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Clinical Study Report

A clinical study to evaluate safety, in-use tolerability and efficacy of HACO-042201 in healthy adults with mild to moderate acne and acne prone skin.

Prepared for

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1. TITLE PAGE

Stages	Details
Study Title:	A clinical study to evaluate safety, in-use tolerability and efficacy of HACO-042201 in healthy adults with mild to moderate acne and acne prone skin.
Investigational Product:	HACO-042201
Design:	An open label, non-randomized, single arm clinical study.
Sponsor:	Himalaya Wellness Company Makali, Bengaluru 562 162, India. Phone: +91-080-67549904
Protocol Details:	Cliantha Protocol Number: C3B03521 Sponsor Protocol Number: HWC/MSCD/CPD/030/2023 Protocol Finalization date: 05 Sep 23
Date of Receipt of Ethics Approval	13 Sep 23
Date of Study commencement:	18 Sep 23
Principal Investigator:	Dr. Bhagirath Patel, MD – Dermatology
Sponsor Representative:	Dr Swathi B Team Lead – Clinical Operations
Good Clinical Practice Statement:	The study was conducted in accordance with this protocol, relevant in-house SOPs, pertinent requirements of the ICMR ethical guidelines and ICH (Step 5) 'Guidance on Good Clinical Practice' and 'Declaration of Helsinki'.
Date of Report:	12 Oct 23

2. SYNOPSIS

Name of Sponsor/Company:	Himalaya Wellness Company Makali, Bengaluru 562 162, India. Phone: +91-080-67549904
Name of Finished Product:	HACO-042201
Title of the study:	A clinical study to evaluate safety, in-use tolerability and efficacy of HACO-042201 in healthy adults with mild to moderate acne and acne prone skin.
Investigators:	**Principal Investigator:** Dr. Bhagirath Patel, MD - Dermatology **Sub-Investigator(s):** Dr. Parth Joshi, BDS
Study Site Details:	Cliantha Research Corporate House 17, Sigma 1 Corporate House, BH. Rajpath Club, Off Sindhubhavan Road, Nr. Mann Party Plot Cross Road, Bodakdev, Ahmedabad-380054, Gujarat. Phone# +91-79-66135601
Ethics Committee Details:	OM – Institutional Ethics Committee, OM Children's Hospital, 304-305, Silver Star Commercial Complex, Silver Star Crossroads, New Chandlodia, Ahmedabad – 382481 Tel# +91-79-27602050 | Email ID: omch.iec@gmail.com
Study Duration and Study Visits:	Study Duration: 08 days from enrollment visit (Day 01) Study visits: Study consisted of a total of 03 visits. • Visit 01: Screening, Enrollment and Baseline Visit (Day 01) • Visit 02: Evaluation phase (Day 04) • Visit 03: Evaluation phase (Day 08 + 2 days)
Date of Study commencement:	18 Sep 23
Objectives:	• To evaluate the safety and in-use tolerability of the test product.

	• To evaluate the efficacy of the test product by the following: ✓ In reducing the appearance of post acne scar in terms of size, depth & discoloration using 6-point grading scale, Acne Scar Assessment Scale and 9-point grading scale, respectively, by Dermatologist, ✓ In reducing the severity and number of existing acne lesions using Investigator's Global Assessment (IGA) Scale and counting of inflammatory & non inflammatory acne lesions, respectively, by Dermatologist, ✓ In preventing the appearance of new acne using Investigator's Global Assessment (IGA) Scale and counting of inflammatory & non inflammatory acne lesions, by Dermatologist, ✓ In reducing the visibility of marks using 9-point scale by Dermatologist and 3D Analysis System (Antera), ✓ In reducing the red spots/erythema using 5-point grading scale by Dermatologist and 3D Analysis System (Antera), ✓ In improving the skin tone evenness using Felix Von Luschan Skin colour chart by Dermatologist. ✓ In improving the skin roughness using 5-point grading scale by Dermatologist, ✓ In reducing the skin sebum level using Sebumeter® SM 815, ✓ In improving skin moisturization using MoistureMeterSC, ✓ In improving the skin barrier function by measuring TEWL using Vapometer, ✓ In improving the skin gloss/glow using Skin-Glossymeter GL 200, ✓ In reducing the porphyrins using Visiopor® PP 34N, ✓ In reducing the severity of facial pores, in improving the skin texture in terms of roughness, in improving the skin brightness/fairness and in reducing the size of acne in terms of area and volume using 3D analysis system (Antera), ✓ Subjective Satisfaction Questionnaire response, ✓ Digital Photography

Methodology / Study Design:	This was an open label, non-randomized, single-arm clinical study to evaluate safety, in-use tolerability and efficacy of HACO-042201 in healthy adult subjects with mild to moderate acne. The potential subjects were screened as per the inclusion and exclusion criteria only after obtaining written informed consent from the subjects. All eligible subjects underwent clinical evaluation by a Dermatologist, instrument evaluation and subjective evaluation. Safety was assessed throughout the study by monitoring adverse events.
Number of Subjects:	20 subjects
Key Criteria for Inclusion:	Subjects fulfilled all of the following main inclusion criteria to be eligible for participation in the study. 1) Healthy adult and adolescent males and/or non-pregnant/non-lactating females with age 12 to 30 years (both inclusive at the time of consent/assent). 2) Subjects with acne-prone skin and with mild to moderate acne condition as per IGA scale for Acne severity. 3) Subjects with acne marks/spots and post acne scar. 4) Subjects with visible facial pores.
Key Criteria for Exclusion	Subjects were not enrolled in the study if they met any one of the following criteria: 1) Subjects with drug induced acne as disclosed by subjects. 2) Subjects who are receiving topical or systemic treatments for acne and acne marks. 3) Subjects with any pigmentary disorder including freckles and melasma. 4) Subjects having any active dermatological skin diseases (e.g., psoriasis, atopic dermatitis, rosacea etc.), that might interfere with clinical assessments. 5) Subject having excessive hair, moles, open wounds, cuts, abrasions, irritation symptoms, tattoos, scars, sunburn or any dermatological condition on the test site(s) that can interfere with the reading.

Test Product Details:	**Product Name**: HACO-042201; **Batch No.**: HACO/28042023/VDL/01
Dose and Mode of Application/Usage:	Subjects were instructed to apply approximately 2 gm (2ml /3-5 drops) of test product over cleansed face. The product was applied once at the facility on Day 01. The product was used once daily (preferable at night) starting from Day 02 till the end of the study. *Note: Subjects were advised to avoid contact of test product with eyes. They were informed that they may experience slight tingling.*
Criteria for evaluation:	**Efficacy:** Primary Endpoints: 1. To evaluate the effectiveness of test product on reduction in appearance of post acne scar by Dermatologist using 6-point grading scale for size of scar, Acne Scar Assessment Scale for depth of scar and 9-point grading scale for discoloration of scar at Day 01 (before application) and Day 08 (+ 2 days). 2. To evaluate the effectiveness of test product on acne reduction by using Investigator's Global Assessment (IGA) Scale for Acne Vulgaris and counting of inflammatory *(papules & pustules)* and non-inflammatory *(i.e., blackheads and whiteheads)* lesions at Day 01 (before application) and Day 08 (+ 2 days). Secondary Endpoints: 1. To evaluate the effectiveness of test product in preventing the appearance of new acne by using Investigator's Global Assessment (IGA) Scale for Acne Vulgaris and counting of inflammatory *(papules & pustules)* and non-inflammatory *(i.e., blackheads and whiteheads)* lesions at Day 01 (before application) and Day 08 (+ 2 days). 2. To evaluate the effectiveness of test product in reducing the visibility of acne marks by assessing pigmentation using 9-point scale by Dermatologist at Day 01 (before application), Day 04 and Day 08 (+ 2 days).

	3. To evaluate the effectiveness of test product in reducing red spots/erythema by Dermatologist using 5-point grading scale at Day 01 (before application and 30 mins (+15 mins) after application), Day 04 and Day 08 (+ 2 days). 4. To assess the effect of test product on uneven skin tone using Felix Von Luschan Skin colour chart at Day 01 (before application) and Day 08 (+ 2 days). 5. To assess the effect of test product on skin roughness by Dermatologist using 5-point grading scale at Day 01 (before application) and Day 08 (+ 2 days). 6. To evaluate the effectiveness of test product on skin sebum level using Sebumeter® SM 815 at Day 01 (before application and 30 mins (+15 mins) after application) and Day 08 (+ 2 days). 7. To assess the effect of test product on Skin Moisturization using MoistureMeterSC at Day 01 (before application and 30 mins (+15 mins) after application) and Day 08 (+ 2 days). 8. To evaluate the effectiveness of test product in Restoring/ Improving the skin barrier function by measuring Transepidermal Water Loss (TEWL) using Vapometer at Day 01 (before application) and Day 08 (+ 2 days). 9. To assess the effect of test product on Skin Gloss/Glow using Skin-Glossymeter GL 200 at Day 01 (before application) and Day 08 (+ 2 days). 10. To evaluate the effect of test product on porphyrins using Visiopor® PP 34N at Day 01 (before application), Day 04 and Day 08 (+ 2 days). 11. To evaluate the effectiveness of test product on pores (total volume, density, count and porosity index), acne (volume and area of acne), skin brightness/fairness (L* and ITA), erythema (a* value), skin texture (roughness) and acne marks/spots (average concentration of melanin) using 3D analysis system (Antera) at Day 01 [before application and 30 mins (+15 mins) after application (only for erythema)], Day 04 (only for erythema and acne marks/spots) and Day 08 (+ 2 days). 12. To assess the Subject Satisfaction Questionnaire after product usage at Day 01 (30 mins post application), Day 04 and Day 08 (+ 2 days).

	Safety: Safety was assessed by incidence of undesirable /adverse event reported: Either self-reported by subject or assessed by Investigator.
Statistical Methods:	The statistical analysis was done by using SAS® statistical software (Version: 9.4 or higher; SAS Institute Inc., USA). For Primary Endpoints: 1. For assessment of the appearance of acne scar using 6-point grading scale for size of scar, Acne Scar Assessment Scale for depth of scar and 9-point grading scale for discoloration of scar: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 08 (+ 2 days). CFB and % CFB along with Wilcoxon sign rank test was used to analyze the data. 2. For assessment of acne reduction using Investigator's Global Assessment (IGA) Scale for Acne Vulgaris and counting of inflammatory *(papules & pustules)* and non-inflammatory *(i.e., blackheads and whiteheads)* lesions: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 08 (+ 2 days). CFB and % CFB along with Wilcoxon sign rank test was used to analyze the data. For Secondary Endpoints: 1. For assessment of preventing the appearance of new acne by using Investigator's Global Assessment (IGA) Scale for Acne Vulgaris and counting of inflammatory *(papules & pustules)* and non-inflammatory *(i.e., blackheads and whiteheads)* lesions: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 08 (+ 2 days). CFB and % CFB along with Wilcoxon sign rank test was used to analyze the data. 2. For assessment of the visibility of acne marks by assessing pigmentation using 9-point scale: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 04, Day 08 (+ 2 days). CFB and % CFB along with Wilcoxon sign rank test was used to analyze the data.

	3. For assessment of red spots/erythema using 5-point grading scale: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 01 (30 mins (+15 mins) after application), Day 04, Day 08 (+ 2 days). CFB and % CFB along with Wilcoxon sign rank test was used to analyze the data. 4. For assessment of uneven skin tone using Felix Von Luschan Skin colour chart: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 08 (+ 2 days). CFB and % CFB along with Wilcoxon sign rank test was used to analyze the data. 5. For assessment of skin roughness using 5-point grading scale: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 08 (+ 2 days). CFB and % CFB along with Wilcoxon sign rank test was used to analyze the data. 6. For assessment of skin sebum level using Sebumeter® SM 815: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 01 (30 mins (+15 mins) after application), Day 08 (+ 2 days). CFB and % CFB along with Paired t-test was used to analyze the data. 7. For assessment of Skin Moisturization using MoistureMeterSC: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 01 (30 mins (+15 mins) after application), Day 08 (+ 2 days). CFB and % CFB along with Paired t-test was used to analyze the data. 8. For assessment of the skin barrier function by measuring Transepidermal Water Loss (TEWL) using Vapometer: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 08 (+ 2 days). CFB and % CFB along with Paired t-test was used to analyze the data. 9. For assessment of Skin Gloss/Glow using Skin-Glossymeter GL 200: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 08 (+ 2 days). CFB and % CFB along with Paired t-test was used to analyze the data.

	10. For assessment of porphyrins using Visiopor® PP 34N: Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 04, Day 08 (+ 2 days). CFB and % CFB along with Paired t-test was used to analyze the data. 11. For assessment of pores (total volume, density, count and porosity index), acne (volume and area of acne), skin brightness/fairness (L* and ITA), erythema (a* value), skin texture (roughness) and acne marks/spots (average concentration of melanin) using 3D analysis system (Antera): Data obtained was used to analyze the mean change from baseline (before application at Day 01) to Day 01 [30 mins (+15 mins) after application (only for erythema)], Day 04 (only for erythema and acne marks/spots), Day 08 (+ 2 days). CFB and % CFB along with Paired t-test was used to analyze the data. 12. For assessment of Subject Satisfaction Questionnaire after product usage at Day 01 (30 mins post application), Day 04, Day 08 (+ 2 days). Data obtained was summarized with a count and the percentage. Safety endpoints were listed only, no statistical calculation was performed on it. All statistical tests used significance level of $\alpha \leq 0.05$. Two tailed tests were performed for all analysis that used statistical testing.
Date of Report: 12 Oct 23	

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RECORD RETENTION AND PUBLICATION POLICY

4. EFFICACY EVALAUTION

4.1. Data Sets Analyzed

A total of 20 subjects were enrolled in this study and all 20 subjects have completed Visit 03 (Day 08 + 2 days). The data of all 20 subjects who completed Visit 03 was analysed.

4.2. Demographic and Other Baseline Characteristics

Summary of Demographic Characteristics		
Variables		**(N=20)**
Gender n (%)	Female	12
	Male	8
Race n (%)	Asian	20
Age (Years)	n	20
	Mean (SD)	21.4 (6.29)
	Median	21.5
	Min, Max	12, 29

There were 8 males and 12 females; age of the subjects ranged from 12 to 29 years with average being 21.4 years.

4.3. Efficacy Results and Tabulations

4.3.1. Assessment of the appearance of post acne scar using 6-point grading scale for size of scar, Acne Scar Assessment Scale for depth of scar and 9-point grading scale for discoloration of scar.

Descriptive Statistics

		Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Parameters	**Statistics**	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
Size of post acne scar	**N**	20	20	20	20
	Mean	2.3	2.1	-0.2	-8.3
	StdDev	0.44	0.51	0.41	17.52
	p Value	---	0.1250 (NS)		
Depth of post acne scar	**N**	20	20	20	20
	Mean	2.4	2.3	-0.2	-5.0
	StdDev	0.50	0.44	0.37	12.21
	p Value	---	0.2500 (NS)		
Discoloration of post acne scar	**N**	20	20	20	20
	Mean	2.3	1.9	-0.5	-17.1
	StdDev	0.73	0.59	0.51	20.32
	p Value	---	0.0039*		

*NS = Statistically Not Significant; * = Statistically Significant*

Size of post acne scar was assessed using 6-point grading scale; where 0 = Clear (No Visible Scars from Acne); 1 = Almost Clear (Hardly visible scars from 2.5m away); 2 = Mild (Easily recognizable; less than half the affected area involved); 3 = Moderate (More than half the affected area involved; 4 = Severe (Entire area involved); 5 = Very Severe (Entire area with prominent atrophic or hypertropic scars)

Depth of post acne scar was assessed using Acne Scar Assessment Scale; where 0 = Clear (No depressions are seen in the treatment area. Macular discoloration may be seen); 1 = Very Mild [A single depression is easily noticeable with direct lightening (deep). Most or all of the depressions seen are only readily apparent with tangential lightening (shallow)]; 2 = Mild [A few to several, but less than half of all the depressions are easily noticeable with direct lightening (deep). Most of the depressions seen are only readily apparent with tangential

lightening (shallow)]; 3 = Moderate [More than half of the depressions are apparent with direct lightening (deep)]; 4 = Severe [All or almost all the lesions can be seen with direct lightening (deep)]

Discoloration of scar was assessed using 9-point grading scale; where -4 = Strongly lighter in color than normal skin; -3 = Markedly lighter in color than normal skin; -2 = Moderately lighter in color than normal skin; -1 = Slightly lighter in color than normal skin; 0 = No difference in color than normal skin; 1 = Slightly darker in color than normal skin; 2 = Moderately darker in color than normal skin; 3 = Markedly darker in color than normal skin; 4 = Strongly darker in color than normal skin

Clinical Interpretation:

For assessment of size of post acne scar

After using the test product for 07 days, the score of 6-point grading scale showed no significant change in size of post acne scar on Day 08, as compared to baseline.

For assessment of depth of post acne scar

After using the test product for 07 days, the score of acne scar assessment scale showed no significant change in depth of post acne scar on Day 08, as compared to baseline.

For assessment of discoloration of post acne scar

After using the test product for 07 days, the score of 9-point scale showed statistically significant reduction in the visibility of discoloration of post acne scar 17.1% on Day 08 *(p value 0.0039)*, as compared to baseline.

The results indicated that there was 17.1% lightening of post acne scar on use for 07 days. The above data also indicated that the test product is effective in lightening the post acne scar in 1 week with significant results.

Also, there was no effect of test product on the size and depth of post acne scar on use for 07 days.

4.3.2. Assessment of acne reduction and prevention in the appearance of new acne by using Investigator's Global Assessment (IGA) Scale for Acne Vulgaris and counting of inflammatory and non-inflammatory lesions.

A. Assessment of acne reduction and prevention in the appearance of new acne by using Investigator's Global Assessment (IGA) Scale for Acne Vulgaris.

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	**Visit 03: Day 08 (+ 2 days)** *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
N	20	20	20	20
Mean	2.1	1.8	-0.3	-13.3
StdDev	0.31	0.41	0.47	21.36
p Value	---	0.0313*		

** = Statistically Significant*

Acne reduction and prevention in the appearance of new acne was assessed using Investigator's Global Assessment (IGA) Scale; where 0 = Clear skin (No inflammatory or non-inflammatory lesions); 1 = Almost clear (Rare non-inflammatory lesions with no more than one small inflammatory lesion); 2 = Mild severity (Greater than Grade 1; some non-inflammatory lesions with no more than a few inflammatory lesions (papules/pustules only, no nodular lesions)); 3 = Moderate severity (Greater than Grade 1; some-to-many non-inflammatory lesions and possibly some inflammatory lesions, but no more than one small nodular lesion); 4 = Severe (Greater than Grade 3; some-to-many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions); 5 = Very severe (Greater than Grade 4; many non-inflammatory and/or inflammatory lesions with some or many nodular lesions)

B. Assessment of acne reduction and prevention in the appearance of new acne by counting of inflammatory (papules & pustules) and non-inflammatory (i.e., blackheads and whiteheads) lesions

Descriptive Statistics

		Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Parameters	**Statistics**	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
Total Number of Inflammatory Acne Lesions	**N**	20	20	20	18
	Mean	4.1	3.1	-1.1	-23.6
	StdDev	3.40	2.16	1.76	26.31
	p Value	---	0.0153*		
Total Number of Non-Inflammatory Acne Lesions	**N**	20	20	20	20
	Mean	15.2	8.0	-7.2	-48.8
	StdDev	9.69	5.46	4.83	19.32
	p Value	---	<0.0001*		

** = Statistically Significant*

Clinical Interpretation:

For assessment of acne reduction and prevention in the appearance of new acne by using Investigator's Global Assessment (IGA) Scale for Acne Vulgaris

After using the test product for 07 days, the Investigator's Global Assessment (IGA) score showed statistically significant reduction by 13.3% on Day 08 *(p value 0.0313)*, as compared to baseline.

Since there was no increase in the Investigator's Global Assessment (IGA) score as compared to baseline, indicating that no new acne lesions appeared during the course of the study. This also indicated that the test product is effective in preventing the appearance of new acne lesions.

On the other hand, there was 13.3% reduction in the severity of acne lesions on use for 07 days. The above data also indicated that the test product is effective in reducing the severity of acne lesions in 1 week with significant results.

For assessment of acne reduction and prevention in the appearance of new acne by counting the inflammatory and non-inflammatory lesions.

After using the test product for 07 days, the counting of inflammatory acne lesions showed statistically significant reduction by 23.6% on Day 08 *(p value 0.0153)* and the counting of non-inflammatory acne lesions showed statistically significant reduction by 48.8% on Day 08 *(p value <0.0001)*, as compared to baseline.

Since there was no increase in the mean count of inflammatory and non-inflammatory acne lesions as compared to baseline, indicating that no new acne lesions appeared during the course of the study. This also indicated that the test product is effective in preventing the appearance of new acne lesions.

On the other hand, there was 23.6% reduction in the count of inflammatory acne lesions and 48.8% reduction in the count of non-inflammatory acne lesions on use for 07 days. The above data also indicated that the test product is effective in reducing the number of inflammatory and non-inflammatory acne lesions in 1 week with significant results.

4.3.3. Assessment of visibility of acne marks by assessing pigmentation using 9-point scale.

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	**Visit 02: Day 04** *Evaluation phase*			**Visit 03: Day 08 (+ 2 days)** *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**	**Post Baseline**	**CFB**	**%CFB**
N	20	20	20	20	20	20	20
Mean	2.2	2.2	0.1	2.5	1.7	-0.5	-20.4
StdDev	0.75	0.77	0.22	11.18	0.67	0.61	27.37
p Value	---	1.0000 (NS)			0.0063*		

*NS = Statistically Not Significant; * = Statistically Significant*

Pigmentation was assessed using a 9-point scale; where -4 = Strongly lighter in color than normal skin; -3 = Markedly lighter in color than normal skin; -2 = Moderately lighter in color than normal skin; -1 = Slightly lighter in color than normal skin; 0 = No difference in color than normal skin; 1 = Slightly darker in color than normal skin; 2 = Moderately darker in color than normal skin; 3 = Markedly darker in color than normal skin; 4 = Strongly darker in color than normal skin

Clinical Interpretation:

After using the test product for 07 days, the score of 9-point scale showed statistically significant reduction in the visibility of acne marks by 20.4% on Day 08 *(p value 0.0063)*, as compared to baseline. There was no significant change in the visibility of acne marks on Day 04 *(i.e., after using the test product for 03 days)*.

The results indicated that there was a 20.4% reduction in the visibility of acne marks on use for 07 days. The above data also indicated that the test product is effective in reducing the visibility of acne marks in 1 week with significant results.

4.3.4. Assessment of red spots/erythema using 5-point grading scale.

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	**Visit 01: Day 01** *Evaluation at 30 mins (+15 mins) after application*			**Visit 02: Day 04** *Evaluation phase*			**Visit 03: Day 08 (+ 2 days)** *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**	**Post Baseline**	**CFB**	**%CFB**	**Post Baseline**	**CFB**	**%CFB**
N	20	20	20	20	20	20	20	20	20	20
Mean	2.5	1.7	-0.9	-31.7	1.7	-0.9	-31.7	1.0	-1.5	-60.0
StdDev	0.51	0.59	0.75	26.44	0.59	0.75	26.44	0.73	0.76	25.59
p Value	---	0.0002*			0.0002*			<0.0001*		

** = Statistically Significant*

Severity of red spots/erythema was assessed using a 5-point scale; where 0 = Clear with no signs of erythema; 1 = Almost clear; slight redness, 2 = Mild erythema; definite redness; 3 = Moderate erythema; marked redness and 4 = Severe erythema; fiery redness.

Clinical Interpretation:

After using the test product for 07 days, the score of 5-point scale showed statistically significant reduction in severity of red spots/erythema by 31.7% 30 mins after product application *(p value 0.0002)*, 31.7% on Day 04 *(p value 0.0002)* and 60.0% on Day 08 *(p value <0.0001)*, as compared to baseline.

The results indicated that there was 60.0% reduction in the severity of red spots/erythema on use for 07 days. The above data also indicated that the test product is effective in reducing the severity of red spots/erythema within 30 mins with significant results.

4.3.5. Assessment of uneven skin tone using Felix Von Luschan Skin colour chart

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	**Visit 03: Day 08 (+ 2 days)** *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
N	20	20	20	20
Mean	27.2	26.9	-0.3	-1.1
StdDev	1.01	1.02	0.47	1.71
p Value	---	0.0102*		

** = Statistically Significant*

Clinical Interpretation:

After using the test product for 07 days, the score of Felix Von Luschan Skin colour chart showed statistically significant reduction in the score by 1.1% on Day 08 *(p value 0.0102)*, as compared to baseline.

The results indicated that there was 1.1% reduction in the score of uneven skin tone on use for 07 days. The above data also indicated that the test product is effective in making the skin tone even in 1 week with significant results.

4.3.6. Assessment of skin roughness using a 5-point grading scale.

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	**Visit 03: Day 08 (+ 2 days)** *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
N	20	20	20	20
Mean	1.6	1.3	-0.4	-20.0
StdDev	0.50	0.55	0.49	29.91
p Value	---	0.0156*		

** = Statistically Significant*

Skin roughness was assessed using a 5-point grading scale; where 0 = Absent (Perfectly smooth and pliable) ; 1 = Slight (Slightly irregular and scratchy on tangential tactile evaluation); 2 = Moderate (Definitely irregular and scratchy and possibly slightly stiffened on vertical tactile evaluation); 3 = Severe (Advanced irregularly and scratchy feeling associated with some stiffening); 4 = Extreme (Gross irregularity and major disturbance of skin marking and definite stiffening)

Clinical Interpretation:

After using the test product for 07 days, the score of 5-point grading scale showed statistically significant reduction in skin roughness by 20.0% on Day 08 *(p value 0.0156)*, as compared to baseline.

The results indicated that there was a 2.0% reduction in skin roughness on use for 07 days. The above data also indicated that the test product is effective in reducing the skin roughness in 1 week with significant results.

4.3.7. Assessment of skin sebum level using Sebumeter® SM 815

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 01: Day 01 *Evaluation at 30 mins (+15 mins) after application*			Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**	**Post Baseline**	**CFB**	**%CFB**
N	20	20	20	20	20	20	20
Mean	217.106	213.042	-4.064	-1.884	208.139	-8.967	-4.157
StdDev	10.5662	10.9881	1.3305	0.6555	11.4388	1.5080	0.8298
p Value	---	<0.0001*			<0.0001*		

** = Statistically Significant*

Clinical Interpretation:

After using the test product for 07 days, the Sebumeter readings showed statistically significant reduction in skin sebum level by 1.89% 30 mins after product application *(p value <0.0001)* and 4.16% on Day 08 *(p value <0.0001)*, as compared to baseline.

The results indicated that there was 4.16% reduction in skin sebum level on use for 07 days. The above data also indicated that the test product is effective in reducing the skin sebum level in 1 week with significant results.

4.3.8. Assessment of Skin Moisturization using MoistureMeterSC.

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 01: Day 01 *Evaluation at 30 mins (+15 mins) after application*			Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**	**Post Baseline**	**CFB**	**%CFB**
N	20	20	20	20	20	20	20
Mean	35.27	37.80	2.53	7.18	40.56	5.29	15.06

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 01: Day 01 *Evaluation at 30 mins (+15 mins) after application*			Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**	**Post Baseline**	**CFB**	**%CFB**
StdDev	1.246	1.231	0.467	1.391	0.987	0.698	2.386
p Value	---	<0.0001*			<0.0001*		

** = Statistically Significant*

Clinical Interpretation:

After using the test product for 07 days, the MoistureMeterSC readings showed statistically significant improvement in skin moisturization/hydration by 7.18% 30 mins after product application *(p value <0.0001)* and 15.06% on Day 08 *(p value <0.0001)*, as compared to baseline.

The results indicated that there was 15.06% improvement in skin moisturization/hydration on use for 07 days. The above data also indicated that the test product is effective in improving the skin moisturization/hydration in 1 week with significant results.

4.3.9. Assessment of skin barrier function by measuring Transepidermal Water Loss (TEWL) using Vapometer.

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
N	20	20	20	20
Mean	10.65	9.95	-0.70	-6.56
StdDev	0.668	0.614	0.130	1.076
p Value	---	<0.0001*		

** = Statistically Significant*

Clinical Interpretation:

After using the test product for 07 days, the Vapometer readings showed statistically significant reduction in trans-epidermal water loss by 6.56% on Day 08 *(p value <0.0001)*, as compared to baseline.

The results indicated that there was 6.56% reduction in trans-epidermal water loss on use for 07 days. It can also be stated that the test product provides a protective layer on top of the skin thereby reducing the trans-epidermal water loss and maintaining healthy skin condition. Above data also indicates that the test product is effective in improving the skin barrier function in 1 week with significant results.

4.3.10. Assessment of Skin Gloss/Glow using Skin-Glossymeter GL 200.

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	**Visit 03: Day 08 (+ 2 days)** *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
N	20	20	20	20
Mean	1.265	1.315	0.050	4.342
StdDev	0.3599	0.3579	0.0086	1.6114
p Value	---	<0.0001*		

** = Statistically Significant*

Clinical Interpretation:

After using the test product for 07 days, the Glossymeter readings showed statistically significant improvement in skin gloss/glow by 4.34% on Day 08 *(p value <0.0001)*, as compared to baseline.

The results indicated that there was 4.34% improvement in skin gloss/glow on use for 07 days. The above data also indicated that the test product is effective in improving the skin gloss/glow in 1 week with significant results.

4.3.11. Assessment of porphyrins using Visiopor® PP 34N.

Descriptive Statistics

		Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 02: Day 04 *Evaluation phase*			Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Parameters	**Statistics**	**Baseline**	**Post Baseline**	**CFB**	**%CFB**	**Post Baseline**	**CFB**	**%CFB**
Size	**N**	20	20	20	20	20	20	20
	Mean	0.614	0.580	-0.034	-10.927	0.549	-0.065	-19.924
	StdDev	0.9842	0.9434	0.0444	4.7763	0.9027	0.0823	8.1009
	p Value	---	0.0028*			0.0024*		
Quantity	**N**	20	20	20	20	20	20	20
	Mean	8.7	7.5	-1.2	-14.6	7.0	-1.8	-19.7
	StdDev	6.38	5.75	0.70	6.02	5.23	1.29	8.69
	p Value	---	<0.0001*			<0.0001*		
Value	**N**	20	20	20	20	20	20	20
	Mean	147.0	140.1	-6.9	-4.6	128.4	-18.6	-12.8
	StdDev	23.36	21.58	2.29	1.03	21.59	3.22	1.84
	p Value	---	<0.0001*			<0.0001*		

** = Statistically Significant*

Clinical Interpretation:

For Porphyrins Size (%)

After using the test product for 07 days, the Visiopor readings showed statistically significant reduction in porphyrins size by 10.93% on Day 04 *(p value 0.0028)* and 19.92% on Day 08 *(p value 0.0024)*, as compared to baseline.

For Quantity of Porphyrins (a.u.)

After using the test product for 07 days, the Visiopor readings showed statistically significant reduction in the quantity of porphyrins by 14.6% on Day 04 *(p value <0.0001)* and 19.7% on Day 08 *(p value <0.0001)*, as compared to baseline.

For Porphyrins Value (a.u.)

After using the test product for 07 days, the Visiopor readings showed statistically significant reduction in porphyrins value by 4.6% on Day 04 *(p value <0.0001)* and 12.8% on Day 08 *(p value <0.0001)*, as compared to baseline.

The results indicated that there was a 19.92%, 19.7% and 12.8% reduction in the size of porphyrins, quantity of porphyrins and porphyrins value, respectively, on use for 07 days. The above data also indicated that the test product is effective in reducing the porphyrins in 3 days with significant results

4.3.12. Assessment of pores, acne, skin brightness/fairness, erythema, skin texture and acne marks/spots using 3D analysis system (Antera).

A. Assessment of Pores

Descriptive Statistics

		Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Parameters	**Statistics**	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
Total Volume (mm^3)	**N**	19	20	19	19
	Mean	8.9	7.1	-1.7	-19.4
	StdDev	3.35	2.86	0.67	5.05
	p Value	---	<0.0001*		
Density (number of pores/mm^2)	**N**	19	20	19	19
	Mean	49.0	41.2	-7.2	-16.1
	StdDev	17.18	16.22	1.28	5.04
	p Value	---	<0.0001*		
Count	**N**	19	20	19	19
	Mean	133.8	115.6	-17.9	-14.3
	StdDev	40.00	37.96	3.67	4.05
	p Value	---	<0.0001*		

		Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Parameters	**Statistics**	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
Porosity index (a.u.)	**N**	19	20	19	19
	Mean	8.3	6.6	-1.6	-20.0
	StdDev	2.21	1.94	0.67	7.72
	p Value	---	<0.0001*		

** = Statistically Significant*

B. Assessment of Acne

Descriptive Statistics

		Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Parameters	**Statistics**	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
Volume of acne (mm^3)	**N**	19	20	19	19
	Mean	8.3	7.0	-1.5	-17.2
	StdDev	2.24	2.01	0.68	6.79
	p Value	---	<0.0001*		
Area of acne (mm^2)	**N**	19	20	19	19
	Mean	27.0	25.7	-3.6	-17.0
	StdDev	22.07	22.68	2.17	6.87
	p Value	---	<0.0001*		

** = Statistically Significant*

C. Assessment of Skin Brightness/Fairness

Descriptive Statistics

		Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Parameters	**Statistics**	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
L* value (a.u.)	**N**	19	20	19	19
	Mean	54.6	55.3	1.2	2.3
	StdDev	5.18	5.51	0.53	1.01
	p Value	---	<0.0001*		
ITA^0	**N**	19	20	19	19
	Mean	11.3	12.9	2.8	125.8
	StdDev	11.77	13.49	2.24	395.93
	p Value	---	0.0010*		

** = Statistically Significant*

D. Assessment of erythema (a* value) (a.u.)

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 01: Day 01 *Evaluation at 30 mins (+15 mins) after application*			Visit 02: Day 04 *Evaluation phase*			Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**	**Post Baseline**	**CFB**	**%CFB**	**Post Baseline**	**CFB**	**%CFB**
N	19	20	19	19	20	19	19	20	19	19
Mean	13.2	12.4	-0.8	-6.4	11.3	-2.0	-14.9	10.1	-3.2	-24.2
StdDev	1.82	1.66	0.31	2.19	1.72	0.69	5.24	1.93	1.03	8.34
p Value	---	<0.0001*			<0.0001*			<0.0001*		

** = Statistically Significant*

E. Assessment of skin texture (Ra) (a.u.)

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**
N	19	20	19	19
Mean	9.6	8.8	-1.3	-14.4
StdDev	2.92	3.48	0.56	5.70
p Value	---	<0.0001*		

** = Statistically Significant*

F. Assessment of acne marks/spots (average concentration of melanin) (a.u.)

Descriptive Statistics

	Visit 01: Day 01 *Screening and Enrollment and Baseline Visit*	Visit 02: Day 04 *Evaluation phase*			Visit 03: Day 08 (+ 2 days) *Evaluation phase*		
Statistics	**Baseline**	**Post Baseline**	**CFB**	**%CFB**	**Post Baseline**	**CFB**	**%CFB**
N	19	20	19	19	20	19	19
Mean	56.6	55.5	-1.4	-2.5	54.1	-2.9	-5.1
StdDev	8.45	8.30	0.64	1.17	8.18	0.82	1.48
p Value	---	<0.0001*			<0.0001*		

** = Statistically Significant*

Clinical Interpretation:

For Pores (Total Volume, Pore Density, Count, Porosity Index)

After using the test product for 07 days,

- the total volume of pores showed statistically significant reduction by 19.4% on Day 08 *(p value <0.0001)*, as compared to baseline.
- the pore density showed statistically significant reduction by 16.1% on Day 08 *(p value <0.0001)*, as compared to baseline.
- the pore count showed statistically significant reduction by 14.3% on Day 08 *(p value <0.0001)*, as compared to baseline.
- the porosity index showed statistically significant reduction by 20.0% on Day 08 *(p value <0.0001)*, as compared to baseline.

The results indicated that there was 19.4%, 16.1%, 14.3% and 20.0% reduction in the total volume of pores, pore density, pore count and porosity index, respectively, on use for 07 days. The above data also indicated that the test product is effective in reducing the severity of facial pores in 1 week with significant results.

For Acne (Volume and Area of Acne)

After using the test product for 07 days,

- the volume of acne showed statistically significant reduction by 17.2% on Day 08 *(p value <0.0001)*, as compared to baseline.
- the area of acne showed statistically significant reduction by 17.0% on Day 08 *(p value <0.0001)*, as compared to baseline.

The results indicated that there was more than 17% reduction in the volume ad area of acne on use for 07 days. The above data also indicated that the test product is effective in reducing the size of acne in 1 week with significant results.

For Skin Brightness/Fairness (L value and ITA^0)*

After using the test product for 07 days,

- the L* value showed statistically significant increase by 2.3% on Day 08 *(p value <0.0001)*, as compared to baseline.
- the ITA^0 showed statistically significant increase by more than 100% on Day 08 *(p value 0.0010)*, as compared to baseline.

The results indicated that there was 2.3% and more than 100% increase in L* value and ITA^0, respectively, on use for 07 days. The above data also indicated that the test product is effective in improving the skin brightness/fairness in 1 week with significant results.

For Erythema i.e., a value*

After using the test product for 07 days, the a* value showed statistically significant reduction by 6.4% 30 mins after product application *(p value <0.0001)*, 14.9% on Day 04 *(p value <0.0001)* and 24.2% on Day 08 *(p value <0.0001)*, as compared to baseline.

The results indicated that there was 24.2% reduction in the red spots/erythema on use for 07 days. The above data also indicated that the test product is effective in reducing the red spots/erythema within 30 mins with significant results.

For Skin Texture (Ra)

After using the test product for 07 days, the Ra value showed statistically significant reduction in skin roughness by 14.4% on Day 08 *(p value <0.0001)*, as compared to baseline.

The results indicated that there was 14.4% reduction in skin roughness on use for 07 days. The above data also indicated that the test product is effective in improving the skin texture by reducing the skin roughness in 1 week with significant results.

For Acne Marks/Spots (Average Concentration of Melanin)

After using the test product for 07 days, the average concentration of melanin showed statistically significant reduction by 2.5% on Day 04 *(p value <0.0001)* and 5.1% on Day 08 *(p value <0.0001)*, as compared to baseline.

The results indicated that there was 5.1% lightening of acne marks/spots on use for 07 days. The above data also indicated that the test product is effective in lightening the acne marks/spots in 3 days with significant results.

4.3.13. Assessment of Subject Satisfaction Questionnaire

Frequency and Percentage for Day 01 (30 mins (+15 mins).

Question	Visit	Response	Count (Percent)
1. The test product helped in reducing the skin sebum level	Visit 01: Day 01 Evaluation at 30 mins (+15 mins) post product use	Agree	20 (100%)
2. The test product helped in moisturizing my skin.	Visit 01: Day 01 Evaluation at 30 mins (+15 mins) post product use	Agree	20 (100%)
3. The test product does not make my skin feel dry.	Visit 01: Day 01 Evaluation at 30 mins (+15 mins) post product use	Agree	20 (100%)
4. The test product helped in reducing the red spots/erythema.	Visit 01: Day 01 Evaluation at 30 mins (+15 mins) post product use	Agree	20 (100%)

Frequency and Percentage for Day 04.

Question	Visit	Response	Count (Percent)
1. The test product helped in reducing the visibility of acne marks/spots.	Visit 02 (Day 04)	Agree	20 (100%)
2. The test product helped in reducing the red spots/erythema.	Visit 02 (Day 04)	Agree	20 (100%)

Frequency and Percentage for Day 08 (+ 2 days).

Question	Visit	Response	Count (Percent)
1. The test product helped in minimizing the appearance of post-acne scar.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
2. The test product helped in reducing the visibility of acne lesions.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
3. The test product helped in preventing future acne breakouts.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
4. The test product helped in improving the skin texture.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
5. The test product helped in making the skin smoother.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
6. The test product helped in making the skin tone even.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
7. The test product helped in reducing the skin’s oiliness.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)

Question	Visit	Response	Count (Percent)
8. The test product helped in making the skin look radiant.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
9. The test product helped in moisturizing my skin.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
10. The test product helped in retaining my skin's moisture.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
11. The test product does not make my skin feel dry.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
12. The test product helped in reducing the visibility of facial pores.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
13. The test product helped in reducing the red spots/erythema.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
14. The test product helped in reducing the visibility of acne marks/spots.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
15. The test product provided soothing effect on acne lesions and surrounding area.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
16. The test product makes the skin look clearer and healthier.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)
17. The test product improves skin's overall appearance.	Visit 03 (Day 08 + 2 Days)	Agree	20 (100%)

Clinical Interpretation:

After 30 mins of product application,

100% subjects agree that the test product helped in reducing the skin sebum level; helped in moisturizing their skin; did not make my skin feel dry and helped in reducing the red spots/erythema.

After using the test product for 03 Days,

100% subjects agree that the test product helped in reducing the visibility of acne marks/spots and helped in reducing the red spots/erythema.

After using the test product for 07 Days,

100% subjects agree that the test product helped in minimizing the appearance of post-acne scar; helped in reducing the visibility of acne lesions and in preventing future acne breakouts; helped in improving the skin texture and making the skin smoother; helped in making the skin tone even and skin look radiant; helped in reducing the skin's oiliness; helped in moisturizing their skin and also in retaining their skin's moisture; did not make their skin feel dry; helped in reducing the visibility of

facial pores; helped in reducing the red spots/erythema; helped in reducing the visibility of acne marks/spots; provided soothing effect on acne lesions and surrounding area, makes the skin look clearer and healthier and improves skin's overall appearance.

5. SAFETY EVALAUTIONS

5.1. Adverse Events

There was no local intolerance observed in any of the study subjects during the study period confirming the safety of the test product and no adverse events were neither reported nor observed during the course of the study.

6. DISCUSSION AND CONCLUSION

In this study, the objective was to evaluate the safety, in-use tolerability and efficacy of test product in terms of reduction in the appearance of post acne scar in terms of size, depth & discoloration using 6-point grading scale, Acne Scar Assessment Scale and 9-point grading scale, respectively, by Dermatologist; reduction in the severity and number of existing acne lesions using Investigator's Global Assessment (IGA) Scale and counting of inflammatory & non inflammatory acne lesions, respectively, by Dermatologist; Prevention of the appearance of new acne using Investigator's Global Assessment (IGA) Scale and counting of inflammatory & non inflammatory acne lesions, by Dermatologist; reduction in the visibility of marks using 9-point scale and red spots/erythema using 5-point grading scale by Dermatologist and 3D Analysis System (Antera); improvement in the skin tone evenness using Felix Von Luschan Skin colour chart by Dermatologist; improvement in skin roughness using 5-point grading scale by Dermatologist, reduction in the skin sebum level using Sebumeter® SM 815, improvement in skin moisturization using MoistureMeterSC, improvement in the skin barrier function by measuring TEWL using Vapometer, improvement in the skin gloss/glow using Skin-Glossymeter GL 200, reduction in the porphyrins using Visiopor® PP 34N and reduction in the severity of facial pores, in improving the skin texture in terms of roughness, in improving the skin brightness/fairness and in reducing the size of acne in terms of area and volume using 3D analysis system (Antera).

On the basis of the overall clinical evaluation and statistical analyses of the data of 20 subjects, the results obtained from the conduct of the study are as below:

After 30 mins of product application,

- Assessment of severity of red spots/erythema by Dermatologist using 5-point scale showed statistically significant reduction in the score by 31.7% *(p value 0.0002)*. **This clinically indicates that the test product helps in reducing the severity of red spots/erythema.**
- Assessment of skin sebum level using Sebumeter® SM 815 showed statistically significant reduction in skin sebum level by 1.89% *(p value <0.0001)*. **This clinically indicates that the test product helps in reducing the skin sebum level.**
- Assessment of Skin Moisturization/Hydration using MoistureMeterSC showed statistically significant improvement in skin moisturization/hydration by 7.18% *(p value*

<0.0001). **This clinically indicates that the test product helps in improving the skin moisturization/hydration.**

- Assessment of erythema of acne performed using 3D analysis system (Antera) showed statistically significant reduction by 6.4% *(p value <0.0001)*. **This clinically indicates that the test product helps in reducing the red spots/erythema.**
- Based on Subjective Questionnaire, 100% subjects agree that the test product helped in reducing the skin sebum level; helped in moisturizing their skin; did not make my skin feel dry and helped in reducing the red spots/erythema.

After using the test product for 03 Days (i.e., on Day 04),

- Assessment of severity of red spots/erythema by Dermatologist using 5-point scale showed statistically significant reduction in the score by 31.7% *(p value 0.0002)*. **This clinically indicates that the test product helps in reducing the severity of red spots/erythema.**
- Assessment of porphyrins performed using Visiopor showed statistically significant reduction in porphyrins size by 10.93% *(p value 0.0028)*, in the quantity of porphyrins by 14.6% *(p value <0.0001)* and in porphyrins value by 4.6% *(p value <0.0001)*. **This clinically indicates that the test product helps in reducing the porphyrins.**
- Assessment of erythema of acne performed using 3D analysis system (Antera) showed statistically significant reduction by 14.9% *(p value <0.0001)*. **This clinically indicates that the test product helps in reducing the red spots/erythema.**

  Assessment of average concentration of Melanin performed using 3D analysis system (Antera) showed significant reduction in the melanin concentration by 2.5% *(p value <0.0001)*. **This clinically indicates that the test product helps in lightening of acne marks/spots.**
- Based on Subjective Questionnaire, 100% subjects agree that the test product helped in reducing the visibility of acne marks/spots and helped in reducing the red spots/erythema.

After using the test product for 07 Days (i.e., on Day [illegible]),

- Assessment of discoloration of post acne scar using 9-point scale showed statistically significant reduction in the visibility of discoloration of post acne scar 17.1% *(p value 0.0039)*. **This clinically indicates that the test product helps in lightening the post acne scar.**

- Assessment of acne reduction and prevention in the appearance of new acne performed using Investigator's Global Assessment (IGA) score by Dermatologist showed statistically significant reduction by 13.3% *(p value 0.0313)*. **This clinically indicates that the test product helps in reducing the severity of acne lesions. Since the Investigator's Global Assessment (IGA) score has not increased, this clinically indicates that the test product helps in preventing the appearance of new acne lesions.**

  Assessment of acne reduction and prevention in the appearance of new acne performed by counting the number of inflammatory and non-inflammatory acne lesions showed statistically significant reduction in the number by 23.6% *(p value 0.0153)* and 48.8% *(p value <0.0001)*, respectively. **This clinically indicates that the test product helps in reducing the number of inflammatory and non-inflammatory acne lesions. Since the number of acne lesions has not increased, this clinically indicates that the test product helps in preventing the appearance of new acne lesions.**

- Assessment of visible reduction of acne marks by Dermatologist using 9-point scale showed statistically significant reduction in pigmentation by 20.4% *(p value 0.0063)*. **This clinically indicates that the test product helps in reducing the visibility of acne marks.**
- Assessment of severity of red spots/erythema by Dermatologist using 5-point scale showed statistically significant reduction in the score by 60.0% *(p value <0.0001)*. **This clinically indicates that the test product helps in reducing the severity of red spots/erythema.**
- Assessment of uneven skin tone using Felix Von Luschan Skin colour chart showed statistically significant reduction in the score by 1.1% *(p value 0.0102)*. **This clinically indicates that the test product helps in making the skin tone even.**
- Assessment of skin roughness using a 5-point grading scale showed statistically significant reduction in skin roughness by 20.0% *(p value 0.0156)*. **This clinically indicates that the test product helps in reducing skin roughness.**
- Assessment of skin sebum level using Sebumeter® SM 815 showed statistically significant reduction in skin sebum level by 4.16% *(p value <0.0001)*. **This clinically indicates that the test product helps in reducing the skin sebum level.**
- Assessment of Skin Moisturization/Hydration using MoistureMeterSC showed statistically significant improvement in skin moisturization/hydration by 15.06% *(p value*

<0.0001). **This clinically indicates that the test product helps in improving the skin moisturization/hydration.**

- Assessment of skin barrier function performed using Vapometer showed statistically significant improvement in TEWL readings by 6.56% *(p value <0.0001)*. **This clinically indicates that the test product provides a protective layer on top of the skin thereby reducing the trans-epidermal water loss and maintaining healthy skin condition.**
- Assessment of skin gloss/glow using Glossymeter GL 200 showed statistically significant improvement in skin gloss/glow by 4.34% *(p value <0.0001)*. **This clinically indicates that the test product helps in improving the skin gloss/glow.**
- Assessment of porphyrins performed using Visiopor showed statistically significant reduction in porphyrins size by 19.92% *(p value 0.0024)*, in the quantity of porphyrins by 19.7% *(p value <0.0001)* and in porphyrins value by 12.8% *(p value <0.0001)*. **This clinically indicates that the test product helps in reducing the porphyrins.**
- Assessment of total volume of pores, pore density, pore count and porosity index using 3D analysis system (Antera) showed statistically significant reduction in the total volume by 19.4%*(p value <0.0001)*, 16.1% *(p value <0.0001)*, 14.3% *(p value <0.0001)* and 20.0% *(p value <0.0001)*, respectively. **This clinically indicates that the test product helps in reducing the severity of facial pores.**

  Assessment of volume and area of acne performed using 3D analysis system (Antera) showed significant reduction in the volume by 17.2% *(p value <0.0001)* and 17.0% *(p value <0.0001)*, respectively. **This clinically indicates that the test product helps in reducing the size (in terms of volume and area) of acne.**

  Assessment of L* value and ITA^0 performed using 3D analysis system (Antera) showed significant increase by 2.3% *(p value <0.0001)* and by more than 100% *(p value 0.0010)*, respectively. **This clinically indicates that the test product helps in improving the skin brightness/fairness.**

  Assessment of erythema of acne performed using 3D analysis system (Antera) showed statistically significant reduction by 24.2% *(p value <0.0001)*. **This clinically indicates that the test product helps in reducing the red spots/erythema.**

  Assessment of skin texture in terms of reduction in skin roughness performed using 3D analysis system (Antera) showed significant reduction in Ra value by 14.4% *(p value*

<0.0001). **This clinically indicates that the test product helps in improving the skin texture.**

Assessment of average concentration of Melanin performed using 3D analysis system (Antera) showed significant reduction in the melanin concentration by 5.1% *(p value <0.0001)*. **This clinically indicates that the test product helps in lightening of acne marks/spots.**

- Based on Subjective Questionnaire, 100% subjects agree that the test product helped in minimizing the appearance of post-acne scar; helped in reducing the visibility of acne lesions and in preventing future acne breakouts; helped in improving the skin texture and making the skin smoother; helped in making the skin tone even and skin look radiant; helped in reducing the skin's oiliness; helped in moisturizing their skin and also in retaining their skin's moisture; did not make their skin feel dry; helped in reducing the visibility of facial pores; helped in reducing the red spots/erythema; helped in reducing the visibility of acne marks/spots; provided soothing effect on acne lesions and surrounding area, makes the skin look clearer and healthier and improves skin's overall appearance.

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The results of the study is the property of Sponsor and therefore no one can publish study data without seeking permission of Sponsor. Investigator has to take permission from the Sponsor for publication of any study related data. The Sponsor agrees, however, not to use the name Cliantha Research or any derivation thereof, in advertising or marketing without the prior written consent of Cliantha Research. All study documents and a copy of the final clinical study report will be on file with Cliantha Research for the period indicated in the study protocol or financial contract.

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