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SPONSOR

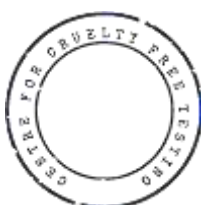
Era Botanics

CLINICAL RESEARCH ORGANIZATION

MITTAL GLOBAL CLINICAL TRIAL SERVICES (MGCTS)

CCFT1590

Study Title: “A Clinical Study to Evaluate the Safety and Efficacy of Era Botanics Acne Spot Corrector in the Reduction of Acne.”

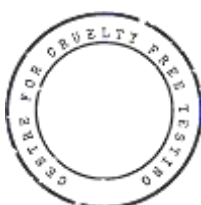


Clinical Study Report

Title Page

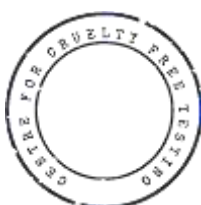
Study Title: “A Clinical Study to Evaluate the Safety and Efficacy of Era Botanics Acne Spot Corrector in the Reduction of Acne.”

Protocol No.	CCFT1590
Version Number and Date	1.0 dated 07 Apr 2026
Investigational Product	Acne Spot Corrector
Name & Address of Sponsor	Era Botanics Plot No. 5, Sector 2 Dwarka New Delhi 110075
Name & Affiliation of the Investigator (s)	Name: Dr. Robin Chugh Designation: Dermatologist Telephone: +91-7078103723 E-mail: robinder75@gmail.com
Date of First patient in the Study	13 April 2026
Date of Last patient follow up	20 April 2026
No. of patients	36
Report Number	CCFTCSR1590
Date of the draft report	21 April 2026
Date of Final Report	21 April 2026



Confidential

The information in this document is confidential and is to be used only in connection with matters authorized by Era Botanics no part of it is to be disclosed to the others without prior written permission from Era Botanics. 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.

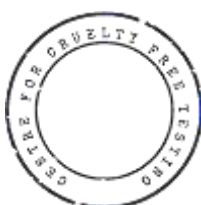


INVESTIGATOR(S) SIGNATURE(S)

A Clinical study titled: “A Clinical Study to Evaluate the Safety and Efficacy of Era Botanics Acne Spot Corrector in the Reduction of Acne.”

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

Name: Dr. Robin Chugh Designation: Dermatologist Telephone: +91-7078103723 Email: robinder75@gmail.com CCFT Laboratories, Mittal Group Building, 121-B Mansarovar Industrial Estate, Panchli, Baghpat Road, Meerut, UP, 250005-India	 21 Apr 2026 SIGNATURE & DATE
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STATEMENT OF COMPLAINE

A Clinical study titled: “A Clinical Study to Evaluate the Safety and Efficacy of Era Botanics Acne Spot Corrector in the Reduction of Acne.”

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 (DD MM YYYY)
PUNEET MITTAL	Director- Clinical Research, MGCTS, Mittal Building 121-B, Mansarovar Ind Estate, Panchli, Baghpat Road, Meerut-250002, India		21 Apr 2026





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

A Clinical study titled: “A Clinical Study to Evaluate the Safety and Efficacy of Era Botanics Acne Spot Corrector in the Reduction of Acne.”

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.

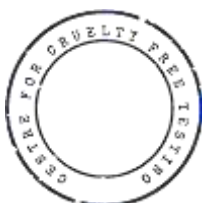
S. No	Name and Designation	Signature	Date (DD MM YYYY)
1	NIDHI DIXIT Study Director CCFT- Meerut		21 Apr 2026
2	SHEETAL, Data Management Associate CCFT- Meerut	<i>Sheetal</i>	21 Apr 2026





REPORT SUMMARY:

Title of the Study	"A Clinical Study to Evaluate the Safety and Efficacy of Era Botanics Acne Spot Corrector in the Reduction of Acne."
Name of Investigational product	Acne Spot Corrector
Name of Sponsor	Era Botanics
SITE	CCFT Laboratories, Mittal Group Building, 121-B Mansarovar Industrial Estate, Panchli, Baghpat Road, Meerut, UTTAR PRADESH, 250005-India
Investigator (s)	Dr. Robin Chugh
Study Objective	<u>Primary objective:</u> The primary objective of this study is to evaluate the acne size reduction of Acne Spot Corrector. <u>Secondary Objective</u> • To study the safety and tolerability • To check if the product reduction in acne redness-Erythema
Study Phase	NA
Study Design	An open label one arm study. Each participant entering the trial will be assigned to a regimen of investigational product with the below assessments. - Skin Erythema (by Mexameter): (T0, T6 hour) - HD Imaging with DSLR (T0, T6 hour) - Dermat evaluation on a 5 point ordinal scale (0-4) would be used for the Blemishes (T0, T6 hour) - Dermat evaluation on a 5 point ordinal scale would be used for the inflammation (T0, T6 hour)





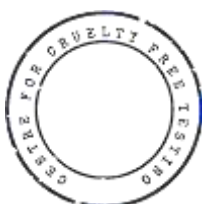
	• Subject's Self Assessments. (T6hr only) - Does this help visible reduction in acne size in 6 hour? - Do you agree that this Test Product gives skin comfort? - Did this product reduce skin redness?
Sample size	36 Subjects
Study Inclusion Criteria	Inclusion Criteria 1. Gender: Male and female aged between 18 to 50. 2. Subject with active acne & scars. 3. Subjects willing to give written informed consent 4. Women of child bearing potential must have a negative urine pregnancy test prior to study entry. 5. Are free of any systemic or dermatologic disorder, which, in the opinion of the investigator, will interfere with the study results or increase the risk of adverse events. 6. Are willing to avoid prolonged exposure of the treatment area to ultraviolet radiation (natural or artificial) for the duration of the study
Study Exclusion Criteria	1. Subjects who are pregnant, breast feeding, or planning to become pregnant during the study 2. Volunteers with skin conditions such as eczema, psoriasis, etc 3. Have any evidence of systematic cancer, squamous cell carcinoma, basal cell carcinoma in the last 5 years, or any other confounding skin condition. 4. Have open sore or open lesions in the treatment area 5. Have any condition that, in the opinion of the investigator, would confound the safety and efficacy assessments of the product. 6. Have participated in any interventional clinical trial in the previous 30 days. 7. Have a known sensitivity to any of the constituents of the test product including sensitivities to any of the constituents. 8. Have used, are using, or are planning to use immunosuppressive or immunomodulatory medications (i.e., biologics), including corticosteroids. 9. Have a history of alcohol or illegal drug/ substance abuse or suspected alcohol or illegal drug/substance abuse in the past 2 years.



Test Product Study Product, Dose	<u>Test Product:</u> Acne Spot Corrector <u>Dose:</u> Apply sufficient quantity on the acne (affected area) applying every 2hours,i.e.at baseline (0min), 2hour, and 4hour time points. <u>Route of Administration:</u> Topical
Clinical assessment and Laboratory Assessment	• Mexammeter Assessment • Imaging by Dermascope • Dermat Evaluation
Outcome Measures	<u>Efficacy:</u> • Change in skin Erythema • Change in Skin Blemishes • Change in Skin Inflammation • Change in Acne Size • Subject Self-Assessment All the parameters will be taken as X% improvement in the parameter, and X% users observed improvement in the parameter. <u>Safety:</u> • Adverse Events • Tolerability Subject's Self-Assessment 1. X% of users agreed that their acne size reduced in 6 hour. 2. X% of users agreed that the product gives skin comfort. 3. X% of users agreed that the product reduced redness.

CCFT1590

Client Name: Era Botanics





SAFETY EVALUATION	Incidence of AE
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 end of treatment. Here data will be analysed 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. Quantitative Assessments Quantitative assessments (continuous data) will be summarized by reporting the number of subjects (n), mean, standard deviation (SD), median, minimum value, and maximum. Qualitative Assessments Qualitative assessments (categorical data) will be summarized by reporting the frequency (count and percent) of subjects falling within the category. Unless specified otherwise for a particular assessment, the denominator for calculating a percentage will be the total number of subjects in the analysis population for the subgroup being analysed; for example, within study arm, the number of subjects within the study arm in the analysis population will be the denominator. For overall summaries, the total number of subjects in the analysis population will be used as the denominator.





	Methods for Handling Missing Data Missing efficacy data will be imputed using the last observation carried forward unless specified otherwise; unscheduled visit data will be included in the carry forward procedure. No imputations will be made for missing safety data.
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 Results	Out of 36 subjects screened, No one was found dropout, No were found screen failure. 36 subjects who underwent the full trial period. The mean age of the subjects was 30.08 years in the study. The mean height of the subjects was 161.62 cm. The mean weight of the subjects was 63.86 kg. The BMI of the subjects were 24.53. The assessment for Acne size was done with dermoscopy images at 60x followed by scaling in the dinolite software for the size measured as diameter. This value of acne size was assessed at the baseline, and in 6 hours and the assessment was done as X% reduction in the acne size and X% users observing the reduction. The percentage change was measured for the same acne where test product was used. The % reduction in acne size was 12.2% in 6 hours. 86.1 % users observed reduction in acne size in 6 hours. The assessment for skin erythema was done with Mexameter by emitting light of specific wavelengths onto the skin and analyzing the reflected light. It uses two wavelengths (red: 660 nm and near infrared: 880 nm) specifically chosen for their varying absorption rates by erythema pigments. By calculating the difference between emitted and reflected light, the Mexameter quantifies the amount of erythema in the skin. This value of Erythema is assessed at the baseline, and 6 hours, and the assessment was done as X% change in the Skin Erythema and X% users observing the reduction. The percentage change was measured on the same area where test product was used. The % reduction in skin erythema was 8.8% in 6 hours.





91.7 % users observed reduction in skin erythema in 6 hours.

The dermat evaluation was done at the baseline and 6 hours. All the evaluations are done on 5 point ordinal visual scale where 0 means the least parameter, and 4 means the most parameter. The assessment was done as change in Skin Blemishes and Skin inflammation. For the Skin inflammation, 45.6% reduction was observed in 6 hours with 77.8% users observing the reduction. For the skin blemishes, no significant change was observed, with only 1 out of the 36 users observing the change in 6 hours.

The users own evaluation was done as their observations in 6 hours about the product and represented as X% users noticing the change. The results were noted as %users experiencing the change in Subjective Efficacy Feedback. 83.3% of users felt that it help visibly reduction in acne size in 6 hour, 100% users agree that this Test Product gives skin comfort, 100% users feel that the product reduce skin redness.

Concomitant medicines were allowed only for fever and injury.

During the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

None of the patients withdrawn the consent

100% of Panel found No-side effects.

No adverse event was reported during the study.

Concomitant medicines were allowed only for fever and injury.

During the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

There were no protocol violations and deviations reported. There were no patients who lost to follow up.

None of the patients withdrawn the consent



Conclusion	In conclusion, Acne Spot Corrector showed reduction in the acne size, skin erythema, and inflammation in 6 hours, with no significant change in blemishes. 100% of Panel found No-side effects
Date of Report	21 Apr 2026





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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
ECG	Electrocardiogram
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	Patient-reported outcome
QOL	Quality of Life
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SD	Standard deviation
SGA	Subject's global assessment
SUSAR	Suspected unexpected serious adverse reaction
TC	Telephone call
UPT	Urine pregnancy test





Patient Information and Consent

All patients provided written informed consent to participate in the study prior to being screened. The patient information sheet detailed the procedures involved in the study (aims, methodology, potential risks and anticipated benefits) and the investigator explained these to each patient. The patient signed the consent form to indicate that the information had been explained and understood. The patients 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 patients 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	Era Botanics
Principal Investigator (S)	Dr. Robin Chugh (MD, Dermatology)
ETHICS COMMITTEE (S)	ARMHRC INSITUTIONAL ETHICS COMMITTEE
SITE(S) ADDRESS	CCFT Laboratories, CCFT Laboratories, Mittal Group Building, 121-B Mansarovar Industrial Estate, Panchli, Baghpat Road, Meerut, UTTAR PRADESH, 250005-India
NAME AND ADDRESS OF LABORATORY	SAME AS ABOVE





1. INTRODUCTION

1.1. Background

An acne spot corrector is a targeted topical treatment designed to reduce individual pimples quickly—rather than treating the entire face like a full acne regimen.

1.2. Rationale of the Trial

Acne spot correctors are designed to deliver high concentrations of active ingredients directly to individual lesions. This localized delivery enables rapid intervention at the site of inflammation, helping to reduce lesion size, erythema, and microbial load without exposing surrounding healthy skin to unnecessary irritation.

1.3. Benefit-risk Assessment

The subject population will be composed of healthy volunteers.

The active ingredients in the investigational products are known to be effective for control Acne. The safety and efficacy profiles for marketed products with these ingredients are well known.

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

2. TRIAL OBJECTIVES AND PURPOSE

2.1. Primary objective

The primary objective of this study is to evaluate the acne size reduction of Acne Spot Corrector.

2.2. Secondary objective

- To study the safety and tolerability
- To check if the product reduction in acne redness-Erythema
- Subject's Self Assessments





3. TRIAL DESIGN

3.1. Overall Trial Design

An open label one arm study.

Each participant entering the trial will be assigned to a regimen of investigational product with the below assessments.

- Skin Erythema (by Mexameter): (T0, T6 hour)
- HD Imaging with DSLR (T0, T6 hour)
- Dermat evaluation on a 5 point ordinal scale (0-4) would be used for the Blemishes (T0, T6 hour)
- Dermat evaluation on a 5 point ordinal scale would be used for the inflammation (T0, T6 hour)
 - Subject's Self Assessments. (T6hr only)
- Does this help visible reduction in acne size in 6 hour?
- Do you agree that this Test Product gives skin comfort?
- Did this product reduce skin redness?

3.2. Trial Endpoints

3.2.1. Endpoints

Efficacy:

- Change in Skin Erythema
- Change in Skin Blemishes
- Change in Skin inflammation
- Change in Acne size

All the parameters will be taken as X% improvement in the parameter, and X% users observed improvement in the parameter.

Safety:

- Adverse Events
- Tolerability





4. SELECTION OF TRIAL POPULATION

4.1. Subject Population

Subjects (36 in no.) were enrolled for the primary analysis. An individual subject was allowed to participate in the trial one time only.

Each potential subject signed and dated an informed consent document before any trial-specified procedures were performed. Subjects were provided authorization for use of their personal data in accordance with the applicable regulations regarding privacy and data protection.

4.2. Inclusion Criteria

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

1. Gender: Male and female aged between 18 to 50.
2. Subject with active acne & scars.
3. Subjects willing to give written informed consent
4. Women of child bearing potential must have a negative urine pregnancy test prior to study entry.
5. Are free of any systemic or dermatologic disorder, which, in the opinion of the investigator, will interfere with the study results or increase the risk of adverse events.
6. Are willing to avoid prolonged exposure of the treatment area to ultraviolet radiation (natural or artificial) for the duration of the study

4.3. Exclusion Criteria

1. Subjects who are pregnant, breast-feeding, or planning to become pregnant during the study.
2. Volunteers with skin conditions such as eczema, psoriasis, etc
3. Have any evidence of systematic cancer, squamous cell carcinoma, basal cell carcinoma in the last 5 years, or any other confounding skin condition.
4. Have open sore or open lesions in the treatment area
5. Have any condition that, in the opinion of the investigator, would confound the safety and efficacy assessments of the product.
6. Have participated in any interventional clinical trial in the previous 30 days.
7. Have a known sensitivity to any of the constituents of the test product including sensitivities to any of the constituents.
8. Have used, are using, or are planning to use immunosuppressive or immunomodulatory medications (i.e., biologics), including corticosteroids.
9. Have a history of alcohol or illegal drug/ substance abuse or suspected alcohol or illegal drug/substance abuse in the past 2 years.





4.4. 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. 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 (eCRF) 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.

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.

4.5. Replacement Policy

After trial enrolment has been completed, subjects who prematurely discontinue the trial after were not replaced.





5. TRIAL TREATMENTS

5.1. Investigational Product

Acne Spot Corrector

5.2. Dosing Regimen

Apply sufficient quantity on the acne (affected area) applying every 2 hours, i.e. at baseline (0 min), 2 hour, and 4 hour time points.

5.3. Dose Modification

Subjects classified as clear at on actual visits may stop the treatment at the investigator's discretion. They should remain in the trial and attend visits up to whole trial.

5.4. Packaging, Labeling, and Storage

Medication labels for the IPs will comply with the legal requirements of the country where the trial is performed and be printed in the local language.

The IPs will be supplied by the **Era Botanics** designated vendor and stored securely at the site under the control of the investigator. The temperature will be monitored and documented.

The Acne spot corrector was supplied to the clinical site. The product to be protected from sunlight, stored in a cool and dry place at a temperature of 25°C (below 77°F) at the site, and below 25°C (below 77°F) after dispensing to the subject however the product must not be refrigerated.

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

5.5.1. Washout of Prohibited Medications Prior to Enrollment

A washout period of up to 2 weeks was completed if the subject has been treated with any medication as specified in the exclusion criteria.





5.5.2. Prohibited Medications during the Trial

Use of any medication that would exclude the subject from participation in the trial (as specified in Section 5.2 Exclusion Criteria) is also prohibited during the treatment which includes medications in the following categories:

Patients should not use any form of the topical interventions

5.5.3. Rescue Medication

In case the patient does not respond to the treatment, any other medication as judged by the Investigator would be better for the subject will be given to subjects. No other concomitant medicine will be allowed except study drug and rescue medication throughout study duration.

5.6. Treatment Compliance

Records of trial product used and dosages administered were kept during the trial. The trial monitor has noted product accountability during site visits and at the completion of the trial.

At all on-treatment visits, the subjects were asked if he/she has used the medication as prescribed. If this is not the case, the degree and nature of noncompliance was specified. In addition, subjects were asked to complete a dosing diary during the treatment period as a measure of treatment compliance.

Subjects who are consistently noncompliant were counseled.





6. VISIT SCHEDULE AND ASSESSMENTS

6.1. Trial Procedures

The visit schedule and assessments are summarized in Table 1.

Parameters	Screening	
Day	1	
Hours	00:00	06:00
Written Informed Consent	X	
Inclusion/Exclusion Criteria	X	
Medical History	X	
Physical Examination	X	
Vital Signs	X	
Demographic Information	X	
Product administration	X	
Dermascope Imaging	X	X
SGA Questionnaire		X
Mexameter Assessment	X	X
HD imaging	X	X
Dermat Evaluation	X	X
Urine Pregnancy Test (In case of a female subject)	X	
Adverse Events	X	
Concomitant Medication	X	

Table 1: Visit Schedule and Assessments





6.2. Trial Visits and Assessments

6.2.1. Visit 1/Baseline (T0):Day1

Screening procedures should be completed no more than 1 days prior to Visit 1/ (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 skin related study within last two months
- Review and record any current medical diagnoses.
- Perform the following assessments:
 - Mexameter Assessment
 - Imaging by Dermascope
 - Skin inflammation and blemishes by dermat evaluation
 - HD imaging
- Perform a urine pregnancy test (UPT) in female subjects of childbearing potential and instruct these female subjects to use approved form(s) of contraception.

6.2.2. Visit 2 T 6 Hours (Day 1)

Take Vital signs (Body temperature systolic and diastolic blood pressure and heart rate and pulse rate).

Perform the following assessments:

- Mexameter Assessment
- Imaging by Dermascope
- Skin inflammation and blemishes by dermat evaluation
- HD imaging
- Record any AE

6.2.3. 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.





6.2.3 Unscheduled Visit and Telephone Calls

An unscheduled visit may be performed at any time during the trial if judged necessary by the Investigator, such as for a severe reaction and clinically significant AE. Details of the event must be recorded in the subject's records.

6.3 Investigator Assessments

The investigator assessments are to be performed by a dermatologist, a dermatologist with at least 1 year of experience in dermatology. For dermatologist and dermatologist Assistants who do not fulfill the requirement regarding dermatologist experience and other state licensed professionals who have the ability to diagnose, treat and prescribe medications, the person must be preapproved by the sponsor. The assessments are to be performed as specified in the visit schedule (Table 1).

6.4 Assessment of Safety

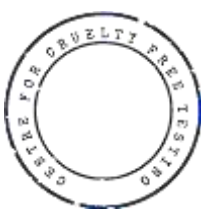
6.4.3 Adverse Events

6.4.3.1 Adverse Events Assessments

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

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

Any AE that meets the serious criteria must be reported on the CRF and on 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 nondirective 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 standards of medical care to protect the health and well-being of the subject. Treatment due to an AE will be recorded in the subject's records and on the appropriate CRF. Any AE that is considered related to the trial product must be followed by the investigator until it is resolved or until the medical condition of the subject is stable; all relevant follow-up information will be reported to the Sponsor/CRO or designee.

The outcome of an AE was classified as recovered, recovered with sequel, recovering/resolving, ongoing, or death.

No AE were observed in the study in either of the arms.

6.4.4 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.

6.4.5 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).





6.4.7 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 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.





6.4.8 Trial Medication Overdose

An overdose of the IP, i.e., a dose that is higher than the highest dose under clinical investigation or the known therapeutic dose, will be fully documented even if no toxic effects were observed and will be considered as an AE.

6.4.9 Serious Adverse Event

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

- Results in death
- Is life-threatening
- Requires in-patient 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). 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.

6.4.10 Vital Signs

At all the visits, the investigator or designee will take measurements of vital signs, including blood pressure and heart rate (pulse) with the subject in the sitting position with approximately 5 minutes rest prior to measurement. The same arm is to be used for all measurements.

6.4.11 Physical Examination

At Visit 1/Baseline the investigator or designee will complete a general physical examination including measurements of height (at screening only) and weight (with indoor clothing and without shoes) the investigator also takes all the vitals and examine any delayed erythema response on the site.

During the trial, any new clinically significant findings of signs/symptoms that could indicate systemic safety will be reported as AEs.

6.4.12 Appropriateness of Measurements

The assessments to be used in this trial are the standardized and most widely accepted methods for Anti Acne activity testing as per guidelines.





7. Statistical Methods and Analytical Plans

Prior to the analysis of the final study data, a detailed Statistical Analysis Plan (SAP) was written describing all analyses that will be performed. Data was analyzed using a combination of NCSS & R software version 2.15.0 (R Development core team, R Foundation for statistical computing, Vienna, Austria) with appropriate statistical test. The SAP may contain any modifications to the analysis plan described below.

7.4 Data Sets Analyzed

All eligible patients who are included into the study and receive single dose on same day of the study

7.5 Demographic and Baseline Characteristics

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

7.6 Analysis of Endpoints

All data will be expressed as percentage of subjects with improvement in the condition, with no statistical Safety and tolerability data was summarized by treatment group.

Adverse event rates were coded by body system and MedDra classification term. Adverse events were tabulated by treatment group and include the number of patients for whom the event occurred, the rate of occurrence, and the severity and relationship to study drug.

7.7 Sample Size

Sample size for this protocol is 36. The eligible patients will be assigned to study drug randomly and there is no need of randomization in it.





8. CHANGES IN THE PLANNED TRIAL

8.4 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.

8.5 Termination or Suspension of the Trial

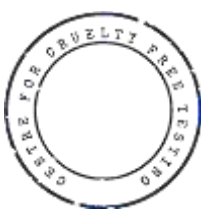
SPONSOR/CRO reserves the right to terminate or suspend the trial at any time. In case of premature termination or suspension of the trial, the contract research organization (CRO) project manager has to promptly inform the investigators, regulatory authorities, and s about the premature termination or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

9. DATA HANDLING AND RECORD KEEPING

9.4 Recording of Data

9.4.7 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. For each subject enrolled, the investigator will indicate in the source record(s) that the subject participated in the trial.

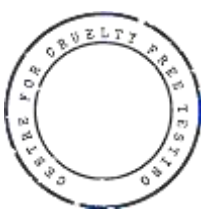
9.4.8 Case Report Forms

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).





9.5 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.

10. QUALITY CONTROL AND QUALITY ASSURANCE

10.4 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.

10.5 Monitoring Procedures

The Clinical Trial Monitor will contact and/or visit 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 will cooperate with the trial monitor to ensure that any discrepancies that may be identified are resolved.

10.6 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.

11. ETHICS

11.4 Ethical Conduct of the Trial

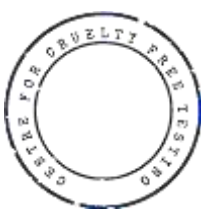
This trial must be carried out in compliance with the protocol and the applicable laws and regulatory requirements of the appropriate regulatory agency. The trial must be conducted in accordance with the ethical principles originating from the Declaration of Helsinki and amendments and the ICH-GCP guidelines.

11.5 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 10 April 2026 by ARMHRC Institutional Ethics Committee.

11.6 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.





11.7 Disclosure and Confidentiality

11.7.7 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.

11.7.8 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.

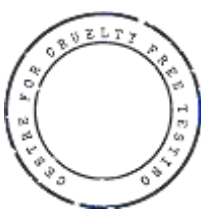
11.8 Reporting of Serious Adverse Events and Pregnancies

11.8.7 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:

Email: Naze.dhankar@consciouschemist.com

Name: Naze Dhankar





11.8.8 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.

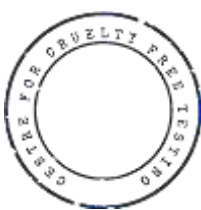
12. INSURANCE

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

14.1. Subject disposition:

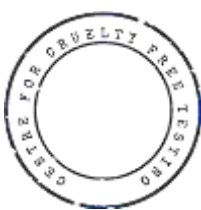
Out of 36 subjects screened, No one was found dropout, No were found screen failure.
36 subjects who underwent the full trial period.

S. No	Variable	Number of subjects
1.	No. of subjects screened for study	36
2.	No. of subject's screen failure	0
3.	No. of subjects enrolled in the study	36
4.	Number of subjects completed the Study	36
5.	Dropout	0

Table 2: Patient disposition details

S. No	Schedule	Dates
1.	First subject ICF date	13 April 2026
2.	Last subject ICF date	20 April 2026
3.	First subject screening date	13 April 2026
4.	Last subject screening start date	20 April 2026
5.	Date of first subject completed study	13 April 2026
6.	Date of Last subject completed study	20 April 2026

Table 3: Study dates/schedules:





Subject disposition chart

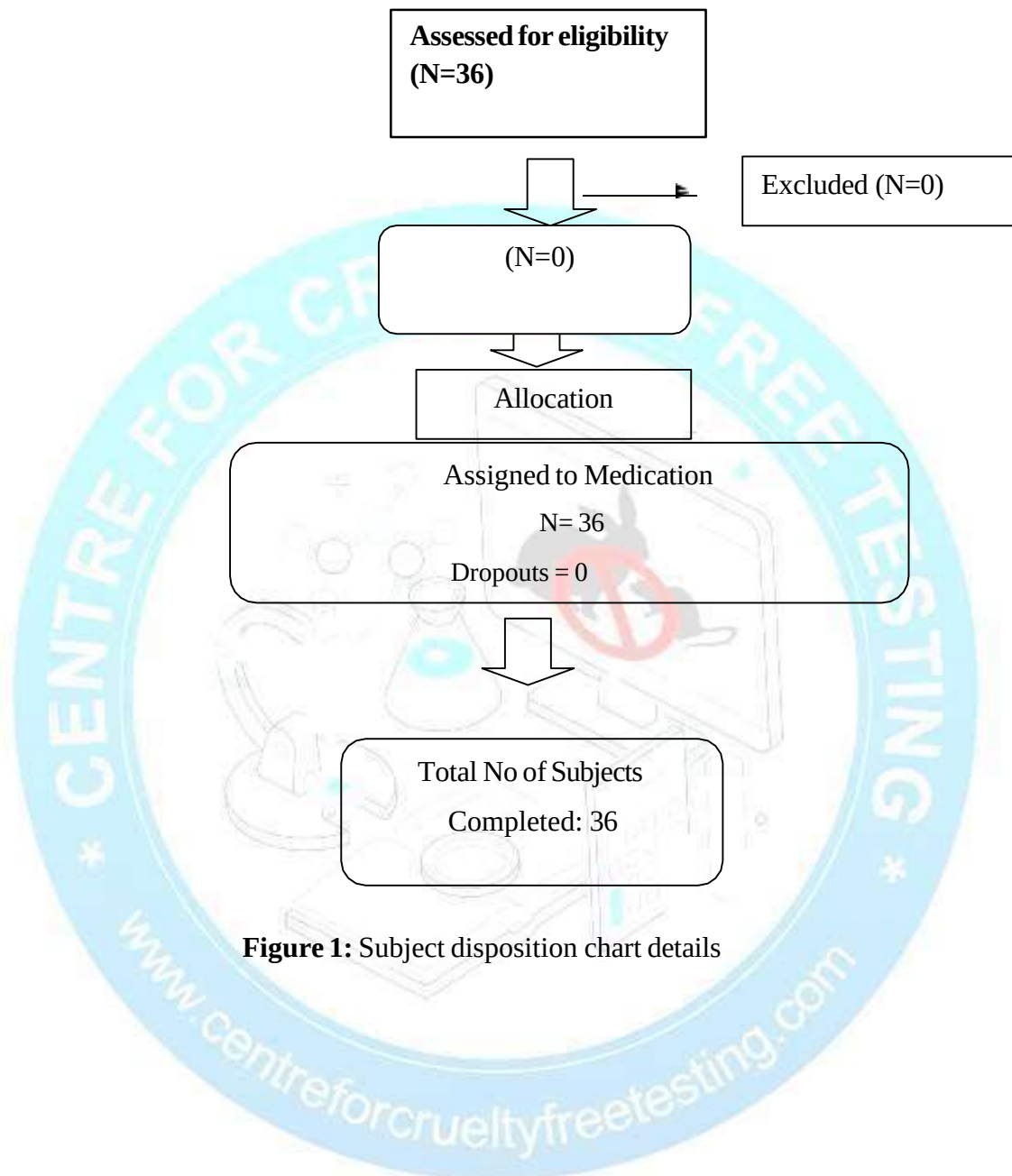


Figure 1: Subject disposition chart details





14.5 Demographic and Other Baseline Characteristics

The mean age of the subjects was 30.08 years in the study. The mean height of the subjects was 161.62 cm. The mean weight of the subjects was 63.86 kg. The BMI of the subjects were 24.53.

15. Efficacy Evaluations

Data sets Analyzed. Data from 36 patients who completed the study were analyzed.

Treatments	Acne Spot Corrector
Total screened	36
Enrolled	36
No. of patients completed	36

Efficacy Parameters-

15.1 CHANGE IN ACNE SIZE:

The assessment for Acne size was done with dermoscopy images at 60x followed by scaling in the dinolite software for the size measured as diameter. This value of acne size was assessed at the baseline, and in 6 hours and the assessment was done as X% reduction in the acne size and X% users observing the reduction. The percentage change was measured for the same acne where test product was used.

Acne Size	Baseline	6 hours
Mean	1.85	1.625
%Reduction	--	12.2%

Table 5: Acne Size

The % reduction in acne size was 12.2% in 6 hours. 86.1 % users observed reduction in acne size in 6 hours.



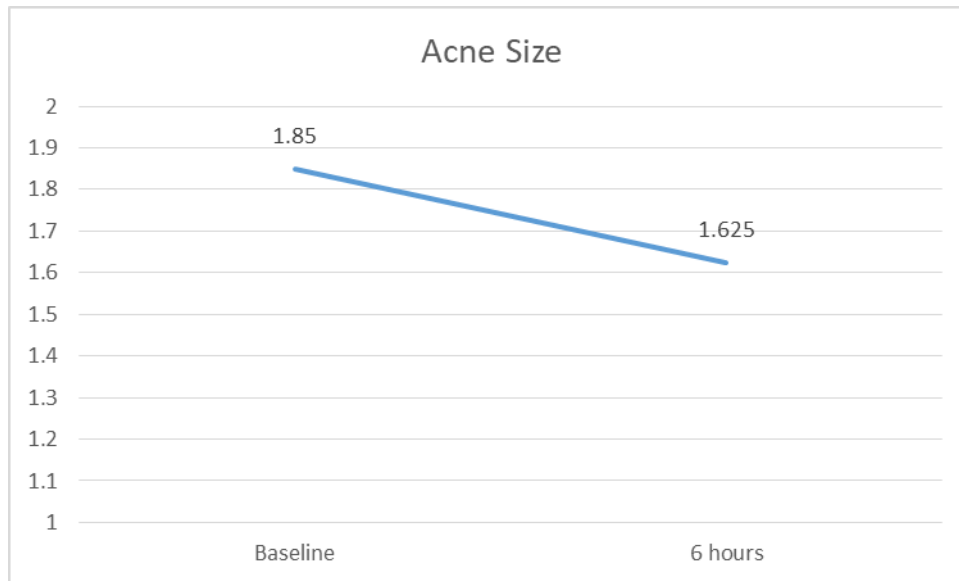


Figure 2: Reduction in Acne Size

15.2 CHANGE IN SKIN ERYTHEMA:

The assessment for skin erythema was done with Mexameter by emitting light of specific wavelengths onto the skin and analyzing the reflected light. It uses two wavelengths (red: 660 nm and near infrared: 880 nm) specifically chosen for their varying absorption rates by erythema pigments. By calculating the difference between emitted and reflected light, the Mexameter quantifies the amount of erythema in the skin. This value of Erythema is assessed at the baseline, and 6 hours, and the assessment was done as X% change in the Skin Erythema and X% users observing the reduction. The percentage change was measured on the same area where test product was used.

Skin Erythema	Baseline	6 hours
Mean	255.454	233.083
%Reduction	--	8.8%

Table 6: Skin erythema

The % reduction in skin erythema was 8.8% in 6 hours. 91.7 % users observed reduction in skin erythema in 6 hours.



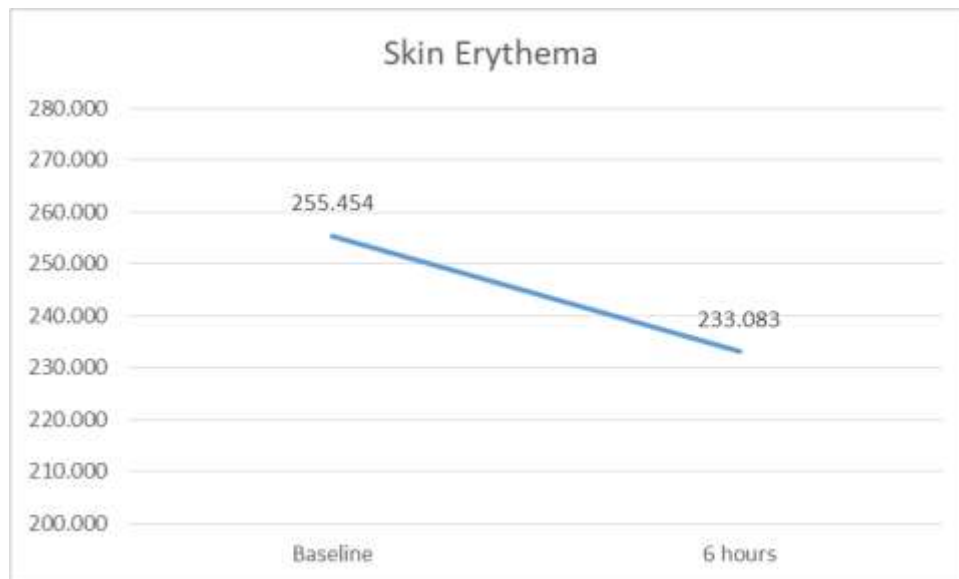


Figure 3: Reduction in Skin Erythema

15.2. CHANGE IN SKIN BLEMISHES AND INFLAMMATION:

The dermat evaluation was done at the baseline and 6 hours. All the evaluations are done on 5 point ordinal visual scale where 0 means the least parameter, and 4 means the most parameter. The assessment was done as change in Skin Blemishes and Skin inflammation.

Parameter	Baseline	6 hours
Skin Inflammation	2.194	1.194
%reduction	--	45.6%
Skin Blemishes	1.306	1.278
%reduction	--	2.1%

Table 7: Skin inflammation and blemishes

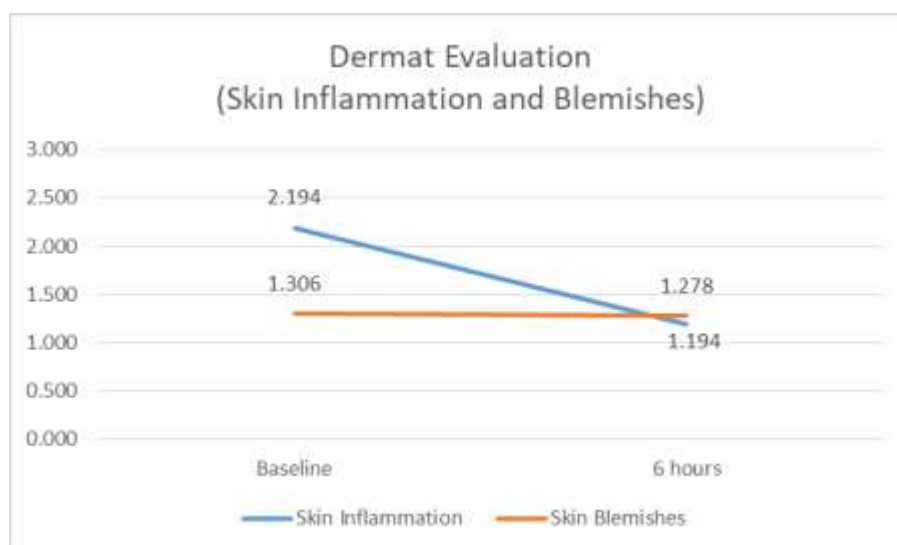


Figure 4: Change in Skin Smoothness and Texture





For the Skin inflammation, 45.6% reduction was observed in 6 hours with 77.8% users observing the reduction. For the skin blemishes, no significant change was observed, with only 1 out of the 36 users observing the change in 6 hours.

15.4 SUBJECTS SELF EVALUATION:

The users own evaluation was done as their observations in 6 hours about the product and represented as X% users noticing the change.

The results were noted as %users experiencing the change in Subjective Efficacy Feedback. 83.3% of users felt that it help visibly reduction in acne size in 6 hour, 100% users agree that this Test Product gives skin comfort, 100% users feel that the product reduce skin redness.





16. Adverse events and other safety assessments:

The adverse events reported was none during the treatment, with special assessment to check for Skin irritation, itching or Erythema. No such issue reported.

S. No.	AE	Test (N=36)
1	No. of AEs	0
2	Skin Irritation	0
3	Skin Itching	0
4	Erythema	0

Table 11: Adverse Events list

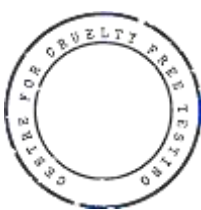
As per the protocol the results are represented as % of Panel found No-side effects; i.e, 100% of Panel found No-side effects.

17. Other concomitant medications:

All standard treatments were given to the subjects as deemed necessary by the Investigator. Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

S. No.	Medicine	Number of subjects / Condition
1.	Metformin	1

Table 14: Other concomitant medication list during the study period.





18. Discussion:

Out of 36 subjects screened, No one was found dropout, No were found screen failure. 36 subjects who underwent the full trial period.

The mean age of the subjects was 30.08 years in the study. The mean height of the subjects was 161.62 cm. The mean weight of the subjects was 63.86 kg. The BMI of the subjects were 24.53.

The assessment for Acne size was done with dermoscopy images at 60x followed by scaling in the dinolite software for the size measured as diameter. This value of acne size was assessed at the baseline, and in 6 hours and the assessment was done as X% reduction in the acne size and X% users observing the reduction. The percentage change was measured for the same acne where test product was used. The % reduction in acne size was 12.2% in 6 hours. 86.1 % users observed reduction in acne size in 6 hours.

The assessment for skin erythema was done with Mexameter by emitting light of specific wavelengths onto the skin and analyzing the reflected light. It uses two wavelengths (red: 660 nm and near infrared: 880 nm) specifically chosen for their varying absorption rates by erythema pigments. By calculating the difference between emitted and reflected light, the Mexameter quantifies the amount of erythema in the skin. This value of Erythema is assessed at the baseline, and 6 hours, and the assessment was done as X% change in the Skin Erythema and X% users observing the reduction. The percentage change was measured on the same area where test product was used. The % reduction in skin erythema was 8.8% in 6 hours. 91.7 % users observed reduction in skin erythema in 6 hours.

The dermat evaluation was done at the baseline and 6 hours. All the evaluations are done on 5 point ordinal visual scale where 0 means the least parameter, and 4 means the most parameter. The assessment was done as change in Skin Blemishes and Skin inflammation. For the Skin inflammation, 45.6% reduction was observed in 6 hours with 77.8% users observing the reduction. For the skin blemishes, no significant change was observed, with only 1 out of the 36 users observing the change in 6 hours.

The users own evaluation was done as their observations in 6 hours about the product and represented as X% users noticing the change. The results were noted as %users experiencing the change in Subjective Efficacy Feedback. 83.3% of users felt that it help visibly reduction in acne size in 6 hour, 100% users agree that this Test Product gives skin comfort, 100% users feel that the product reduce skin redness.





Concomitant medicines were allowed only for fever and injury.

During the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

None of the patients withdrawn the consent

100% of Panel found No-side effects.

No adverse event was reported during the study.

Concomitant medicines were allowed only for fever and injury.

During the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

There were no protocol violations and deviations reported. There were no patients who lost to follow up.

None of the patients withdrawn the consent

19. Conclusion:

In conclusion, Acne Spot Corrector showed reduction in the acne size, skin erythema, and inflammation in 6 hours, with no significant change in blemishes. 100% of Panel found No-side effects. 100% of Panel found No-side effects.



CAMERA PHOTOS

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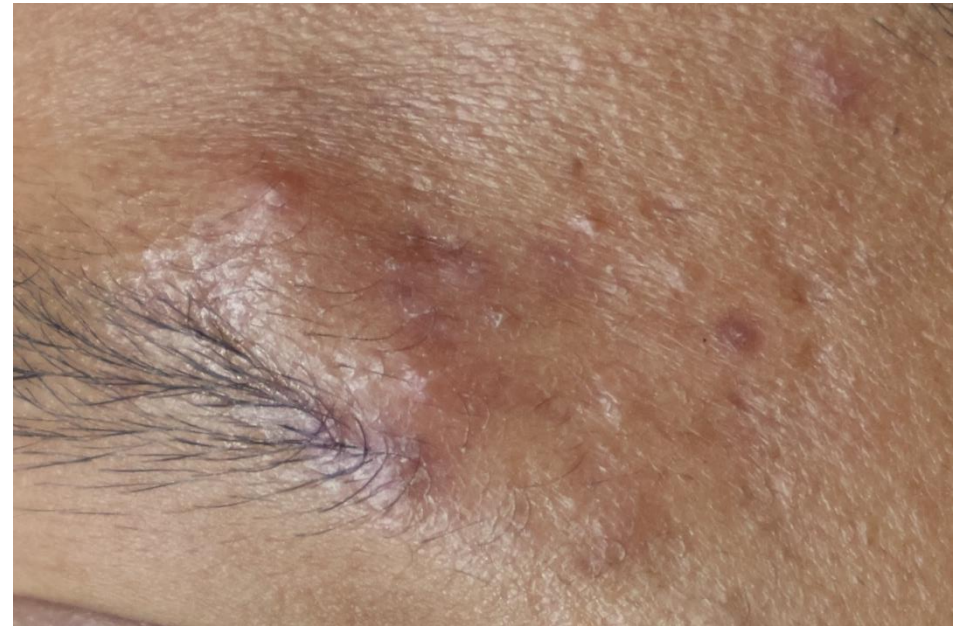
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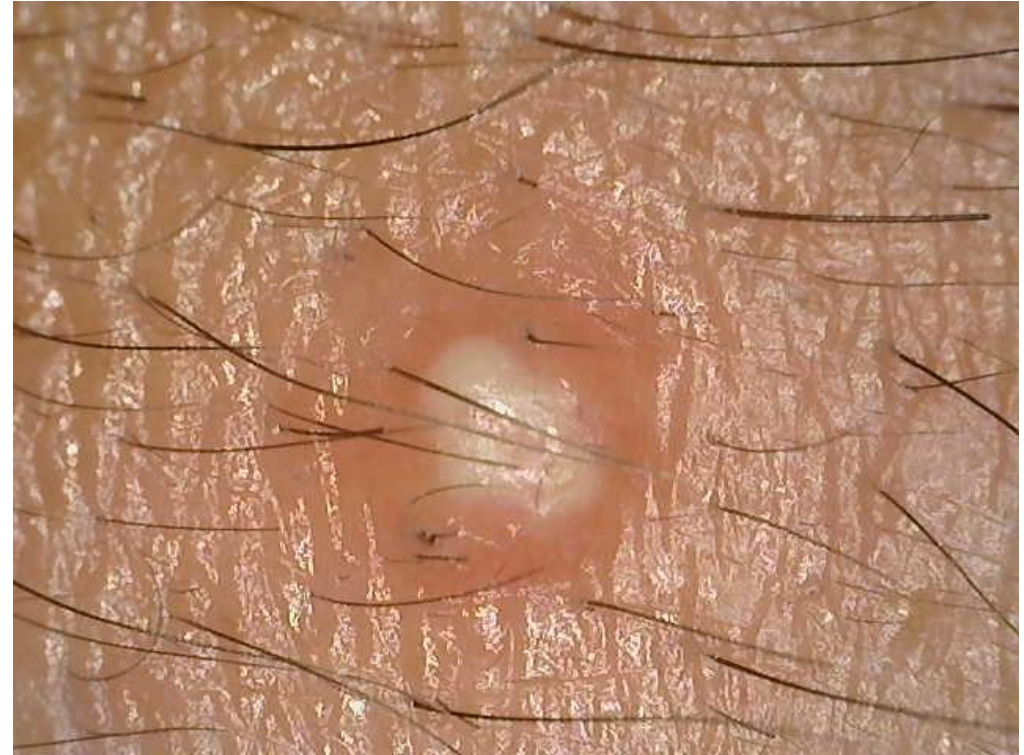
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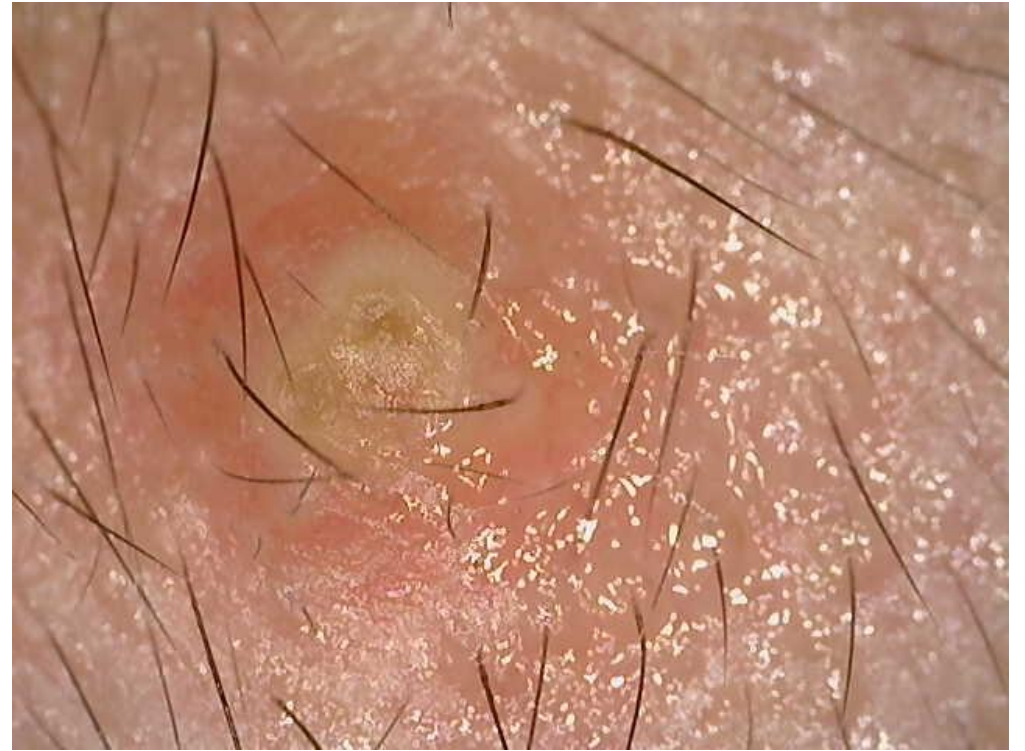
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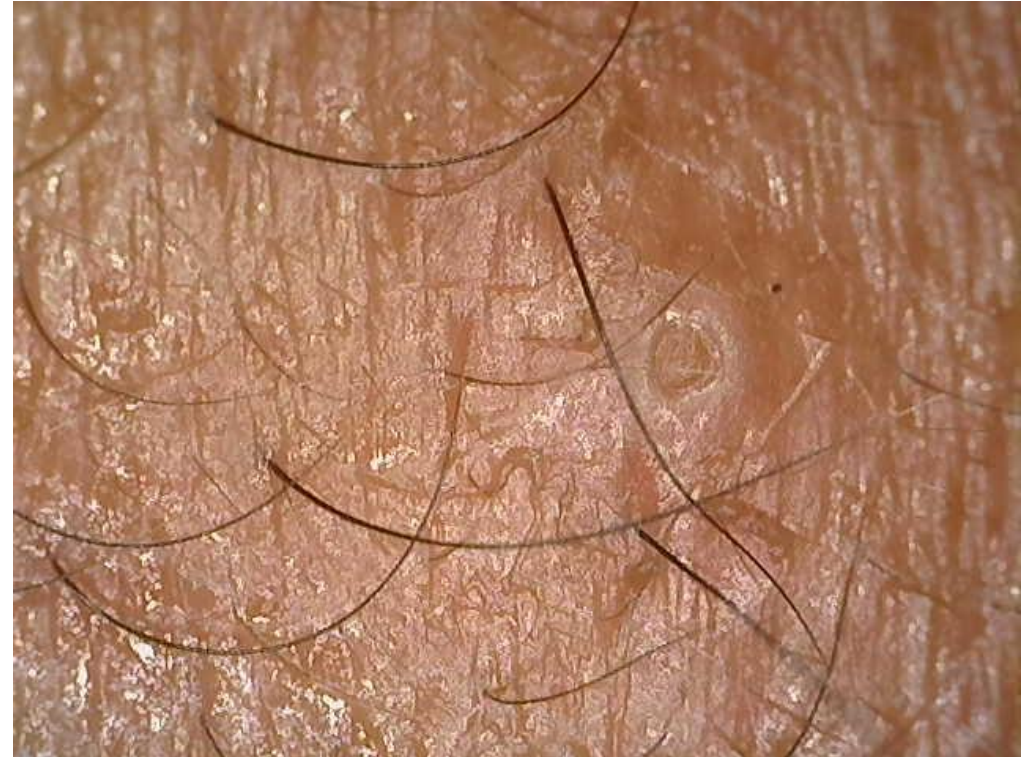
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