizer B topically to their hands and rub the product until the product is absorbed. After product application, the participant will complete a VAS assessment of their touch and feel

experience with Hand Sanitizer B. Participant responses to the assessment will be recorded in the CRF by study staff.

6.1.5. End of Study Activity: Product Preference Questionnaire

After applying the two foam Hand Sanitizers A and B, the participant will complete a Product Preference Questionnaire. Participant responses to the questionnaire will be recorded in the CRF by study staff. When both Hand Sanitizers A and B have been applied and the participant has completed the study VAS Assessments and the Product Preference Questionnaire, the participant will be dismissed from the study.

7. ADVERSE EVENTS (AEs)

7.1. Definition of AE

The FDA definition for an AE is: An AE is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure.

However, a narrower definition of AE will be used for this study. In this study, an AE is any untoward medical occurrence related to the topical use of the hand sanitizers during this study, including skin itching, erythema, edema, or any other skin irritation that occurs.

7.2. Definition of Serious Adverse Event (SAE)

The FDA definition of a SAE will be used in this study: An AE or suspected adverse reaction is considered "serious" if, in the view of either the PI or sponsor, it results in any of the following outcomes:

- Death,
- A life-threatening adverse event,
- Inpatient hospitalization or prolongation of existing hospitalization,
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or
- A congenital anomaly/birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. All SAEs will be reported to Medline, regardless of potential relationship to the study product(s). SAEs will be reported to the reviewing IRB as necessary according to their reporting requirements.

7.3. Severity of AE

The severity of all AEs will be graded on a scale of one through five according to the Common Terminology Criteria for AE guideline, where each grade represents a unique clinical description based on this general guideline:

- **Grade 1:** Mild; asymptomatic or mild symptoms; clinical or diagnostic observation only; intervention not indicated.

- **Grade 2:** Moderate; minimal, local or noninvasive intervention indicated; limited age-appropriate instrumental activities of daily living.
- **Grade 3:** Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting activities of daily living involving self-care.
- **Grade 4:** Life threatening consequences; urgent intervention indicated
- **Grade 5:** Death related to AE

7.4. Relatedness of AE and SAE

- **Unrelated:** This category applies to those AEs which, after careful consideration, are clearly and incontrovertibly due to extraneous causes (disease, environment, etc.)
- **Possible:** This category applies to those AEs for which, after careful medical consideration at the time they are evaluated, a connection with the Investigational Product administration appears unlikely but cannot be ruled out with certainty.
- **Probable:** This category applies to those AEs which, after careful medical consideration at the time they are evaluated, are felt with a high degree of certainty to be related to the study product(s).
- **Definite:** This category applies to those AEs which, after careful consideration, are clearly and incontrovertibly due to the study product(s).

7.5. Expectedness

The PI will be responsible for determining whether an AE or SAE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

7.6. AE Reporting

The AEs will be recorded on the AE form (provided by Medline Industries, LP) by the study staff and reviewed by the PI. Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity. Changes in severity will necessitate a new CRF to document the new level of severity. AEs characterized as intermittent require documentation of onset and duration of each episode.

Non-serious AEs will be reported to the study sponsor on a monthly basis for review or as agreed upon with the study sponsor, and reported to the IRB per IRB reporting requirements.

7.7. SAE Reporting

The PI shall complete an SAE Form (provided by Medline Industries, LP) and submit to the study sponsor as soon as possible, but in no event later than 48 hours after the PI first learns of the effect. The PI will be responsible for reporting the event to the IRB, if applicable, per the IRB's reporting requirements. The study sponsor is responsible for conducting an evaluation of the SAE and shall report the results of such evaluation to the FDA and to all reviewing IRBs, if applicable, within 10 working days after the sponsor first receives notice of the effect. Thereafter, the sponsor shall submit such additional reports concerning the effect as FDA requests.

For questions regarding this process or the event, you may contact your Medline clinical designee or the Medline Director of Clinical Operations:

Name: Julie A. Miller RN, BSN, CCRA
Phone: 630-418-6891
E-mail: clinicaloperations@medline.com

8. STATISTICAL CONSIDERATIONS

8.1. Sample Size Determination

Sample size N of 90 (45 for a foam cohort and 45 for a gel cohort to be evaluated in a future study) was estimated to provide 80% power at the 95% level of significant for the proportion of HCW preferring one gel/foam product over the competing gel/foam product using the "Non-Inferiority Tests for the Difference Between Two Correlated Proportions" procedure in PASS 2021 Power Analysis and Sample Size Software (2021). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass. The estimated non-inferiority margins were .03 to .08 with estimated proportion differences of .1, .15 and .20. This study will utilize the sample of N=45 for the foam cohort.

8.2. Randomization

The order in which the participants test a hand sanitizer product first or second will also be randomly assigned. The participants, as well as on-site staff will be blinded to testing products. If a participant is unable to complete the study or has missing data, the participant will be replaced such that the new participant will be assigned to the randomization cohort of the replaced participant. Randomization schedule will be generated using SAS® software, Version 9.4 of the SAS System for Windows. Copyright © 2013 SAS Institute Inc.

8.3. Populations for Analyses

The analyses will be performed on the intent-to-treat population which consists of all subjects who were qualified for entry criteria and adhered to the protocol, meaning completing the satisfaction and user experience questionnaire for both testing products.

No per protocol, safety, or other analyses groups are planned.

8.4. Statistical Analysis

Descriptive and/or summary statistics will be calculated for the primary endpoints, which are the user touch and feel experience of the hand sanitizer products evaluated by visual analog scale assessments of HCWs overall satisfaction and moisturization, and HCWs assessment of product preference. Statistical analyses will be conducted in SAS® software, Version 9.4 or higher of the SAS System for Windows (Copyright © 2013 SAS Institute Inc.) or other appropriate statistical software.

All continuous variables will be summarized using the following descriptive statistics: n (non-missing sample size), mean, standard deviation, median, maximum and minimum. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical measures. In general, all data will be listed, sorted by site, treatment and subject, and when appropriate by visit number within subject. All summary tables will be structured with a column for each treatment in the order (Control, Experimental) and will be annotated with the total population size relevant to that table/treatment, including any missing observations.

All protocol deviations will be recorded and examined for potential bias in accordance with section 9.

8.4.1 Assessment of Satisfaction and Moisturization

HCWs' overall satisfaction of the interventions will be evaluated for each intervention using a VAS scale in millimeters. Summary statistics will be calculated for the VAS score by intervention for each statement in the survey. The satisfaction scores will be compared across the two interventions using either ANOVA/t-tests or another method, as appropriate for the data distribution.

8.4.2 Assessment of Product Preference

A product preference questionnaire will be filled out by the participants after testing both hand sanitizer products. The proportion of participants showing preference of the sanitizer products will be compared within each cohort using McNemar Test for Two Correlated Proportions or other appropriate methods, depending on the distribution of data.

8.4.3 Demographic and Baseline Variables

Age will be collected as a continuous measure, with all participants being >=18 years of age. Age will be considered for secondary analysis.

Sex will be collected as a categorical equal to 0=male, 1=female, or 2=other. Sex will be considered for secondary analysis.

9. SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.1. Regulatory and Ethical Considerations

9.1.1. Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the PI, the staff, and the sponsor. Therefore, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to

any unauthorized third party without prior written approval of the sponsor. All study data and study records will be managed and stored in accordance with the site's policies on data storage and security. All electronic transmission of data will adhere to Health Insurance Portability and Accountability Act (HIPAA) and any local regulations.

The study monitor, other authorized representatives of the sponsor, representatives of the IRB, and regulatory agencies may inspect all documents and records required to be maintained by the PI. The clinical study site will permit access to such documents.

A master list with participant numbers will be maintained in a secure database by the PI or paper files in secure cabinet(s). The study participant's contact information will be securely stored at each clinical site for internal use during the study. The PI will agree to notify the sponsor of any intent to move or destroy these documents.

9.1.2. Safety Oversight

Safety oversight will consist of monitoring of visit activity, AEs and SAEs by the PI, who is suitably qualified and experienced to evaluate any AEs or SAEs. The PI will review all AEs and SAEs and make any necessary safety determinations or visit activity modification that are in the best interest of the participant as necessary. See also Section 7.0 AEs for reporting and management requirements.

9.1.3. Study Discontinuation

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the PI, sponsor, and IRB. If the study is prematurely terminated or suspended, the PI, in collaboration with the sponsor, will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstance(s) that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants as determined by AE review

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and the sponsor and/or IRB satisfied.

9.1.4. Study Closeout

Upon completion of the study, Medline Industries, LP and/or its designees will notify the site of closeout related procedures and will coordinate with the site the return of equipment and/or any unused product. Medline CRA will communicate closely with the PI at that time point and will review all close out steps and materials. All study data, related study documents, and unused study product, will be returned to the sponsor or as per agreement with the study contract. The site will also notify the IRB that the study has been completed.

9.1.5. Data Handling and Record Keeping

Data collection is the responsibility of the study staff under the supervision of the PI. The PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported in the CRFs or any other study activity documentation as part of this study. All the documents should be completed in accordance with Good Documentation Practices (GDP) to ensure accurate interpretation of data.

Final storage of Medline data will be per ICH/GCP guidelines and kept stored in a protected access area for the length of the time required.

9.1.6. Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed.

9.2. Protocol Deviations

It is the responsibility of the PI and study staff to use continuous vigilance to identify and report deviations on a routine basis. All deviations must be addressed in the study source documents, and reported to Medline Industries, LP. Protocol deviations must be sent to the reviewing IRB per reporting requirements and should be reported to the sponsor in a timely manner. The PI is responsible for knowing and adhering to the reviewing IRB requirements.

9.3. Abbreviations

AE	Adverse Event
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CMP	Clinical Monitoring Plan
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GDP	Good Documentation Practice

HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IRB	Institutional Review Board
PI	Principal Investigator
SAE	Serious Adverse Events
SOA	Schedule of Activities
U.S.	United States
VAS	Visual Analog Scale
WHO	World Health Organization

10. REFERENCES

1. Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51(No. RR- 16): 11, 13.

2. World Health Organization (WHO). WHO Guidelines on Hand Hygiene in Health Care. Geneva: WHO, 2009.

11. APPENDIX

11.1. Hand Sanitizer Product Ingredients

11.1.1. Spectrum™ Advanced Hand Sanitizer Foam

Ingredients (Active): 70% v/v Ethyl Alcohol
Ingredients (Inactive): (Alphabetical) denatonium benzoate, Glycerin, Glyceryl caprylate, Isopropyl myristate, PEG-12 dimethicone, t-butyl alcohol, Water

11.1.2. PURELL® Advanced Foam Hand sanitizer

Ingredients (Active): 70% v/v Ethyl Alcohol
Ingredients (Inactive): (Alphabetical) Caprylyl glycol, Glycerin, Isopropyl alcohol, Isopropyl myristate, PEG-12 dimethicone, Tocopheryl acetate, Water

Spectrum vs Purell Protocol_MED_2022_DIV60_001_V3.0

Final Audit Report 2022-11-18

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