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Hivefy Lifestyle Pvt Ltd

CLINICAL RESEARCH ORGANIZATION

MITTAL GLOBAL CLINICAL TRIAL SERVICES (MGCTS)

CCFT/CT/2024/338

**Study “A Clinical Study to Evaluation Of Skin Irritation Potential of
Hivefy Rosemary Essential Oil On Healthy Human Volunteers.”**



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Clinical Study Report

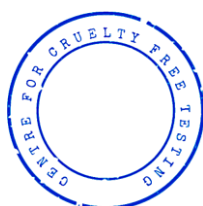
Title Page

Study Title: “A Clinical Study to Evaluation of Skin Irritation Potential of Hivify Rosemary Essential Oil on Healthy Human Volunteers.”

Protocol No.	CCFT338
Version Number and Date	1.0 dated 11 Sep 2024
Investigational Product	Rosemary Essential Oil
Name& Address of Sponsor	Hivify Lifestyle Pvt Ltd, Surat Gujarat-394105
Name & Affiliation of the Investigator (s)	Name: Dr. Robin Chugh (MD- Dermatology) Designation: Principal Investigator
Date of First subject in the study	1 Oct 2024
Date of Last subject follow up	08 Oct 2024
No. of subjects	24
Report Number	CCFT/CT/2024/338
Date of the draft report	08 Oct 2024
Revision Date	08 Oct 2024

Confidential

The information in this document is confidential and is to be used only in connection with matters authorized by Hivify Lifestyle Pvt Ltd and no part of it is to be disclosed to the others without prior written permission from Hivify Lifestyle Pvt Ltd. This study was performed in accordance with ICH E6 R2, Schedule-Y (2017) and Ethical Principles as per the Declaration of Helsinki (2013) including archiving of all the essential documents.

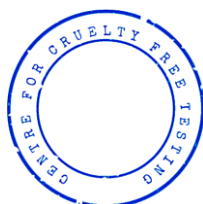


INVESTIGATOR(S) SIGNATURE(S)

“A Clinical Study to evaluate the skin irritation potential of Hivify Rosemary Essential Oil on healthy human subjects.”

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	 08 Oct 2024 SIGNATURE & DATE
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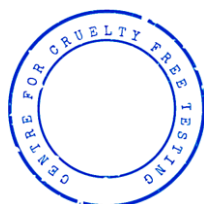


STATEMENT OF COMPLAINE

“A Clinical Study to evaluate the skin irritation potential of Hivify Rosemary Essential Oil on healthy human subjects.”

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 (DDMM YYYY)
PUNEET MITTAL	Director-Clinical Research, MGCTS, Mittal Building 121-B, Mansarovar Ind Estate, Panchli, Baghpat Road, Meerut-250002, India		08 Oct 2024



STATEMENT OF COMPLAINE
(DATA SAFETY MONITORING BOARD)

“A Clinical Study to evaluate the skin irritation potential of Hivefy Rosemary Essential Oil on healthy human subjects.”

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 (DD MMM YYYY)
1	Ms. Anshika, Data Manager CCFT Laboratories, Meerut		08 Oct 2024
2	Ms. Sheetal, Data Manager CCFT Laboratories, Meerut		08 Oct 2024



REPORT SUMMARY:

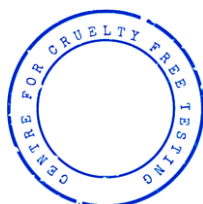
Title of the Study	“A Clinical Study to evaluate the skin irritation potential of Hivefy Rosemary Essential Oil on healthy human subjects.”
Rationale of Investigational product	Rosemary Essential Oil
Name of Sponsor	Hivefy Lifestyle Pvt Ltd
SITE	CCFT Laboratories, Skin & Hair Testing Zone, First Floor, AR Multispecialty Hospital & Research Centre 135, Panjabipura, Delhi Road, Opp. Ramleela Ground, Meerut-250002, U.P, India
Investigator (s)	Dr Robin Chugh
Study Objective	<u>Primary objective:</u> To evaluate the irritation potential of Hivefy Rosemary Essential Oil on healthy human subjects by Single application (Open) patch test method. (Primary Irritation Patch Test).
Study Phase	NA
Study Design	Each trial participant will be assigned to a regimen of investigational products and advised to take general precautions as needed. Patients will be assigned to an investigational product for 24 Hours, Starting on day 1 st , followed by 2 nd day. A follow up visit would be done after 1 week of patch removal.
Number of subjects	24
Subject disposition	Single Arm Study- all subjects would be assigned to patches with all Products.
Study Inclusion Criteria	Subjects were included based on the following criteria. 1. Voluntary Man/Women between 18 and 65 years. 2. Photo type III to V.



	3. Having apparently healthy skin on test area. 4. For whom the investigator considers that the compliance will be correct. 5. Cooperating, informed of the need and duration of the examinations and ready to comply with protocol procedures. 6. Having signed a Consent Form. 7. Willingness to avoid intense UV exposure on test site (sun or artificial UV), during the course of the study. 8. Willingness to avoid excessive water contact (for example swimming) or activity which causes excessive sweating (that is exercise, sauna), during the course of the study. 9. Should be able to read and write (in English, Hindi or local language). 10. Having valid proof of identity and age.
Study Exclusion Criteria	Subjects were excluded based on the following criteria 1. Pregnant/nursing mothers. 2. Scars, excessive terminal hair or tattoo on the studied area. 3. Henna tattoo anywhere on the body (in case of studies involving hair dyes). 4. Dermatological infection/pathology on the level of studied area. 5. Hypersensitivity, allergy antecedent (to any cosmetic product, raw material or hair dye). 6. Any clinically significant systemic or cutaneous disease, which may interfere with study treatment or procedures. 7. Chronic illness which may influence the outcome of the study. 8. Subjects on any medical treatment either systemic or topical which may interfere with the performance of the study treatment (presently or in the past 1 month). 9. Subject in an exclusion period or participating in another food, cosmetic or therapeutic trial.



Test Product/ Study Product	Rosemary Essential Oil
Study Methodology	8 Days [3 days and T8 (T+1 week after 0 hour of patch removal) visit was scheduled to monitor follow up reactions]. Screening & T0 (before batch application) T1 (0 hour after the patch removal) T2 (24 hours after the patch removal) T8 (T+1 week after of patch removal)
Clinical assessment	Erythema & Oedema Scoring on 5-point Severity Scale [0-4], where 0 is no irritation & 4 being the highest. Scoring to be taken at below time points. T2 (24 hours after the patch removal) T8 (T+1 week after of patch removal)
Primary Outcome	Change in Skin Irritation Score- erythema and oedema.
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. Assessment would be done on Erythema & Oedema data received from CRF for visit T2 and T3.
Ethical Conduct of the study	The study was initiated after written approval from the hospital's 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 24 subjects screened, none were found screen failures, none were dropouts. 24 subjects underwent the Trial. The mean age of the subjects was 32 years. The mean height of the



	Subjects was 159m. The mean weights of the subjects were 68.5 kg. Data from all 24 subjects who completed the study were analyzed. The primary end point change in the Erythema & Oedema Score was calculated as total irritation score was measured at 24 hours after the patch removal. Patch 1 product- Rosemary Essential Oil showed/was found non-Irritant to the skin. Patch 2 product (Negative Control) - 0.9% Isotonic Saline Solution showed/was found non-Irritant to the skin. Patch 3 product (Positive Control) - 1% Sodium Lauryl Sulphate showed/was found Irritant to the skin. There were no subjects lost to follow up. There was no subject who withdrawn the consent.
Conclusion	In conclusion, Rosemary Essential Oil was tested dermatologically as per BIS standard IS4011:2018 by the Dermatologist and was found non-irritant with 24-hour Primary Irritation Open Patch Test.
Date of Report	08 Oct 2024

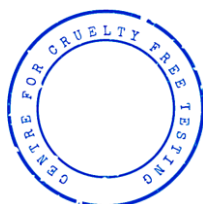
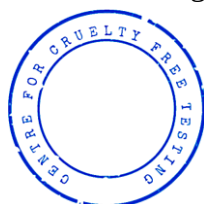


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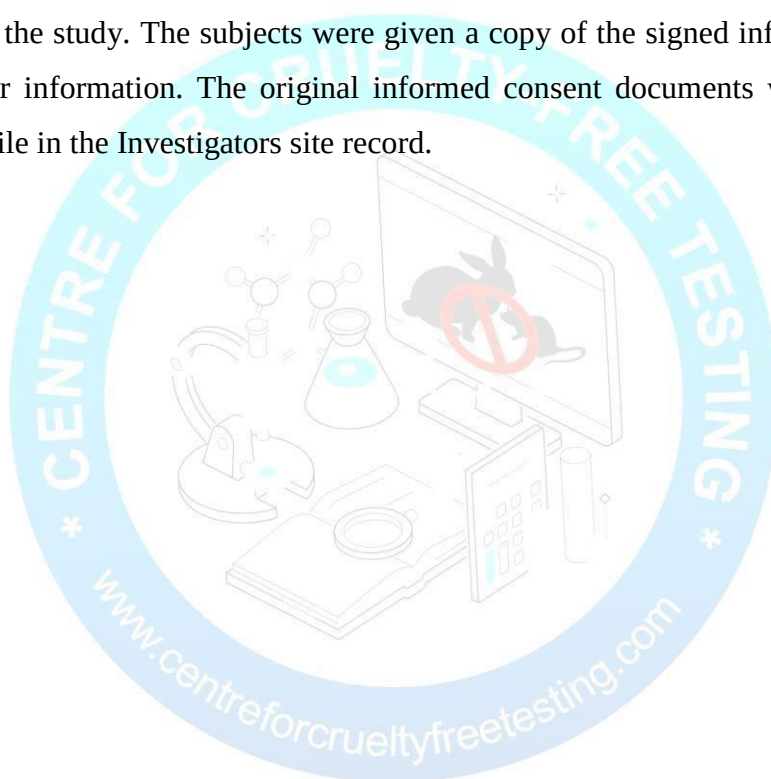
List of Abbreviations

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
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



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.



Investigators and Study Administrative Structure

Sponsor	Hivefy Lifestyle Pvt Ltd
Principal Investigator (S)	Dr. Robin Chugh
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



1. INTRODUCTION

Background

An essential oil is a concentrated hydrophobic liquid containing volatile (easily evaporated at normal temperatures) chemical compounds from plants. Essential oils are also known as volatile oils, ethereal oils, aetheroleum, or simply as the oil of the plant from which they were extracted, such as oil of clove.

Essential oils are generally extracted by distillation, often by using steam.

They are used in perfumes, cosmetics, soaps, air fresheners and other products and for adding scents to incense and household cleaning products.

Rationale of the Trial

Rosemary Essential Oil

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.

2. TRIAL OBJECTIVES AND PURPOSE

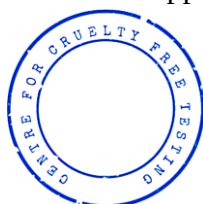
Primary objective

To evaluate the skin irritation potential of Hivify Rosemary Essential Oil on healthy human subject's application patch test method. (Primary irritation patch test)

3. TRIAL DESIGN

Overall Trial Design

Evaluate the irritation potential of Hivify Rosemary Essential Oil on healthy human subjects by Single application patch test method. (Primary irritation patch test). The evaluation of the product to be tested was carried out versus a positive control: 1% (w/w) SLS, and versus a negative control: 0.9% isotonic solution. The trial subjects will be enrolled at one investigative site in India with approximately 24 patients who meet the



trial inclusion criteria and will be given the investigational product. The maximum trial duration for each subject will be about 8 days after being provided with the written informed consent; then, the issue will undergo screening procedures. At the end of the screening period, the eligible subjects will be included in the trial, and the ineligible will be excluded from the problem.

Methodology of patch application

- The procedure for the open patch is mentioned in the Patch Application Section above. The sample is used as an open patch, however the positive and negative controls are in finn chambered closed patches. (Together termed as the Patch)
- The patch application was carried out at T0 by the CRC.
- Wash hands with disinfectant.
- Began application of the strip from the bottom, pressing the rooms up to release the air.
- When the tape is fully in place, gently press each patch containing a test product or control, to ensure an even distribution of the substance.
- Apply the pressure to the tape and especially its edges to ensure good fixation. The person being tested should avoid sudden movements.

During the treatment period, subjects will return to the trial site according to the trial schedule to assess compliance with the treatment regimen, concomitant medications, and adverse events (AEs).

During the treatment period, the investigator will assess the severity using the patch, and the subjects will be asked to fill the form before the screening of the trial. All the safety assessments will be done during the treatment period.

Table: Trial Design

T0= (before patch application)	Patch application
T1 day= (0 hr after patch removal)	Patch removal
T2 day= (24 hr after patch removal)	Patch reading by the Dermatologist
T8* = (T+1 week after 0 hr of patch removal)	Checking of the evaluation of the positive cases



Trial Endpoints

Primary Endpoint

Change in Skin Irritation Score- erythema and oedema.

Safety Endpoints

Safety endpoints include the following:

- Assessment and reporting of the Adverse Events.
- Tolerability of Test product.

4. SELECTION OF TRIAL POPULATION

Subject Population

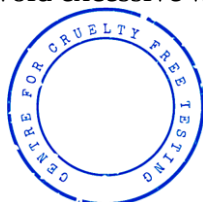
24 subjects will be enrolled to provide about 24 completed subjects evaluable for the primary analysis. An individual subject will be allowed to participate in the trial once.

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.

Inclusion Criteria

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

1. Voluntary man/women between 18 and 65 years.
2. Photo type III to V.
3. Having apparently healthy skin on test area
4. For whom the investigator considers that the compliance will be correct.
5. Cooperating, informed of the need and duration of the examinations and ready to comply with protocol procedures.
6. Having signed a Consent Form.
7. Willingness to avoid intense UV exposure on test site (sun or artificial UV), during the course of the study.
8. Willingness to avoid excessive water contact (for example swimming) or activity which



causes excessive sweating (that is exercise, sauna...), during the course of the study.

9. Should be able to read and write (in English, Hindi or local language).

10. Having valid proof of identity and age

Exclusion Criteria.

1. Pregnant/nursing mothers
2. Scars, excessive terminal hair or tattoo on the studied area.
3. Henna tattoo anywhere on the body (in case of studies involving hair dyes).
4. Dermatological infection/pathology on the level of studied area.
5. Hypersensitivity, allergy antecedent (to any cosmetic product, raw material or hair dye).
6. Any clinically significant systemic or cutaneous disease, which may interfere with study treatment or procedures.
7. Chronic illness which may influence the outcome of the study.

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 (Section 9.2).



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.

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.

5. TRIAL TREATMENTS

5.1. Investigational Product

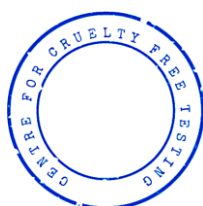
Rosemary Essential Oil

Comparator Product

1. Negative Control (0.9% Isotonic Saline Solution)
2. Positive Control (1% Sodium Lauryl Sulphate)

Testing Regimen

- The procedure for the open patch is mentioned in the Patch Application Section above. The sample is used as an open patch, however the positive and negative controls are in finn chambered closed patches. (Together termed as the Patch)
- The patch application was carried out at T0 by the CRC.
- Wash hands with disinfectant.
- Began application of the strip from the bottom, pressing the rooms up to release the air.
- When the tape is fully in place, gently press each patch containing a test product or control, to ensure an even distribution of the substance.
- Apply the pressure to the tape and especially its edges to ensure good fixation. The person being tested should avoid sudden movements.



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.

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 store them securely at the site under the investigator's control. For all the products, the room temperature was ideal.

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 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.



i. 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.

ii. Rescue Medication

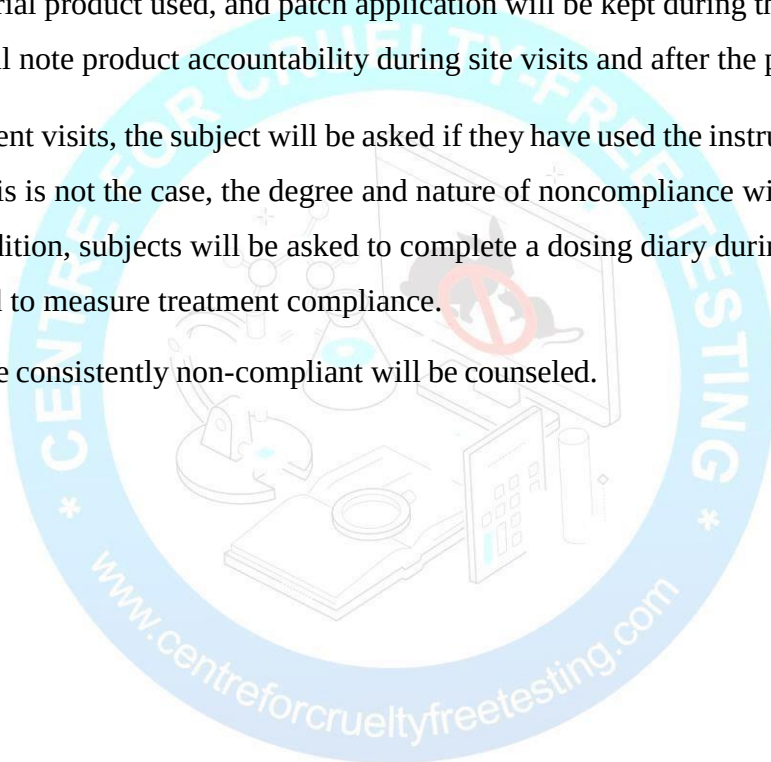
In case of severe irritation, a Dermatologist together would decide what best rescue medicine is suitable for the subject.

Treatment Compliance

Records of the trial product used, and patch application 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 noncompliance 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.



6. VISIT SCHEDULE AND ASSESSMENTS

Trial Procedures

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

Table1-1: Visit Schedule and Assessments

	Screening	Visit 0 (before patch application) Patch Application day	Visit 1 (0 hour after the patch removal) Patch Removal Day	Visit 2(24 hours after patch removal)	Visit 3: 8 Days (T+1 week after 0 hour of patch removal)
Registration	X				
Protocol Briefing	X				
Informed Consent Form	X				
Inclusion and Non- Inclusion criteria	X	X			
History Questionnaire	X				
Routine Check up	X				
Clinical observation	X				
Site identification		X			
Proscriptions and Restrictions			X	X	X
Concomitant Medication		X	X	X	X
Patch Application		X			
Patch Removal			X		
Dermatological Evaluation reading of Patch Test				X	X
AE/SAE Monitoring		X	X	X	X
					End of study

SAE = Serious adverse event; AE = adverse event.

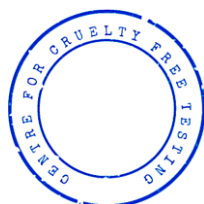
Trial Visits and Assessments

i. Visit 0/Screening & Baseline (Day 0)

- Review trial information with the subject and obtain written informed consent.
- Review inclusion and exclusion criteria with the subject to determine the subject's eligibility.
- Collect Physical examination, demographics, and medical history of the subject.
- Review and record prior treatment (used within the previous 30 days) and concomitant medication (medications currently used).
- Review and record any current medical diagnoses.
- Perform the following: (As mentioned in the Section 6.3: Patch Assessment)
- Wash hands with disinfectant
- Began application of the strip from the bottom, pressing the rooms up to release the air.
- When the tape is fully in place, gently press each patch containing a test product or control, to ensure an even distribution of the substance.
- Apply the pressure to the tape and especially its edges to ensure good fixation. The person being tested should avoid sudden movements.
- Strengthen the application of patches by applying the micro pore tape on all the four sides of patch.
- Dispense the IP and diary. Provide instructions to the subject on the IP application.
- Schedule the next visit after 24 hours the same time of day as the current visit.

ii. Visit 1 (Day 1)

Patch removal after 24 hours from the 1st visit and record the vital information. The CRC removes the patch from the bottom to the top. The area is gently wipe off with a soft tissue paper.



iii. Visit 2/ (Day2)

- On Day 2, the skin reaction was assessed under a constant artificial daylight source.
- The Dermatologist scored the reactions namely erythema (including, dryness, scaliness and wrinkles) on a 0-4 point scale and oedema on another 0-4 point scale as per Draize scale as per IS 4011:2018 methods of test for safety evaluation of cosmetics – 3rd revision)
- Review any concomitant medication used since the previous trial visit.
- Perform a physical examination, including weight without shoes and measuring vital signs (systolic and diastolic blood pressure and heart rate).
- Record any AEs.

iv. Visit 3(Day 8)

- At day 8th the subject is asked for any skin irritation at the application site and records the needful data.
- Release subject from the trial.

v. Early Termination

- The issue is considered a dropout if a subject withdraws from the trial before the Visit 3 (End of Treatment) visit. All End of Treatment procedures should be performed.
- Review any concomitant medication used since the previous trial visit.
- Perform a physical examination, including weight without shoes and measuring vital signs (systolic and diastolic blood pressure and heart rate).
- Perform a UPT for females of childbearing potential. Ensure that female subjects of potential childbearing use approved method(s) of contraception methods.
- Record any AEs.



- Collect any remaining trial materials from the subject.
- Release subject from the trial.

Patch Assessment

Patch Preparation

The patches were prepared in the morning of the application one hour before the visit i.e. at T0.

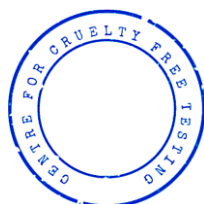
Products	Patch no (Finn chamber)	Application frequency	Application duration
Rosemary Essential Oil	1 (no Finn chamber)	Once	24 hours
Negative Control (0.9% Isotonic Saline Solution)	2	Once	24 hours
Positive Control (1% Sodium Lauryl Sulphate)	3	Once	24 hours

Patch Application

1. Approx 0.04ml (40microliter) of test sample was measured with the help of micropipette.
2. 0.04ml or 40 microliter of the test sample was transferred on previously numbered area. (Open Patch)
3. The Finn chambers with the negative and positive controls loaded filter paper disc were taped onto the back of the subjects.

The patch application was carried out by the CRC.

- The Dermatologist determined and the site that poses to be the most appropriate based on moles, body hair, freckles of the selected area was sound, without excessive hair growth.
- Location of patch application: between scapula and waist.
- The application of the patches was made as follows by the CRC:



- Hands were washed with disinfectant.
- The finn chambers/patches were applied.
- Then the tape was fully in place, each patch was gently pressed containing a test product or control, to ensure an even distribution of the substance.
- Pressure was applied to the tape and especially its edges to ensure good fixation. The person being tested avoided sudden movements.
- The applications of patches were strengthened by applying micro tape on all four sides of patch.

Study Procedures

Principle:

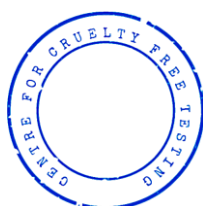
The patch test under occlusion is a method used to check safety in terms of irritation potential of any cosmetic or cosmeceutical formulation which is to be applied topically on healthy human subjects.

Irritants are the substance that may damage the skin. The damage will depend upon the nature, concentration and duration of exposure. Irritation is manifested as inflammatory responses such as erythema (redness) and oedema (swelling) vesiculation and finally to an intense suppurate reaction without the involvement of immune system.

The evaluation of the different products to be tested was carried out versus a negative control: 0.9% isotonic solution and versus positive control: 1%(w/w) SLS.

The kinetic of the evaluation was as follows:

T0= (before patch application)	Patch application
T1 day= (0 hr after patch removal)	Patch removal
T2 day= (24 hr after patch removal)	Patch reading by the Dermatologist
T8* = (T+1 week after 0 hr of patch removal)	Checking of the evaluation of the positive Cases



Methodology of patch application

- The procedure for the open patch is mentioned in the Patch Application Section above. The sample is used as an open patch, however the positive and negative controls are in Finn chambered closed patches. (Together termed as the Patch)
- The patch application was carried out at T0 by the CRC
- Wash hands with disinfectant
- Began application of the strip from the bottom, pressing the rooms up to release the air.
- When the tape is fully in place, gently press each patch containing a test product or control, to ensure an even distribution of the substance.
- Apply the pressure to the tape and especially its edges to ensure good fixation. The person being tested should avoid sudden movements.
- Strengthen the application of patches by applying the micro pore tape on all the four sides of patch.



STUDIED AREA AND LOCATION

The patches were applied on the on applied the top of the back of the shoulder blade.

The Dermatologist determined the best area to apply the patch, depending on the naevi, the porosity and the freckles. The selected area was the healthy, without an excessive pilosity. Patches were not applied on a back.

The patches were applied on the right or left part of the back: the side was mentioned in the CRF by the investigator(s).

Position of the subject

It was recommended that the subject sat with the back slightly bent forward.

Methodology of the patch removal

The CRA removes the patch from the bottom to the top. The area is gently wipe off with a soft tissue paper.

Methodology of patch reading by the Investigator(s)

The skin reaction was assessed under a constant artificial daylight source.

The Investigator(s) scored the reactions namely erythema (including, dryness, scaliness and wrinkles) on a point scale and oedema on another 0-4 point scale as per Draize scale (clause observation and scoring for skin irritation test, Draize scale for scoring the treatment sites – IS 4011:2018 methods of test for safety evaluation of cosmetics – 3rd revision)

Score of erythema /dryness/wrinkles	Reaction	Score of oedema	Reaction
0	No reaction	0	No reaction
1	Very slight erythema / dryness with shinny appearance	1	Very slight oedema
2	Slight erythema /dryness/wrinkles	2	Slight oedema
3	Moderate erythema /dryness /wrinkles	3	Moderate oedema
4	Severe erythema / wrinkles and scales	4	Severe oedema



Investigator Assessment

The investigator assessments must be performed by a Dermatologist with at least one year of experience. For Physician 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.

Erythema Scoring

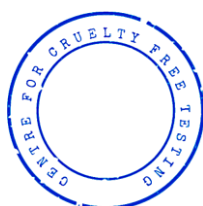
After the 24 hours of Patch removal, and on day 8, the Erythema Assessment was done with a Dermatologist as below Scoring table.

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

vi. Oedema Scoring

After the 24 hours of Patch removal, and on day 8, the Oedema Assessment was done with a Physician as below Scoring table.

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



Adverse Events

Adverse Events Assessment

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 administration, start and stop dates, seriousness, severity, action taken, and outcome.

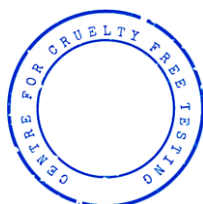
Any AE meeting the stringent criteria must be reported on the CRF and a separate SAEs report form. SAEs must be reported to the Ethics Committee within 24 hours of awareness.

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 a sequel, 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 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 designer. An AE is considered “unexpected” if its nature or severity is not consistent with information 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 specifically mentioned as occurring with the particular drug under investigation.

Pregnancy

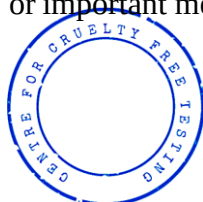
Any pregnancy occurring from date of the Informed Consent signature until study completion must be reported immediately to the Sponsor or designee as soon as it becomes known to the investigator and not later than within 24 hours of his/her knowledge of the occurrence of the pregnancy

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

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 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). The report should be submitted within the same timelines as an SAE (within 24 hours of knowledge), although a pregnancy per se is not considered an SAE.

7. STATISTICAL METHODS AND ANALYTICAL PLANS

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

Data Sets Analyzed

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

Demographic and Baseline Characteristics

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

Sample Size

The sample size for this protocol is 24. The eligible patients will be assigned to study treatment. A total of 24 subjects were enrolled, out of which none dropouts have been considered. The design tab used to achieve this sample size is:

Power (Probability of Rejecting $P \leq P_0$ when $P \geq P_1$): 0.9

Alpha (Probability of Rejecting $P \leq P_0$ when $P \leq P_0$): 0.01

P_0 (Maximum Response Rate of a Poor Treatment): 0.05

P_1 (Minimum Response Rate of a Good Treatment): 0.25

CHANGES IN THE PLANNED TRIAL

a. 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.

b. Termination or Suspension of the Trial

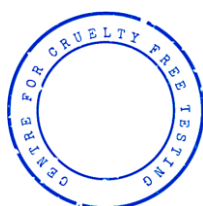
SPONSOR/CRO reserves the right to terminate or suspend the trial at any time. In case of premature termination or suspension of the trial, the contract research organization (CRO) project manager has to promptly inform the investigators, regulatory authorities, and the sponsor about the premature termination 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

Recording of Data

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

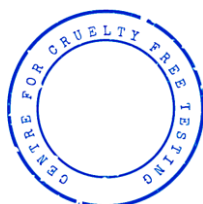
Case Report Forms

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).



8.2.1. 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.

9. QUALITY CONTROL AND QUALITY ASSURANCE

Direct Access to Source Documents

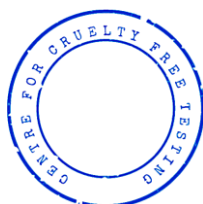
As specified in the investigator's agreement, the investigator agrees to allow trial-related monitoring, audit(s), IEC review(s) and regulatory inspection(s), with direct access to all the required source records, and to allocate his/her time and the time of his/her staff to the auditor/inspector to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

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.

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.

10. ETHICS

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.

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 13 Sep 2024 by ARMHRC Institutional Ethics Committee.

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.



Disclosure and Confidentiality

i. Confidentiality of Trial Documentation

By signing the protocol, the investigator agrees to keep all information provided by the sponsor in strict 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 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.

ii. 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

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: Deeksha Katiyar

Email: bdteam1@farelabs.com

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.

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.

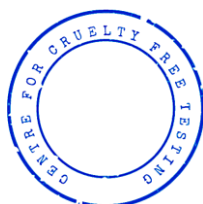
12. INSURANCE

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

13. PUBLICATION POLICY

The clinical trial information should be posted on www.ctri.nic.in or www.clinicaltrial.gov and in accordance with applicable regulations.

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.



14. Results

Subject disposition:

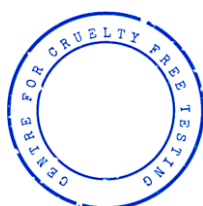
Out of 24 subjects screened, none were found screen failures, none were dropouts. 24 subjects who underwent the testing process.

Table3: Subject disposition details

S. No	Variable	Number of subjects
1.	No. of subjects screened for study	24
2.	No. of subject's screen failure	0
3.	No. of subjects enrolled in the study	24
4.	Number of subjects completed the Study	24

Table 4: Study dates/schedules:

S. No	Schedule	Dates
1.	First subject ICF date	01 Oct 2024
2.	Last subject ICF date	01 Oct 2024
3.	First subject screening date	01 Oct 2024
4.	Last subject screening start date	01 Oct 2024
5.	Date of first subject completed study	08 Oct 2024
6.	Date of Last subject completed study	08 Oct 2024



Subjects disposition chart

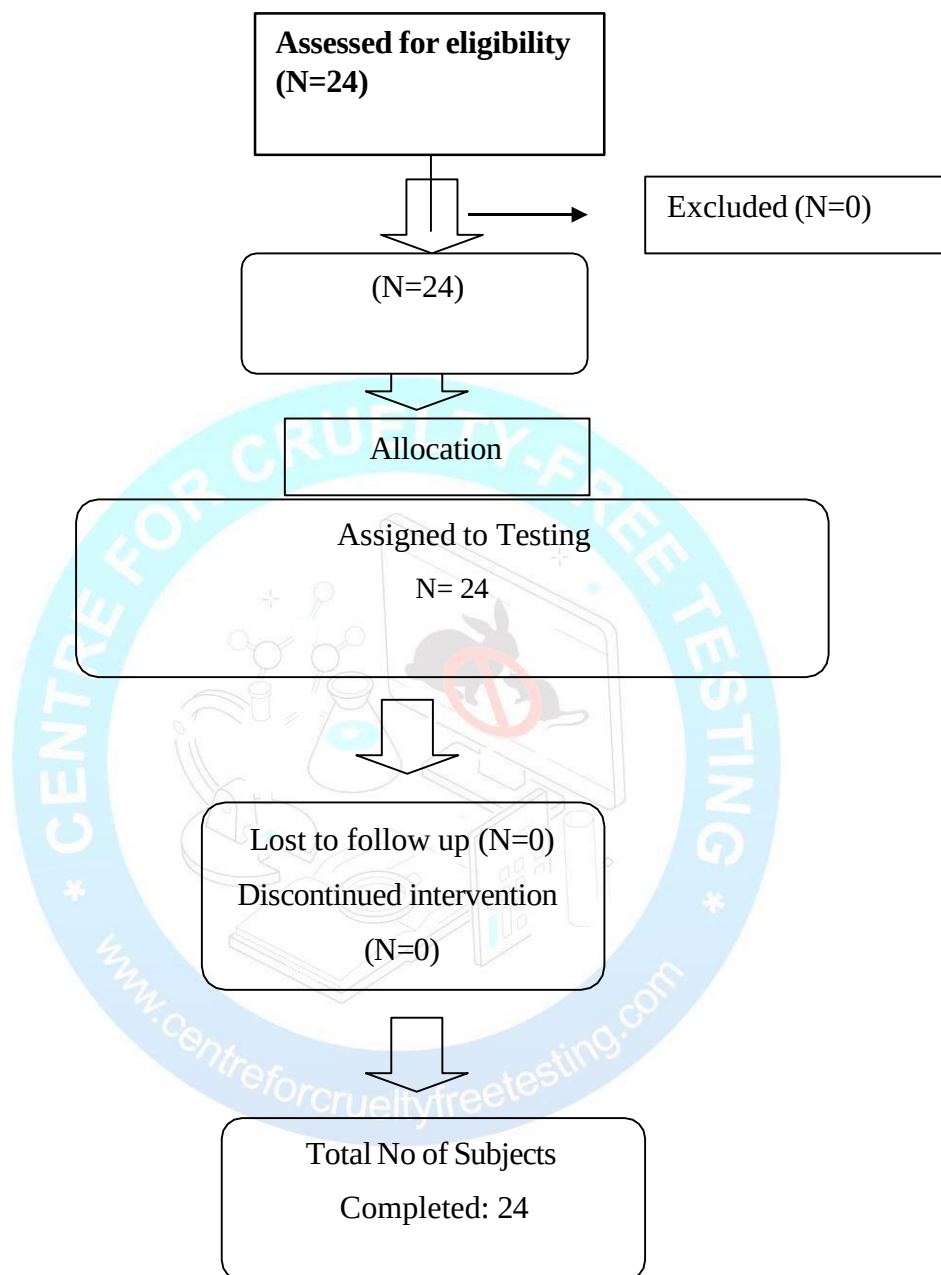


Figure 3: Subject disposition chart details

Demographic and Other Baseline Characteristics

The mean age of the subjects was 32 years. The mean height of the subjects was 159cm. The mean weights of the subjects were 68.5 kg.

Table5: Demographic characteristics

S. No.	Demographics	Variable	(N=24)
1.	Age	Mean	32
		Min	20
		Max	42
2.	Height	Mean	159
		Min	145
		Max	170
3.	Weight	Mean	68.5
		Min	48
		Max	88

Dermatology Evaluation Results:**Erythema Scoring (24 hours after Patch Removal):**

Project Number: CCFT338

Products Under Experiment

Patch 1 product- Rosemary Essential Oil

Patch 2 product (Negative Control)- 0.9% Isotonic Saline Solution

Patch 3 product (Positive Control)- 1% Sodium Lauryl Sulphate

Scoring Day 2: Erythema/ Dryness/ Wrinkle- 5 Point scale[0-4]* 24
Hours After Patch Removal

S.NO.	Subject ID	Patch 1	Patch 2	Patch 3
1	S01	0	0	2
2	AT02	0	0	1
3	AI03	0	0	2
4	VG04	0	0	2
5	NB05	0	0	1
6	S06	0	0	1
7	A07	0	0	2
8	S08	0	0	1
9	TC09	0	0	1
10	B10	0	0	2
11	M11	0	0	1
12	NG12	0	0	2
13	J13	0	0	1
14	M14	0	0	1
15	R15	0	0	1
16	K16	0	0	2
17	A17	0	0	2
18	CG18	0	0	1
19	S19	0	0	2
20	RT20	0	0	2
21	PM21	0	0	2
22	SI22	0	0	1
23	TP23	0	0	2
24	PP24	0	0	3
Total erythema score		0	0	38



Oedema Scoring (24 hours after Patch Removal):

Project Number: CCFT338

Products Under Experiment

Patch 1 product- Rosemary Essential Oil

Patch 2 product(Negative Control)- 0.9% Isotonic Saline Solution

Patch 3 product(Positive Control)- 1% Sodium Lauryl Sulphate

Scoring Day 2: Oedema- 5 Point scale[0-4]* 24 Hours After Patch Removal

S.NO.	Subject ID	Patch 1	Patch 2	Patch 3
1	S01	0	0	3
2	AT02	0	0	2
3	AI03	0	0	2
4	VG04	0	0	3
5	NB05	0	0	2
6	S06	0	0	1
7	A07	0	0	3
8	S08	0	0	2
9	TC09	0	0	3
10	B10	0	0	2
11	M11	0	0	2
12	NG12	0	0	3
13	J13	0	0	2
14	M14	0	0	1
15	R15	0	0	1
16	K16	0	0	3
17	A17	0	0	3
18	CG18	0	0	1
19	S19	0	0	2
20	RT20	0	0	3
21	PM21	0	0	3
22	SI22	0	0	2
23	TP23	0	0	3
24	PP24	0	0	3
Total Oedema score		0	0	55

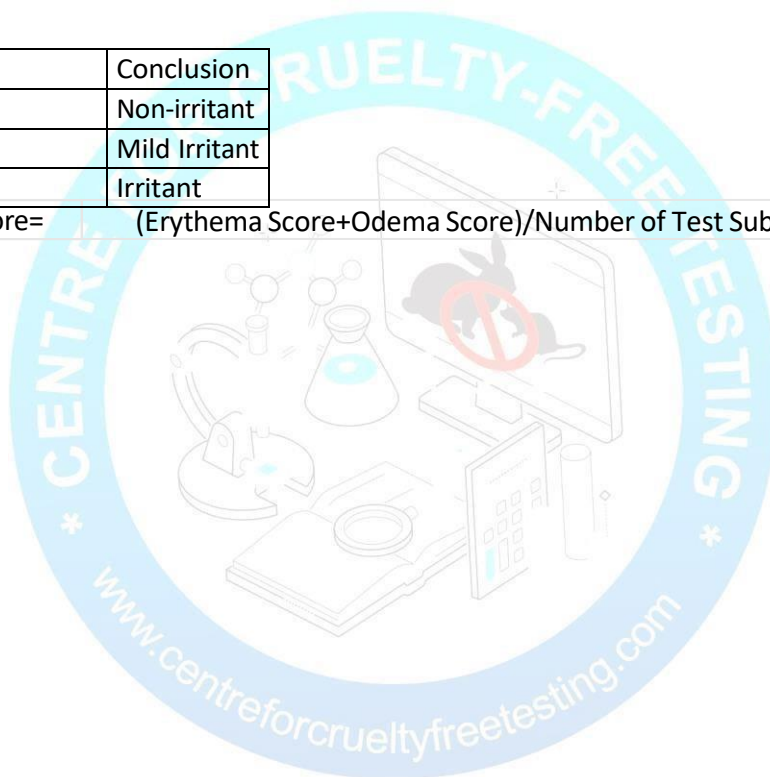


Overall Result:

Parameter- day 2 scores	Patch 1	Patch 2	Patch 3
Total Erythema Score	0	0	38
Total Oedema Score	0	0	55
Erythema + Oedema	0	0	93
Erythema + Oedema/24	0	0	3.875
Results/Conclusion	Non-irritant	Non-irritant	Mild Irritant

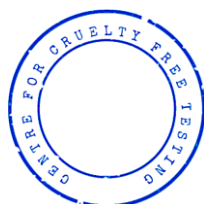
Mean Score	Conclusion
upto 2.0	Non-irritant
2.0 to 4.0	Mild Irritant
Above 4.0	Irritant

Mean Irritation Score= (Erythema Score+Oedema Score)/Number of Test Subjects



1 week follow-up irritation results (day 8):

Project Number:- CCFT338								
Products Under Experiment								
Patch 1 product- Rosemary Essential Oil								
Patch 2 product (Negative Control)- 0.9% Isotonic Saline Solution								
Patch 3 product (Positive Control)- 1% Sodium Lauryl Sulphate								
S. No.	Subject Id	TEST (E/O)	Patch 1		Patch 2		Patch 3	
			Day2	Day8	Day2	Day8	Day2	Day8
1	S01	E	0	0	0	0	2	0
		O	0	0	0	0	3	0
2	AT02	E	0	0	0	0	1	0
		O	0	0	0	0	2	0
3	AI03	E	0	0	0	0	2	0
		O	0	0	0	0	2	0
4	VG04	E	0	0	0	0	2	0
		O	0	0	0	0	3	0
5	NB05	E	0	0	0	0	1	0
		O	0	0	0	0	2	0
6	S06	E	0	0	0	0	1	0
		O	0	0	0	0	1	0
7	A07	E	0	0	0	0	2	0
		O	0	0	0	0	3	0
8	S08	E	0	0	0	0	1	0
		O	0	0	0	0	2	0
9	TC09	E	0	0	0	0	1	0
		O	0	0	0	0	3	0
10	B10	E	0	0	0	0	2	0
		O	0	0	0	0	2	0
11	M11	E	0	0	0	0	1	0
		O	0	0	0	0	2	0
12	NG12	E	0	0	0	0	2	0
		O	0	0	0	0	3	0
13	J13	E	0	0	0	0	1	0
		O	0	0	0	0	2	0
14	M14	E	0	0	0	0	1	0
		O	0	0	0	0	1	0
15	R15	E	0	0	0	0	1	0
		O	0	0	0	0	1	0
16	K16	E	0	0	0	0	2	0
		O	0	0	0	0	3	0
17	A17	E	0	0	0	0	2	0
		O	0	0	0	0	3	0
18	CG18	E	0	0	0	0	1	0
		O	0	0	0	0	1	0
19	S19	E	0	0	0	0	2	0
		O	0	0	0	0	2	0
20	RT20	E	0	0	0	0	2	0
		O	0	0	0	0	3	0
21	PM21	E	0	0	0	0	2	0
		O	0	0	0	0	3	0
22	SI22	E	0	0	0	0	1	0
		O	0	0	0	0	2	0
23	TP23	E	0	0	0	0	2	0
		O	0	0	0	0	3	0
24	PP24	E	0	0	0	0	3	0
		O	0	0	0	0	3	0



Adverse events:

The adverse events reported was none during the treatment.

Discussion:

Out of 24 subjects screened, none were found screen failures, none were dropouts. 24 subjects underwent the Trial.

The mean age of the subjects was 32 years. The mean height of the subjects was 159 cm. The mean weights of the subjects were 68.5 kg. Data from all 24 subjects who completed the study were analyzed.

The primary end point change in the Erythema & Oedema Score was calculated as total irritation score was measured at 24 hours after the patch removal.

Patch 1 product – Rosemary Essential Oil showed/was found non-Irritant to the skin.

Patch 2 product (Negative Control) - 0.9% Isotonic Saline Solution showed/was found non-Irritant to the skin.

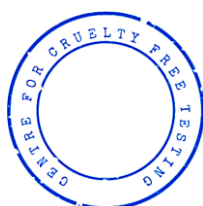
Patch 3 product (Positive Control) - 1% Sodium Lauryl Sulphate showed/was found Irritant to the skin.

There were no subjects lost to follow up.

There was no subject who withdrawn the consent.

Conclusion:

In conclusion, Rosemary Essential Oil was tested dermatologically as per BIS standard IS4011:2018 by the Dermatologist and was found non-irritant with 24-hour Primary Irritation Patch Test.



Reference List

1. IS 4011: 2018: Indian Standard- Methods of Test for Safety Evaluation of Cosmetics (Third Revision)

