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MITTAL GLOBAL CLINICAL TRIAL SERVICES (MGCTS)

CCFT/CT/2025/731

Study Title: “An In-Vivo Study to Determine the Sun Protection Factor of Plum Rice Water & 2% Niacinamide Hybrid Sunscreen.”



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Study Identifier	CCFT731
Study Title	In-vivo SPF Estimation
Guidelines	ISO 24444:2019
Product Name	Plum Rice Water & 2% Niacinamide Hybrid Sunscreen.
Study Sponsor	Pureplay Skin Sciences Pvt Ltd

Clinical Study Report

Title Page

Study Title: “An In-Vivo Study to Determine the Sun Protection Factor of Plum Rice Water & 2% Niacinamide Hybrid Sunscreen.”

Protocol No.	CCFT731
Version Number and Date	1.0 DATED 2 Jul 2025
Investigational Product	Plum Rice Water & 2% Niacinamide Hybrid Sunscreen
Name& Address of Sponsor	Pureplay Skin Sciences Pvt Ltd
Name & Affiliation of the Investigator(s)	Name: Dr. Robin Chugh, MD (Dermatology) Designation: Principal Investigator E-mail: robinder25@gmail.com
Date of First subject in the Study	15 July 2025
Date of Last subject follow up	30 July 2025
No. of subjects	10
Report Number	CCFT/CT/2025/731
Date of the draft report	05 Aug 2025

Confidential

The information in this document is confidential and is to be used only in connection with matters authorized by Pureplay Skin Sciences Pvt Ltd and no part of it is to be disclosed to the others without prior written permission from Pureplay Skin Sciences Pvt Ltd. This study was performed in accordance with ICHE6R2, Schedule-Y(2017) and Ethical Principles as per the Declaration of Helsinki (2013) including archiving of all the essential documents.



Study Identifier	CCFT731
Study Title	In-vivo SPF Estimation
Guidelines	ISO 24444:2019
Product Name	Plum Rice Water & 2% Niacinamide Hybrid Sunscreen.
Study Sponsor	Pureplay Skin Sciences Pvt Ltd

**INVESTIGATOR(S)
SIGNATURE(S)**

An In-Vivo Study to Determine the Sun Protection Factor of Radiance Plum Rice Water & 2% Niacinamide Hybrid Sunscreen.

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Dr Robin Chugh CCFT Laboratories, Skin & Hair Testing Zone, First Floor, AR Multispecialty Hospital & Research Centre135, Panjabipura, Delhi Road, Opp. Ramleela Ground, Meerut-250002, U.P, India	 05 Aug 2025 SIGNATURE & DATE
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Study Identifier	CCFT731
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Guidelines	ISO 24444:2019
Product Name	Plum Rice Water & 2% Niacinamide Hybrid Sunscreen.
Study Sponsor	Pureplay Skin Sciences Pvt Ltd

STATEMENT OF COMPLAINE

An In-Vivo Study to Determine the Sun Protection Factor of Plum Rice Water & 2% Niacinamide Hybrid Sunscreen.

This study was conducted in compliance with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

Name	Designation & Address	Signature	Date
PUNEET MITTAL	Director-Clinical Research, MGCTS, Mittal Building 121-B, Mansarovar Ind Estate, Panchli, Baghpat Road, Meerut-250002, India		05 Aug 2025



Study Identifier	CCFT731
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Guidelines	ISO 24444:2019
Product Name	Plum Rice Water & 2% Niacinamide Hybrid Sunscreen.
Study Sponsor	Pureplay Skin Sciences Pvt Ltd

**STATEMENT OF COMPLAINE
(DATA SAFETY MONITORING BOARD)**

An In-Vivo Study to Determine the Sun Protection Factor of Plum Rice Water & 2% Niacinamide Hybrid Sunscreen. This study was verified and reviewed independently according with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

S. No	Name and Designation	Signature	Date (DDMMYYYY)
1	Ms. Nidhi Dixit, Data Manager CCFT Laboratories, Meerut		05 Aug 2025
2	Ms. Anshika Choudhary, Data Manager CCFT Laboratories, Meerut		05 Aug 2025



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REPORT SUMMARY:

Title of the Study	An In-Vivo Study to Determine the Sun Protection Factor of Plum Rice Water & 2% Niacinamide Hybrid Sunscreen
Name of Investigational product	Plum Rice Water & 2% Niacinamide Hybrid Sunscreen
Name of Sponsor	Pureplay Skin Sciences Pvt Ltd
SITE	CCFT Laboratories, Skin & Hair Testing Zone, First Floor, AR Multispecialty Hospital & Research Centre135, Panjabipura,Delhi Road, Opp. Ramleela Ground, Meerut- 250002, U.P, India
Investigator(s)	Dr Robin Chugh, MD (Dermatology)
Study Objective	<u>Primary objective:</u> The primary objective is to determine the Sun Protection factor <u>Secondary objective:</u> The secondary objective of the study To study the Delayed Erythema Response.
Study Phase	NA
Study Design	An In-vivo study. Each participant entering the trial will be assigned to a regimen of investigational product, and advised to take general precautions as needed. Patients will be assigned to SPF test for 1 day (Visit 1) and MED (iMED) score would be measured by using solar meter. Additional Visit 2/ Follow-up visit is required for determining Delayed Erythema Response on application site and also for any AE.
Number of subjects	10



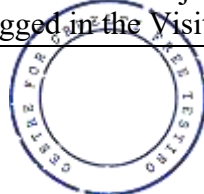
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Study Sponsor	Pureplay Skin Sciences Pvt Ltd

Study Inclusion Criteria	Subjects were included based on the following criteria. 1. Age 18-70 years 2. Individual should have ITA angle in the range of 28-40, 41-55 and >56. 3. Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the investigator. 4. Individuals who have completed a preliminary medical history evaluation. 5. Individuals who have read, understood and signed an informed consent document relating to the specific study to which they are subscribing. 6. Individuals with no known abnormal response to sunlight
Study Exclusion Criteria	Subjects were excluded based on the following criteria 1. Individuals taking medication which in the opinion of the investigator would mask or interfere with the results. 2. Individuals with chronic skin allergies. 3. Individuals with suntan or sunburn. 4. Individuals with abnormal reaction to the sun. 5. Pregnant or lactating females. 6. Subjects accustomed to using sun beds. 7. Subjects who have participated in an SPF study within the last two months
Test Product/ Study Product	Plum Rice Water & 2% Niacinamide Hybrid Sunscreen



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Study Methodology	Step 1: The subject enrolls into the study as per inclusion and exclusion criteria Step 2: Mark 4 different area (Unprotected, Protected, Reference 1 and Reference 2) having size 40 sq. cm of each. Step 3: Erythema induced by artificial UV rays (having wavelength 100-380 nm) on site area. - UV radiation shall not exceed 1600 W/m² otherwise the pain or burn may occur 4 min duration initially is minimum UV exposure time Step 4: IP deliver to the site through plastic volumetric syringe as per standard dose (2mg/ sq. cm $\pm$ 2.5%) followed by spreading with finger Step 5: After 15-30 min of application, 4 minutes of UV exposure will be given to check for MED, the same process will be repeated for upto 5 times until MED is achieved with an increment of 112.5% at each cycle. Similarly, the same series of UV exposure will administer to unprotected site to determine the MED(u), likewise Reference 1 and Reference 2. Step 6: Then the Individual SPF(i) value will calculate by the given formula: [2]
Clinical or Laboratory Assessment	Evaluate the MED Score on assessment day, day 0 for each individual at different time points Subjective and objective analysis will be done. Subjective: Sun Protection of test product Objective: Measure the Sun Protection Factor (SPF) by taking iMED score of each application area.
Outcome Measure	Time Frame: At the Baseline from Day 0 (Screening& Assessment) to Day 1/ Follow-up. Measurement of change in Individual MED (iMED) score of each application site by using Solarmeter of having intensity from 300- 1600 W/m², with 1600 W/m² being the severe.
Statistical Analysis	Statistical Considerations Data listings and summary tables will be provided. Listings will include all data captured on the case report form (CRF) unless specified otherwise. Calculated (derived) variables will be listed as appropriate. Summary tables will be provided for select variables as described in Section 5 through Section 8 of Statistical Analysis Plan. Analyses by visit will be performed on nominal visits regardless of actual visit day. The exception will be the case where a subject discontinued prior to Visit 1 yet data were mistakenly logged in the Visit 1 CRFs, as Visit 1 represents



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	end of treatment. Here data will be analyzed on the appropriate study visit day according to the visit window in which the actual study day falls; this will allow for correct implementation of the last observation carried forward method.
Ethical Conduct of the study	The study was initiated after written approval from the Ethics Committee. The trial was conducted as per ICH E6 R2 Guidelines, Schedule Y (2017), Declaration of Helsinki (Brazil,2013) and in Accordance with other applicable guidelines.
Efficacy and Safety Results	Out of 10 subjects screened, none were found screen failures, none were dropouts. 10 subjects underwent the Trial. The mean age of the subjects was 30 years. The mean height of the subjects was 163 cm. The mean weights of the subjects were 65 kg. Data from all 10 subjects who completed the study were analyzed. The Primary End Point is to determine the SPF was calculated as taking iMED score of each application area. The mean SPF score was 53.98. The mean erythma response was 1.2 on the follow up day There were no protocol violations and deviations reported. There was no subject who withdrawn the consent.
Conclusion	In conclusion, Plum Rice Water & 2% Niacinamide Hybrid Sunscreen was found with the SPF 53.98
Date of Report	05 Aug 2025



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List of Abbreviations

Abbreviation	Definition
AE	Adverse event
ANOVA	Analysis of variance
AUC	Area under the curve
BOCF	Baseline observation carried forward
CI	Confidence interval
CRO	Contract Research Organisation
CRF	Electronic case report form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
IP	Investigational product
IEC	Institutional Ethics Committee
ITT	Intent to treat
MI	Multiple imputation
MedDRA	Medical Dictionary for Regulatory Activities
MED	Minimal Erythmal Dose
OTC	Over the counter
PP	Per protocol
PRO	Subject-reported outcome
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SD	Standard deviation
SUSAR	Suspected unexpected serious adverse reaction
TC	Telephone call



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Subject Information and Consent

All subjects provided written informed consent to participate in the study prior to being screened. The subject information sheet detailed the procedures involved in the study (aims, methodology, potential risks and anticipated benefits) and the investigator explained these to each subject. The subject signed the consent form to indicate that the information had been explained and understood. The subjects were allowed to take sample time to consider the information presented before signing and dating the informed consent form to indicate that they fully understood the information, and willingly volunteered to participate in the study. The subjects were given a copy of the signed informed consent form for their information. The original informed consent documents were kept in a confidential file in the Investigators site record.



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Investigators and Study Administrative Structure

Sponsor	Pureplay Skin Sciences Pvt Ltd
Principal Investigator(S)	Dr. Robin Chugh, MD(Dermatology)
ETHICS COMMITTEE(S)	ARMHRC INSITUTIONAL ETHICS COMMITTEE
SITE(S) ADDRESS	CCFT Laboratories, Skin & Hair Testing Zone, First Floor, AR Multispecialty Hospital & Research Centre 135, Panjabipura, Delhi Road, Opp. Ramleela Ground, Meerut- 250002, U.P, India
NAME OF LABORATORY	CCFT Laboratories
REPORT GENERATION	Ms. Nidhi Dixit, M Pharm (Pharmacology)



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1. INTRODUCTION

1.1. Background

Sunscreen, also known as sunblock or sun cream, is a photoprotective topical product for the skin that helps protect against sunburn and most importantly prevent skin cancer.

Sunscreens are classified into two types: mineral (also referred to as physical) sunscreens (i.e., Zinc oxide and titanium dioxide) and chemical (also referred to as petrochemical, as they are typically derived from petroleum) sunscreens [1].

The sun protection factor (SPF) is a measure of the fraction of sunburn (UV light)-producing UV rays that reach the skin. For example, "SPF 15" means that 1/15 of the burning radiation will reach the skin, assuming sunscreen is applied evenly at a thick dosage of 2 milligrams per square centimeter (2mg/cm²)

The most common conditions that sunburn may cause include the following:

- Black skin
- Tenderness
- Itching

1.2. Rational of the trial

Sunscreen, also known as **sunblock** or **sun cream**, is a photoprotective topical product for the skin that helps protect against sunburn results melanoma and most importantly prevent skin cancer.

The effect comes due to the product block the entry of radiation as result protection from both UVA and UVB. The UVA responsible for skin cancer and UVB for skin burning (sunburn) that later develop the problems related to premature ageing, wrinkles, dark spots and sagging skin.

Benefit-risk Assessment

It would be safe to assume that the risk factor in this clinical trial is minimal. However, the problem is designed to record any adverse event that may take place as well as handle any complications that may arise during the trial.



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2. TRIAL OBJECTIVES AND PURPOSE

Primary objective

The primary objective is to determine the Sun Protection factor

Secondary objective

- To study the delayed Erythema Response

3. TRIAL DESIGN

3.1. Overall Trial Design

This is an In-Vivo study, to determine the Sun Protection Factor (SPF) when applied topically for a single assessment to adults between the ages of 18-70 years. The trial subjects will be enrolled at 1 investigative site in India. The IP will apply topically on scapula line and the waist on an actual day or screening visit.

The maximum trial duration for each subject will be 2 days which includes a screening period and follow-up visit. At the end of the screening period, eligible subjects will be assigned trial medication on Day0 (Visit1/Baseline) and on Day 1 (Visit 2/Follow-up)

During the treatment period, the investigator will score the MED score of each formulation and also other AE: if happen

Study Methodology:

Step 1: The subject enrolls into the study as per inclusion and exclusion criteria

Step 2: Mark 4 different area (Unprotected, Protected, Reference 1 and Reference 2) having size 40 sq. cm of each.

Step 3: Erythema induced by artificial UV rays (having wavelength 100-380 nm) on site area.

- UV radiation shall not exceed 1600 W/m² otherwise the pain or burn may occur
- 4 min duration initially is minimum UV exposure time

Step 4: IP deliver to the site through plastic volumetric syringe as per standard dose (2mg/ sq. cm² ±



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2.5%) followed by spreading with finger

Step 5: After 15-30 min of application, 4 minutes of UV exposure will be given to check for MED, the same process will be repeated for upto 5 times until MED is achieved with an increment of 112.5% at each cycle.

Similarly, the same series of UV exposure will administer to unprotected site to determine the MED(u) likewise Reference 1 and Reference 2.

Step 6: Then the Individual SPF(i) value will calculate by the given formula: [2]

$$\text{SPF (i)} = \text{MED (p)} / \text{MED (u)}$$

where,

MED is the Minimum Erythral Dose

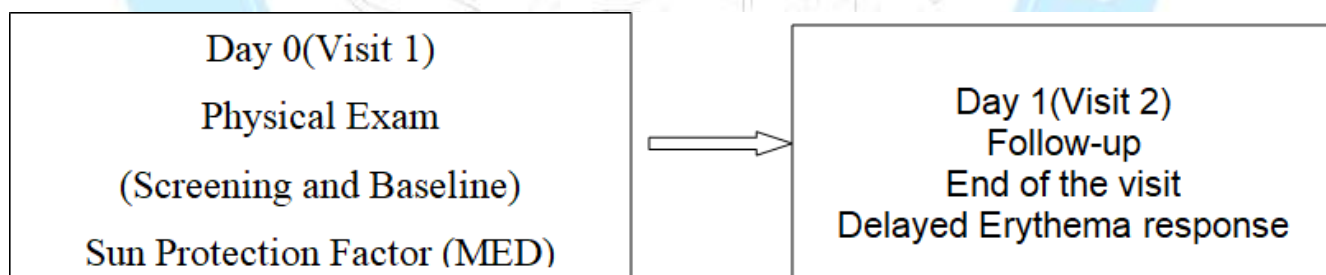
i' stand for individual

MED (p) stands for Minimal Erythral Dose for protected

MED (u) stands for Minimal Erythral Dose for unprotected

The trial design is summarized in Figure 4: 1

Figure4: 1 Trial Design



a. Trial Endpoints

Primary Endpoint

Change in the Individual MED (iMED) score of different application site

Secondary endpoint-

- Delayed Erythema Response



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i. Safety Endpoints

Safety end points include the following:

- Assessment and reporting of the Adverse Events.
- Tolerability of Skin care products.

3.2. SELECTION OF TRIAL POPULATION

3.2.1. Subject Population

10 subjects will be enrolled to provide about 10 completed subjects evaluable for the primary analysis. An individual subject will be allowed to participate in the trial once.

Each potential subject will sign an informed consent document before any trial-specified procedures are performed. Subjects will provide authorization for the use of their data by the applicable regulations regarding privacy and data protection.

3.2.2. Inclusion Criteria

Subjects must meet all the following criteria to be eligible for participation in the trial:

1. Age 18-70 years
2. Individual should have ITA angle in the range of 28-40, 41-55 and >56.
3. Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the investigator.
4. Individuals who have completed a preliminary medical history evaluation.
5. Individuals who have read, understood and signed an informed consent document relating to the specific study to which they are subscribing.
6. Individuals with no known abnormal response to sunlight



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3.2.3. Exclusion Criteria.

1. Individuals taking medication which in the opinion of the investigator would mask or interfere with the results.
2. Individuals with chronic skin allergies.
3. Individuals with suntan or sunburn.
4. Individuals with abnormal reaction to the sun.
5. Pregnant or lactating females.
6. Subjects accustomed to using sun beds.
7. Subjects who have participated in an SPF study within the last two months

3.2.4. Discontinuation of Treatment

In accordance with legal requirements and International Conference on Harmonization (ICH) – Good Clinical Practice (GCP) guidelines, every subject has the right to refuse further participation in this trial at any time and without providing reasons (see also Section 9.2). A subject's participation is to be terminated immediately upon his/her request. The investigator should seek to obtain the reason and record this on the electronic case report form (CRF) whenever possible.

If, at the time of refusal, a trial product has already been administered, the investigator should advise the subject on follow-up safety evaluations.

In the case of an SAE or development of a condition that would have met the trial safety-related exclusion criteria, the subject should be evaluated by the investigator. The investigator should use his/her discretion to determine whether the subject should continue treatment with the IP.

A subject may be withdrawn from the trial at any time at the discretion of the investigator. The reasons for early termination are to be fully documented on the CRF.

In addition, sponsor reserves the right to end or suspend the trial at any time.



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If a subject withdraws from the trial, all efforts will be made to complete a final evaluation if possible. The withdrawal procedures for subjects who withdraw during the treatment period are the same as those for the End of Treatment visit.

Subjects discontinued for an AE will be monitored until the AE is resolved, a reasonable explanation is provided for the event, or the subject is referred to his/her own primary medical doctor. The specific AE in question will be recorded on the appropriate CRF.

3.2.5. Replacement Policy

After trial enrolment has been completed, subjects who prematurely discontinue the trial are not replaced. No such event took place in this study.

4. TRIAL TREATMENTS

4.1. Investigational Product

Plum Rice Water & 2% Niacinamide Hybrid Sunscreen

4.2. Testing Regimen

Step 1: The subject enrolls into the study as per inclusion and exclusion criteria

Step 2: Mark 4 different area (Unprotected, Protected, Reference 1 and Reference 2) having size 40 sq. cm of each.

Step 3: Erythema induced by artificial UV rays (having wavelength 100-380 nm) on site area.

- UV radiation shall not exceed 1600 W/m² otherwise the pain or burn may occur
- 4 min duration initially is minimum UV exposure time

Step 4: IP deliver to the site through plastic volumetric syringe as per standard dose (2mg/ sq. cm ± 2.5%) followed by spreading with finger

Step 5: After 15-30 min of application, 4 minutes of UV exposure will be given to check for MED, the same process will be repeated for upto 5 times until MED is achieved with an increment of 112.5% at each cycle.



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Similarly, the same series of UV exposure will administer to unprotected site to determine the MED(u) likewise Reference 1 and Reference 2.

Step 6: Then the Individual SPF(i) value will calculate by the given formula: [2,3]

$$\text{SPF (i)} = \text{MED (p)} / \text{MED (u)}$$

Where,

MED is the Minimum Erythral Dose

I' stand for individual

MED (p) stands for Minimal Erythral Dose for protected

MED (u) stands for Minimal Erythral Dose for unprotected

4.3. Testing Modification

Subjects classified as evident at any on-treatment visits may stop the treatment at the investigator's discretion. They should remain in the trial and attend all holidays, including the follow-up visit. A subject can discontinue the prosecution anytime, which would be counted as a dropout.

4.4. Packaging, Labeling, and Storage

Packaging for the products was in compliance with the legal requirements of the country where the trial is performed and be printed in the local language. The designated vendor has supplied the IPs and stores them securely at the site under the investigator's control. For all the products, the room temperature was ideal.

4.5. Prior, Concomitant, and Prohibited Therapy

All medications, including over-the-counter (OTC) drugs, taken within 30 days prior to the start of the trial were recorded at Screening. Thereafter, a record of all medications and supportive therapy taken during the course of the trial was made. Information regarding the total daily dose, route of administration, start and



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discontinuation dates, and indication were recorded on the subject's CRF.

A washout period of up to 4 weeks was completed if the subject has been treated with any medication as specified in the exclusion criteria.

4.6. Prohibited Medications during the Trial

Any medication that would exclude the subject from participation in the trial (as specified in Exclusion Criteria) was also prohibited during the treatment and follow-up.

4.7. Rescue Medication

In case of severe irritation, a dermatologist would decide what best rescue medicine is suitable for the subject.

4.8. Treatment Compliance

Records of the trial product used, and SPF testing will be kept during the trial. The trial monitor will note product accountability during site visits and after the problem.

At all on-treatment visits, the subject will be asked if they have used the instructions as prescribed. If this is not the case, the degree and nature of non compliance will be specified. In addition, subjects will be asked to complete a dosing diary during the treatment period to measure treatment compliance.

Subjects who are consistently non-compliant will be counseled.



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5. VISIT SCHEDULE AND ASSESSMENTS

5.1. Trial Procedures

The visit schedule and assessments are summarized in Table 1-1.

Table 1-1: Visit Schedule and Assessments

Visit	Visit 1 Screening / Assessment visit	Visit 2 (End of Trial)
	(Day 0/1)	Day 2
Informed Consent	X	
Inclusion/Exclusion Criteria	X	
Demographics, medical history	X	
Concomitant medication	X	
Concurrent diagnoses	X	
Physical Exam	X	
Vital signs	X	X
Pregnancy Test	X	
MED Score	X	
Delayed erythema assessment		X
Any AE	X	X

MED= Minimum Erythema Dose

AE= Adverse Event



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5.2. Trial Visits and Assessments

Visit1/Screening & Baseline (Day0)

Screening procedures should be completed no more than 1 day prior to Visit 1/Baseline (Day 0). Visit 1/Screening and Visit 1/Baseline can occur on the same day if no washout of prohibited medications is required. The following screening procedures will be performed at the screening visit:

- Review trial information with subject and obtain written informed consent.
- Review inclusion and exclusion criteria with the subject to determine the subject's eligibility.
- Collect medical history;
 - other allergic history if the subject received concomitant medication for this condition
 - If subject participated in an SPF study within last two months
- Review and record any current medical diagnoses.
- Perform the following assessments
 - Individual MED (iMED) of each subject at different time interval
- Perform a urine pregnancy test (UPT) in female subjects of childbearing potential and instruct these female subjects to use approved form(s) of contraception.
- If the Visit 1 Screening or Visit 1/Baseline (Day 0) procedures are being performed on the same day, perform the procedures specified.

Visit2 (Day1) Follow-up/ End of Treatment

- Perform a physical examination: Take Vital signs (Body temperature systolic and diastolic blood pressure and heart rate and pulse rate).
- Perform the following assessments:
 - After 16 to 24 hrs. post exposure, the volunteer instructed to return to the investigational site for evaluation of delayed Erythematous response.
- Assess treatment area for local skin reactions.
- Record any AEs.



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5.3. Early Termination

If a subject withdraws from the trial prior to the Visit 2 (End of Treatment) visit, the subject is to return to the site for assessment of any post exposure AE.

Test application

Step 1: The subject enrolls into the study as per inclusion and exclusion criteria

Step 2: Mark 4 different area (Unprotected, Protected, Reference 1 and Reference 2) having size 40 sq. cm of each.

Step 3: Erythema induced by artificial UV rays (having wavelength 100-380 nm) on site area.

- UV radiation shall not exceed 1600 W/m² otherwise the pain or burn may occur
- 4 min duration initially is minimum UV exposure time

Step 4: IP deliver to the site through plastic volumetric syringe as per standard dose (2mg/ sq. cm ± 2.5%) followed by spreading with finger

Step 5: After 15-30 min of application, 4 minutes of UV exposure will be given to check for MED, the same process will be repeated for upto 5 times until MED is achieved with an increment of 12.5% at each cycle.

Similarly, the same series of UV exposure will administer to unprotected site to determine the MED(u) likewise Reference 1 and Reference 2.

Step 6: Then the Individual SPF(i) value will calculate by the given formula: [2,3]

$$SPF (i) = MED (p) / MED (u)$$

Where,

MED is the Minimum Erythema Dose

I' stand for individual

MED (p) stands for Minimal Erythema Dose for protected

MED (u) stands for Minimal Erythema Dose for unprotected



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5.4. Investigator Assessment

The investigator assessments must be performed by a physician with at least one year of experience. For physicians and Physician Assistants who do not fulfill the requirement. Regarding required knowledge and other state licensed professionals who can diagnose, treat and prescribe medications, the sponsor must pre-approve the person.

Delayed Erythema Scoring

After the 24 hours of the MED assessment, the Erythema Assessment was done with a Physician/Dermatologist as below Scoring table.

Erythema 5 Point Scale [0-4]	SCORE
Score for Erythema	
No Reaction	0
Very Slight Erythema	1
Slight Erythema	2
Moderate Erythema	3
Severe Erythema	4

5.5. Adverse Events

Adverse Events Assessments

The investigator or designee is responsible for obtaining, assessing, and documenting all AEs during the study. Adverse Events information will be collected from the time of the signature of the informed consent form until the end of the study. An AE is any untoward medical occurrence in any subject during the trial which does not necessarily have a causal relationship with the trial drug treatment.

All AEs will be documented in the CRF, including a description of each AE's relationship to trial product R administration, start and stop dates, seriousness, severity, action taken, and outcome.



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Any AE meeting the stringent criteria must be reported on the CRF and a separate SAEs report form. SAEs must be reported to the Ethics Committee within 24 hours of awareness.

Throughout the trial, the occurrence of AEs should be sought by non-directive questioning of the subject at each visit during the trial. Information on AEs can also be obtained from signs and symptoms detected during examination, observations made by the trial site personnel, or spontaneous reports from subjects. Pre-existing conditions that worsen during the trial should also be recorded as AEs.

AEs requiring therapy must be treated with recognized medical care standards to protect the subject's health and well-being. Treatment due to an AE will be recorded in the subject's records and on the appropriate CRF.

The investigator must follow any AE related to the trial product until it is resolved or until the subject's medical condition is stable; all relevant follow-up information will be reported to the Sponsor/CRO or designee.

The outcome of an AE will be classified as recovered, recovered with sequelae, recovering/resolving, ongoing, or death.

Timing

AEs were collected/assessed from the time of the signature of the informed consent form by the subject and first trial-related activity performed.

Severity of Adverse Events

The investigator is to classify the severity (intensity) of an AE according to the following definitions:

- **Mild**–The subject was aware of the signs and symptoms but the signs and symptoms were easily tolerated and does not interfere with daily activity.
- **Moderate**–The signs and symptoms were sufficient to restrict, but did not prevent, usual daily activity for the subject. The subject is still able to



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function.

- Severe–The subject was unable to perform usual daily activity.

The maximum intensity of an AE (mild, moderate, or severe) will be assessed taking into account the possible range of intensity of the symptom(s).

Relationship of an Adverse Event to Trial Treatment

The investigator is responsible to assess the relationship of an AE to the IP using good clinical judgment and the following definitions:

Not Related	The AE is clearly explained by another cause not related to the trial
	Product administration; the temporal relationship of the AE to IP administration makes a causal relationship unlikely, or, concomitant medication, therapeutics interventions, or underlying condition provide a sufficient explanation for the observed AE
Possibly Related	The AE and administration of trial product are temporally related, but the AE can be explained equally well by causes other than the trial product administration
Probably Related	The AE and use of trial product are temporally related, and the AE Is more likely explained by trial product administration than by other causes
Definitely Related	The AE and trial product administration are related in time, and a direct association can be demonstrated. Concomitant medication, therapeutics interventions, or underlying conditions do not provide a sufficient explanation for the observed AE

Unexpected Adverse Events

Any AE assessed as related to the IP will be assessed for expectedness by the sponsor or designee. An AE is considered “unexpected” if its nature or severity is not consistent within formation in the Investigator’s Brochure.

“Unexpected” as used in this definition, also refers to AEs that are mentioned in the Investigator’s Brochure or product prescribing information as occurring with a class of drugs or as anticipated from the pharmacological properties of the drug, but are not



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specifically mentioned as occurring with the particular drug under investigation.

Pregnancy

Any pregnancy occurring from date of the Informed Consent signature until study completion must be reported immediately to the Sponsor or designee as soon as it becomes known to the investigator and not later than within 24 hours of his/her knowledge of the occurrence of the pregnancy

Investigator must actively follow-up, document and report to Sponsor or designee the progress of the pregnancy until outcome is reached.

5.6. Serious Adverse Event

An SAE is any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening
- Requires in-subject hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect, or is an important medical event?
- Other serious or important medical event

The death of a subject enrolled in a trial is per se not an event, but an outcome. Any event resulting in a fatal outcome must be fully documented and reported, regardless of the causality relationship to the IP.

Any medical important events that may not result in death, be life-threatening, or require hospitalization may be considered an SAE when, based on appropriate medical judgment, they may jeopardize the subject, or the subject may require medical or surgical intervention to prevent one of the outcomes listed in the above definitions.

Any pre-planned hospitalizations that are known at the time of signing the ICF will



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not be recorded as SAEs, however they will be recorded as AEs only.

Any SAE, whether or not deemed drug-related or expected, must be reported immediately to the Sponsor or designee as soon as it becomes known to the investigator and not later than within 24 hours of his/her knowledge of the occurrence of an SAE (see Section 13.2). The investigator will document such events in the best possible detail on the SAE Report Form.

A suspected unexpected serious adverse reaction (SUSAR) is an SAE that is both unexpected (not consistent with the current Investigator's Brochure) and for which there is evidence to suggest a causal relationship between the drug and the SAE. The Institutional Ethics Committee (IEC) will be informed of SUSARS according to local requirements. All investigators participating in the trial will also be notified of unexpected SAEs. The sponsor or designee will report SAEs and other events requiring expedited reporting to regulatory authorities as required.

Investigator instructions for reporting SAEs are provided.

Pregnancy Testing

Female subjects of child-bearing potential have undergone a routine urine pregnancy test (UPT) at the Visit 0/Screening and/or before any trial-specific procedures are performed. If the UPT is positive, the subject was not permitted to enroll in the trial.

At the investigator's discretion, additional testing for pregnancy may be performed for verification purposes. If there is a suspicion of pregnancy at any time during the trial, a urine sample was obtained and tested. Should a subject become pregnant during the trial, treatment must be discontinued.

All pregnancies should be immediately reported to the sponsor or designee and followed through to resolution (i.e., delivery, miscarriage, or abortion). There port should be submitted within the same timelines as an SAE (within 24 hours of knowledge), although a pregnancy perse is not considered an SAE.



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6. STATISTICAL METHODS AND ANALYTICAL PLANS

Being an observational study, it does not need to be evaluated by any statistical methods.

6.1. Data Sets Analyzed

All eligible subjects who were included in to the study were included in the safety analysis.

6.2. Demographic and Baseline Characteristics

The following demographic variables at screening were summarized by dose level: race, gender, age, height and weight.

6.3. Sample Size

The sample size for this protocol is 10. The eligible patients will be assigned to study treatment. A total of 10 subjects were enrolled, out of which none dropouts have been considered.

7. CHANGES IN THE PLANNED TRIAL

7.1. Protocol Amendments

Except for administrative changes, any changes or additions to this clinical trial protocol require a written protocol amendment that must be approved by the IEC before implementation.

These requirements for approval should in no way prevent any immediate action from being taken by the investigator or SPONSOR/CRO in the interests of preserving the safety of all subjects included in the trial. If an immediate change to the protocol is felt to be necessary by the investigator and is implemented for safety reasons, SPONSOR/CRO or designee should be notified and the IEC should be informed according to their reporting requirements.



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7.2. Termination or Suspension of the Trial

SPONSOR/CRO reserves the right to terminate or suspend the trial at any time. In case of premature termination or suspension of the trial, the contract research organization (CRO) project manager has to promptly inform the investigators, regulatory authorities, and s about the premature termination or suspension, including the reason for it. In terminating the trial, SPONSOR/CRO and the investigator should ensure that adequate consideration is given to the protection of the subjects' interests.

8. DATA HANDLING AND RECORD KEEPING

8.1. Recording of Data Source Documents

Source data are all the information in original records and copies of original records of clinical findings, observations, or other activities in the trial, which are necessary for their construction and evaluation of the trial. The identification of any data to be recorded directly on the CRFs is to be considered source data.

Trial data collection procedures must ensure that each data element can be traced with a high level of confidence from its originator or recorder to its representation in the trial database and then to its place in the analysis and report of trial results. Once recorded, the trial data must be protected from unauthorized modification or deletion, and all authorized modifications and deletions must be securely linked in the permanent record with their author, time of change, and reason for change (i.e., the audit trail must be maintained).

The investigator should permit trial-related monitoring, audit(s), IEC review(s) and regulatory inspection(s), with direct access to all the required source records.

The principal investigator should certify the data to be accurate and complete and release the data for transmittal to SPONSOR/CRO or designee.

Source records need to be preserved for the maximum period of time permitted by local requirements (see Section 10.2). For each subject enrolled, the investigator will



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indicate in the source record(s) that the subject participated in the trial.

8.2. Case Report Forms

The primary data collection tool for the trial is a CRF designed specifically for the trial. For each subject enrolled in the trial, a CRF was completed by the trial coordinator and signed by the investigator or his/her designate.

The investigator was responsible for ensuring the accuracy of all data entered in the CRFs. All CRFs are to be completed in a timely manner.

Errors occurring in the CRFs were queried. Queries raised by data reviewers must be addressed by site personnel.

On request, the investigator should provide the SPONSOR/CRO with additional data relating to the trial, or copies of relevant source records, duly anonymized (i.e., subject's name is redacted).

8.3. Retention of Documents

The investigator should take responsibility for maintaining adequate and accurate source documents of all observations and data generated during this trial, including any data clarification forms received from the SPONSOR/CRO or designee. Such documentation is subject to inspection by the sponsor or its agents, the FDA and/or other regulatory agencies. The investigator is responsible for retention of essential documents including the Investigator Trial File until SPONSOR/CRO informs the investigator that the documents are no longer to be retained or longer if required by local regulations.



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9. QUALITY CONTROL AND QUALITY ASSURANCE

9.1. Direct Access to Source Documents

As specified in the investigator's agreement, the investigator agrees to allow trial-related monitoring, audit(s), IEC review(s) and regulatory inspection(s), with direct access to all the required source records, and to allocate his/her time and the time of his/her staff to the auditor/inspect or to discuss findings and any issues.

9.2. Monitoring Procedures

The Clinical Trial Monitor has contacted and/or visited the investigator site periodically to verify the adherence to the protocol, the maintenance of trial-related source records, and the completeness and accuracy of all CRF entries compared to source data. The investigator has cooperated with the trial monitor to ensure that any discrepancies that may be identified are resolved. The data has to be preserved for a period of 3 years for all datasets, and 10 years as records archival.

9.3. Audit and Inspection

The investigator has made all the trial-related source data and records available to a quality assurance auditor mandated by the sponsor, or to domestic or foreign regulatory inspectors, after reasonable notice. The main purposes of an audit or inspection are to confirm that the rights and well-being of the subjects have been adequately protected, and that all data relevant for the evaluation of the IP have been processed and reported in compliance with GCP/ICH and applicable regulatory requirements.

The investigator has to notify the SPONSOR/CRO or designee immediately of any inspection by regulatory authorities.



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10. ETHICS

10.1. Ethical Conduct of the Trial

This trial must be carried out in compliance with the protocol and the applicable laws and regulatory requirements of the appropriate regulatory agency. The trial must be conducted in accordance with the ethical principles originating from the Declaration of Helsinki and amendments and the ICH-GCP guidelines.

10.2. Institutional Ethics Committee (IEC)

This protocol, the proposed informed consent form, and other information for subjects must be reviewed and approved by an IEC, before the start of the trial, in compliance with local regulations. This committee must also approve any amendments to the protocol, other than administrative ones, before initiation of the amendment procedures. This protocol was approved dated 02 Jul 2025 by ARMHRC Institutional Ethics Committee.

10.3. Subject Information and Consent

Before participation in the trial, each subject or guardian is required to provide written consent to participate in the trial. No trial-specific procedures should be performed before a subject's informed consent is obtained.

10.4. Disclosure and Confidentiality:

By signing the protocol, the investigator agrees to keep all information provided by the sponsor in confidence and to request similar confidentiality from his/her staff and the or IEC. Trial documents provided by the trial sponsor (i.e., protocols, Investigators' Brochures, CRFs and other material) should be stored appropriately to ensure their



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confidentiality. The information provided by the sponsor to the investigator may not be disclosed to others without direct written authorization from the sponsor, except to the extent necessary to obtain informed consent from subjects who wish to participate in the trial.

Privacy of Individual Health Information

The investigator should undertake to protect the privacy of all individually identifiable health information except as specifically authorized by each individual subject through the written informed consent. The Informed Consent document should include a request of the subject's consent to release the collected data for research purposes in such a way that the individual's identity remains masked. While all data records should be identified by the corresponding subject number, the identity of the subject will be held in confidential source documents at the trial site. All trial personnel with access to this information are legally bound not to disclose such information.

11. EMERGENCY PROCEDURES

11.1. Reporting of Serious Adverse Events and Pregnancies

Contact Person(s) and Number (s)

SAEs and pregnancies must be reported immediately (i.e., not later than 24 hours after first knowledge). The SAE or pregnancy report should be e-mailed or texted to IEC and Sponsor using the following e-mail or fax-number:

Name: Sumit Kubal

Email: sumit.kubal@teampureplay.com

11.2. Reporting Procedures Serious Adverse Events

For each SAE, the investigator should complete a Serious Adverse Event Report Form and assess the relationship of each SAE to trial treatment. The completed form(s) should be sent electronically to the UBC using the SAE Reporting fax number within 24 hours of first knowledge of the SAE.



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Follow-up reports regarding the status of the SAE and the subject's subsequent course should be submitted until the SAE has subsided, the condition stabilized (in the case of persistent impairment), the subject receives alternative therapy, or the subject dies. The form and fax confirmation should be retained. Contacts for reporting SAEs, pregnancies and other safety concerns are provided to each site.

12. INSURANCE

SPONSOR/CRO has taken out appropriate insurance policies covering the subjects in the clinical trial in accordance with applicable laws and regulations.

13. PUBLICATIONPOLICY

All publications (e.g., manuscripts, abstracts, oral/slide presentations, book chapters) based on this trial must be submitted to SPONSOR/CRO for review, as specified in the Clinical Trial Agreement between the institution, investigator, and SPONSOR/CRO or its designee.



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14. RESULTS

Subject disposition:

Out of 10 subjects screened, none were found screen failures, none were dropouts. 10 subjects who underwent the testing process.

Table3: Subject disposition details

S. No	Variable	Number of subjects
1.	No. of subjects screened for study	10
2.	No. of subject's screen failure	0
3.	No. of subjects enrolled in the study	10
4.	Number of subjects completed the Study	10

Table4: Study dates/schedules:

S. No	Schedule	Dates
1.	First subject ICF date	15 July 2025
2.	Last subject ICF date	28 July 2025
3.	First subject screening date	15 July 2025
4.	Last subject screening start date	28 July 2025
5.	Date of first subject completed study	17 July 2025
6.	Date of Last subject completed study	30 July 2025



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14.1. Subjects disposition chart

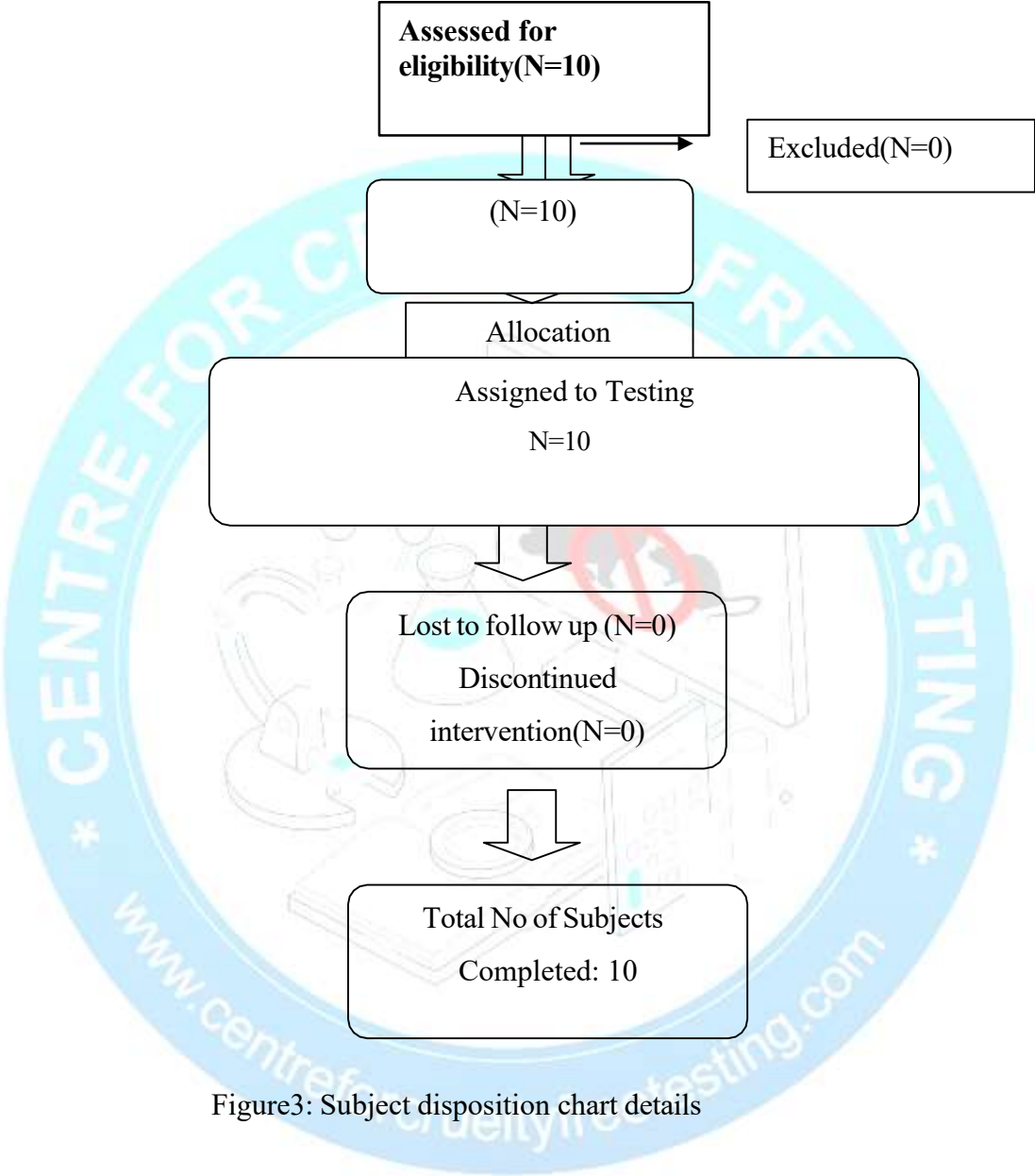


Figure3: Subject disposition chart details



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14.2. Demographic and Other Baseline Characteristics

The mean age of the subjects was 30 years. The mean height of the subjects was 163 cm. The mean weights of the subjects were 65 kg.

Table5: Demographic characteristics

S.No.	Demographics	Variable	(N=10)
1.	Diastolic blood pressure	Mean	120.00
2.	Systolic blood pressure	Mean	81.00
3.	Age	Mean	30
4.	Height	Mean	163
5.	Weight	Mean	65



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14.3. SPF Evaluation Results:

MED Estimations & Calculation.

SUBJECTID	MED(u) (mJ/cm ²)	MED(i) (mJ/cm ²)	SPF(i)
PL01	80.00	4561.39	57.02
PL02	101.25	5701.74	56.31
PL03	80.00	4054.57	50.68
PL04	80.00	4054.57	50.68
PL05	80.00	4561.39	57.02
PL06	80.00	4054.57	50.68
PL07	113.91	6081.86	53.39
PL08	101.25	5701.74	56.31
PL09	80.00	4054.57	50.68
PL10	80.00	4561.39	57.02

Where SPF is calculated as a ratio (factor) of MED(i) Protected and MED(u) Unprotected:
 $SPF(i) = MED(i)/MED(u)$, and MED means Minimal Erythema Dose

SPF VALUE	
MAX	57.017
MIN	50.682
MEAN	53.980
STD. DEV	6.335

Average SPF = Mean (SPF(i))
i.e., Average SPF= 53.98

14.4. 1 day follow-up for delayed Erythema Response:

SUBJECT ID	Erythema Score (0-4)
PL01	2
PL02	1
PL03	1
PL04	1
PL05	2
PL06	1
PL07	1
PL08	1
PL09	1
PL10	1

Erythema 5 Point Scale [0-4]	SCORE
Score for Erythema	
No Reaction	0
Very Slight Erythema	1
Slight Erythema	2
Moderate Erythema	3
Severe Erythema	4



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14.5. Adverse events:

The adverse events reported was none during the treatment.

14.6. Discussion:

Out of 10 subjects screened, none were found screen failures, none were dropouts. 10 subjects underwent the Trial.

The mean age of the subjects was 30 years. The mean height of the subjects was 163 cm. The mean weights of the subjects were 65 kg. Data from all 10 subjects who completed the study were analyzed.

The Primary End Point is to determine the SPF was calculated as taking iMED score of each application area. The mean SPF score was **53.98**

The mean erythma response was 1.2 on the follow up day

There were no protocol violations and deviations reported. There was no subject who withdrawn the consent.

14.7. Conclusion:

In conclusion, The Plum Rice Water & 2% Niacinamide Hybrid Sunscreen was found with the SPF as 53.98



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2. *International Standard ISO 24444 (2019) Second Edition -Cosmetics – Sun Protection Test method- in-vivo determination of Sun Protection Factor (SPF)*

