

Executive Report Summary

TO WHOM SO EVER IT MAY CONCERN

Study In Brief: XXX-ZF01-HV-SR25 was conducted at CRO MASCOT SPINCONTROL INDIA PVT LTD, to evaluate the clinical safety & efficacy of a skin care formulation.

Population Size: 36 (18 male and 18 female) aged between 18 and 30 years old, having moderate to severe acne and oily to mixed oily skin type.

Study Duration: 42 days following the first application of the product on the whole face

Study Duration: T0, T+4 days, T+7 days, T+28 days, T+42 days

Techniques Performed:

- Subject Self Evaluation (SSE)
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Sebumetry
- Digital Photographs

Product Application:

Modalities of application for Product A:

Approximately 0.5 gm of the given face wash was taken on the palm and applied all over the right half of the face. It was gently massaged using only fingers in a circular motion to create lather, starting from the forehead and moving towards the cheek. After waiting for 2 minutes, the right half of the face was washed with tap water and wiped gently with a towel. The product was applied twice a day on the right half of the face for a period of 42 days.

Modalities of application for Product B:

Approximately 0.5 gm of the given face wash was taken on the palm and applied all over the left half of the face. It was gently massaged using only fingers in a circular motion to create lather, starting from the forehead and moving towards the cheek. The left half of the face was then washed with tap water and wiped gently with a towel. The product was applied twice a day on the left half of the face for a period of 42 days

Modalities of application for Product C:

After cleansing the face with Product A and B, a small amount of moisturizer was taken on the fingertips and applied evenly over the face with gentle outward strokes. It was lightly massaged until fully absorbed into the skin. The moisturizer was used twice daily, in the morning and at night, for a period of 42 days.

Note:

The face was washed only with water on study visits, i.e., on T+4 days, T+7 days, T+28 days, and T+42 days in the morning.

The test product was not applied on study visits, i.e., on T+4 days, T+7 days, T+28 days, and T+42 days in the morning.

The test product was applied after going home on T+4 days, T+7 days, and T+28 days visits.

Study methodology:

	Screening	T0	T+4 days	T+7 days	T+28 days	T+42 days
Registration	■					
Protocol Briefing	■					
Consent	■					
ICF		■				
Demographics	■					
Inclusion and Non-Inclusion criteria by the Dermatologist	■	■				
Habits Questionnaire	■					
Clinical Observation	■					
Concomitant Medication	■	■	■	■	■	■
History Questionnaire	■					
Routine check up	■					
Proscriptions and Restrictions			■	■	■	■
Subject Self Evaluation			■	■	■	■
Dermatological Evaluation: Cosmetic Acceptability		■	■	■	■	■
Dermatological Evaluation: Efficacy		■	■	■	■	■
Sebumetry		■	■	■	■	■
Digital Photographs		■	■	■	■	■
Product Weighing		■	■	■		
Distribution of Product and Product Instruction & Diary Sheet		■				
Product Application on site		■				
Product Retrieval					■	■
Adverse Event/ Serious Adverse Event Monitoring		■	■	■	■	■
						End of the study

All the tests were performed in the controlled condition (RH 50 ±10% and temperature 20°C to 25°C) The statistical analysis of the evolution of the measured parameters during the study was performed using the Student test (normality of distributions checked) or with the Wilcoxon test (normality of the distributions rejected). The significance threshold is fixed at 5%.

We hereby certify that we have reviewed the study results and found the data representation to be true and accurate. We also agree to the conclusions that were drawn from the study as mentioned below:

Dermatological Evaluation for Cosmetic Acceptability:

On the basis of Dermatological Evaluation for cosmetic acceptability, on average on the whole panel, no occurrence of the clinical and functional signs was observed at **T0, T+4 days, T+7 days, T+28 days & T+42 days** of application of test product A & product B.

Dermatological Evaluation (Efficacy):

Assessment of reduction in acne (Michaelsson Severity Index)

Product A

The statistical analysis shows a **significant decrease in severity index by -16.3%, -35.2%, -50.5, -64.00%** on average on whole panel, at **T+4 days, T+7 days, T+28 days & T+42 days** after test product A application.

Product B

The statistical analysis shows a **significant decrease in severity index by -5.5%, -8.4%** on average on whole panel at **T+7 days & T+28 days** after the application of Test Product B. However, no significant difference is at T+4 days and T+42 days.

Product A provides 5.0 times, 8.0 times, 7.5 times & 27.7 times reduction in severity index at T+4 days, T+7 days, T+28 days & T+42 days showing 80%, 87%, 87% & 96% improvement compared to Product B.

Assessment of acne lesion

Closed Comedons

Skin Redness

Product A

The statistical analysis shows a **significant decrease in Skin Redness by -17.4%, -20.5, -19.1%** on average on whole panel at **T+7 days, T+28 days & T+42 days** after test product A application. However, no significant difference is at T+4 days.

Product B

The statistical analysis shows that there is no significant difference in skin redness at **T+4 days, T+7 days, T+28 days & T+42 days** after the application of Test Product B.

Product A provides 7.0, 8.0, 7.0 times reduction in Skin Redness at T+7 days, T+28 days & T+42 days showing 86%, 88% & 86% improvement compared to Product B.

Lesion Size

Product A

The statistical analysis shows a **significant decrease in Lesion Size by -9.6%, -29.9%, -35.4% & 46.0%** on average on whole panel at **T+4 days T+7 days, T+28 days & T+42 days** after test product A application

Product B

The statistical analysis shows no significant difference in Lesion Size at **T+4 days T+7 days, T+28 days & T+42 days** after the application of Test Product B.

Product A provides 3.5, 6.7, 7.7 & 9.3 times reduction in Lesion Size at T+4 days T+7 days, T+28 days & T+42 days showing 71%, 85%, 87% & 89% improvement compared to Product B.

Open Comedons

Skin Redness

Product A

The statistical analysis shows a **significant decrease in Skin Redness by -13.3%, -17.0%, -17.5% & -18.7%** on average on whole panel at **T+4 days T+7 days, T+28 days & T+42 days** after test product A application.

(This document is based on client request)

Product B

The statistical analysis shows no significant difference in Skin Redness at **T+4 days, T+7 days, T+28 days & T+42 days** after the application of Test Product B.

Product A provides 6.0, 7.0, 7.0, 7.0 times reduction in Skin Redness at T+7 days T+28 days & T+42 days showing 83%, 86%, 86%, 86% improvement compared to Product B.

Lesion Size

Product A

The statistical analysis shows a **significant decrease in Lesion Size by -14.9, -29.3% & -51.00%** on average on whole panel at **T+7 days, T+28 days & T+42 days** after test product A application. However no significant difference was observed after T+4 days.

Product B

The statistical analysis shows that there is no significant difference in Lesion Size at **T+4 days, T+7 days, T+28 days & T+42 days** after the application of Test Product B.

Product A provides 5.0, 6.3 & 10.3 times reduction in Lesion Size at T+7 days, T+28 days & T+42 days showing 80%, 84% & 90% improvement compared to Product B.

Papules

Skin Redness

Product A

The statistical analysis shows a **significant decrease in Skin Redness by -22.7%, -49.6, -61.4% & -68.7%** on average on whole panel at **T+4 days, T+7 days, T+28 days & T+42 days** after test product A application

Product B

The statistical analysis shows that there is no significant difference in Skin Redness at **T+4 days, T+7 days, T+28 days & T+42 days** after the application of Test Product B.

Product A provides 25, 16.7, 20.0, 21.00 times reduction in Skin Redness at T+4 days, T+7 days, T+28 days & T+42 days showing 96%, 94%, 95% & 95% improvement compared to Product B.

Lesion Size

Product A

The statistical analysis shows a **significant decrease in Lesion Size by -22.5%, -47.1, -57.4 & -65.9%** on average on whole panel at **T+4 days, T+7 days, T+28 days & T+42 days** after test product A application.

Product B

The statistical analysis shows no significant difference in Lesion Size at **T+4 days, T+7 days, T+28 days & T+42 days** after the application of Test Product B.

Product A provides 23.0, 14.7, 17.3 & 18.7 times reduction in Lesion Size at T+4 days, T+7 days, T+28 days & T+42 days showing 96%, 93%, 94% & 95% improvement compared to Product B.

Pustules

Skin Redness

Product A

The statistical analysis shows **a significant decrease in Skin Redness by -22.1%, -39.7%, -45.3% & -49.9%** on average on whole panel at **T+4 days, T+7 days, T+28 days & T+42 days** after test product A application.

Product B

The statistical analysis shows that there is no significant difference in Skin Redness at **T+4 days, T+7 days & T+28 days** after the application of Test Product B.

Product A provides 8.5, 9.3, 10.3 & 10.7 times reduction in Skin Redness at T+4 days, T+7 days, T+28 days & T+42 days showing 88%, 89%, 90% & 91% improvement compared to Product B.

Lesion Size

Product A

The statistical analysis shows **a significant decrease in Lesion Size by -23.0%, -41.4%, -50.4% & -56.6%** on average on whole panel at **T+4 days, T+7 days, T+28 days & T+42 days** after test product A application.

Product B

The statistical analysis shows that there is no significant difference in Lesion Size at **T+4 days, T+7 days, T+28 days & T+42 days** after the application of Test Product B.

Product A provides 10, 11, 13, 13.7 times reduction in Lesion Size at T+4 days, T+7 days, T+28 days & T+42 days showing 90%, 91%, 92% & 93% improvement compared to Product B.

Sebumetry

Product A

The statistical analysis shows **a significant decrease in sebum content by -22.6%, -33.9%, -49.00% & -65.4%** shows **oil control effect** of the product after **T+4 days, T+7 days T+28 days & T+42 days** of application of test product A.

Product B

The statistical analysis shows **a significant decrease in sebum content by -5%, -6.4%, -8.0% & -10.6%** shows **oil control effect** of the product after **T+4 days, T+7 days, T+28 days & T+42 days** of application of test product B.

Product A provides 4.6, 5.3, 6.2 & 6.2 times reduction in sebum content at T+4 days, T+7 days, T+28 days & T+42 days showing 78%, 81%, 84% & 84% improvement compared to Product B.

Subject Self Evaluation

		T+4 days		T+7 days		T+28 days		T+42 days	
Number of subjects		36		34		32		30	
		% agreement	Significant ? (5%)	% agreement	Significant ? (5%)	% agreement	Significant ? (5%)	% agreement	Significant ? (5%)
1	1. The test product helps to reduce active acne.	67%	Yes	85%	Yes	91%	Yes	100%	Yes
2	2. The test product helps to reduce oiliness.	97%	Yes	100%	Yes	100%	Yes	100%	Yes
3	3. The test product helps to reduce pimples.	72%	Yes	85%	Yes	88%	Yes	97%	Yes
4	4. The test product helps make my skin look visibly clearer.	86%	Yes	97%	Yes	97%	Yes	100%	Yes
5	5. The test product helps to make my skin tone even..	69%	Yes	74%	Yes	91%	Yes	93%	Yes
6	6. The test product helps to avoid production of comedons/acne/pimples on the face after application.	89%	Yes	100%	Yes	100%	Yes	100%	Yes
7	7. The test product helps to improve the overall appearance of the skin.	78%	Yes	97%	Yes	100%	Yes	100%	Yes
8	8. The test product makes the skin look healthier.	86%	Yes	100%	Yes	100%	Yes	100%	Yes
9	9. The test product helps to reduce blackheads and whiteheads.	72%	Yes	85%	Yes	91%	Yes	100%	Yes
10	10. The test product helps to reduce acne marks.	75%	Yes	82%	Yes	91%	Yes	100%	Yes
11	11. The test product helps to reduce redness on the skin.	75%	Yes	91%	Yes	94%	Yes	100%	Yes
12	12. The test product helps to reduce the formation of new acne.	75%	Yes	94%	Yes	100%	Yes	100%	Yes
13	13. The test product helps makes the skin Hydrated.	92%	Yes	100%	Yes	100%	Yes	100%	Yes
14	14. The test product helps makes the skin Smooth & softness	89%	Yes	100%	Yes	100%	Yes	100%	Yes
15	15. The test product helps to improve the overall texture of the skin.	75%	Yes	82%	Yes	97%	Yes	100%	Yes
16	1. The test product does not cause itching.	100%	Yes	100%	Yes	100%	Yes	100%	Yes
17	2. The test product does not cause irritation.	100%	Yes	100%	Yes	100%	Yes	100%	Yes
18	3. The test product does not give burning sensation.	100%	Yes	100%	Yes	100%	Yes	100%	Yes

Yes: Significant difference in favor of the product
No: No significant difference
Yes*: Significant difference in disfavor of the product

For test Product A, all the suggested items are significantly and highly recognized by the panel, at T+4days, T+7 days, T+28 days and T+42 days with **67% to 100% agreement** for all the items.

Concerning the product efficacy, test Product A is well appreciated for helping in reducing active acne with **67% to 100% agreement** at 4 days to 42 days of application, helping in reducing oiliness with **97% to 100% agreement** at 4 days to 42 days of application, helping in reducing pimples with **72% to 97% agreement** at 4 days to 42 days of application, helping in making skin look visibly clearer with **86% to 100% agreement** at 4 days to 42 days of application, helping in making skin tone even with **69% to 93% agreement** at 4 days to 42 days of application, helping in avoid production of comedons/acne/pimples on the face after application with **89% to 100% agreement** at 4 days to 42 days of application, helping in improving the overall appearance of the skin with **78% to 100% agreement** at 4 days to 42 days of application, helping in making skin look healthier with **86% to 100% agreement** at 4 days to 42 days of application, helping in reducing blackheads and whiteheads with **72% to 100% agreement** at 4 days to 42 days of application, helping in reducing acne marks, redness on the skin, formation of new acne with **75% to 100% agreement** at 4 days to 42 days of application, helping in making skin hydrated with **92% to 100% agreement** at 4 days to 42 days of application, helping in making skin Smooth & softness with **89% to 100% agreement** at 4 days to 42 days of application, helping in improving the overall texture of the skin with **75% to 100% agreement** at 4 days to 42 days of application

Concerning the product acceptability, test Product A is well appreciated for not causing itching, irritation and burning sensation on the skin with 100% agreement from T+4days, T+7 days, T+28 days and T+42 days of application for test Product A.

Acne Count

Closed Comedons

Product A

The statistical analysis shows a significant decrease in Closed Comedons by **-11.8%, -28.3%, -39.2% & -54.1%** on average on whole panel at **T+4days, T+7 days, T+28 days and T+42 days** after test product A application.

Product B

The statistical analysis shows a significant decrease in Closed Comedons by **-6.5%** on average on whole panel at **T+28 days** after test product B application. However, no significant difference was observed with **-2.5% & 1.7%*** at **T+7 days & T+42 days**.

*Product A provides **5.3 & 6.8 times reduction** in Closed Comedons at **T+4 days and T+28 days** showing **81% & 85% improvement** compared to Product B.*

Open Comedons

Product A

The statistical analysis shows a significant decrease in Open Comedons by **-20.8%, -33.0% & -42.7%** on average on whole panel at **T+7 days, T+28 days and T+42 days** after test product A application. However, no significant difference was observed with **-4.0%** at **T+4days**.

Product B

The statistical analysis shows no significant decrease in Open Comedons with **-5.7% & -2.9%** on average on whole panel at **T+4 days & T+28 days** after test product B application. However, significant difference in disfavour of the product with **10.6%*** at **T+42 days**.

*Product A provides **13.2 times** reduction in Open Comedons at **T+28 days** showing **92% improvement** compared to Product B.*

Total Comedons

Product A

The statistical analysis shows a significant decrease in Total Comedons by **-9.0%, -25.7%, -37.0% & -50.0%** on average on whole panel at **T+4 days, T+7 days, T+28 days & T+42 days** after test product A application.

Product B

The statistical analysis shows a significant decrease in Total Comedons by **-5.3%** on average on whole panel at **T+28 days** after test product B application. However, no significant difference was observed with

-3.6% & 4.8%* at **T+4 days & T+42 days**.

*Product A provides **2.9 & 8.0 times** reduction in **Total Comedons** at **T+4 days & T+28 days** showing **65% & 88% improvement** compared to Product B.*

Papules

Product A

The statistical analysis shows a **significant decrease in Papules by -20.5%, -42.9%, -55.8% & -78.4%** on average on whole panel at **T+4 days, T+7 days, T+28 days & T+42 days** after test product A application.

Product B

The statistical analysis shows a **significant decrease in Papules by -16.8%** on average on whole panel at **T+42 days** after test product B application. However, no significant difference was observed with -3.2%, -15.2% & -14.5% at T+4 days, T+7 days & T+28 days.

Product A provides 8.7, 3.8, 5.3 & 6.4 times reduction in Papules at T+4 days, T+7 days, T+28 days & T+42 days showing 88%, 74%, 81% & 84% improvement compared to Product B.

Pustules

Product A

The statistical analysis shows a significant decrease in Pustules by **-34.3%, -62.3%, -96.4% & -96.0%** on average on whole panel at **T+4 days, T+7 days, T+28 days & T+42 days** after test product A application.

Product B

The statistical analysis shows a significant decrease in Pustules by **-19.8%** on average on whole panel at T+7 days after test product B application. However, no significant difference was observed with -9.1%, -15.3% & -21.8% at T+4 days, T+28 days & T+42 days.

Product A provides 6.0, 5.0, 10.0 & 7.0 times reduction in Pustules at T+4 days, T+7 days, T+28 days & T+42 days showing 83%, 80%, 90% & 86% improvement compared to Product B.

Infiltrated lesions

The statistical analysis shows no significant decrease/ stability in Infiltrated lesions observed after T+4 days, T+7 days, T+28 days & T+42 days after application of test product A & product B.

Cystic Lesion

The statistical analysis shows no significant decrease / stability in Cystic Lesion observed after T+4 days, T+7 days, T+28 days & T+42 days after application of test product A & product B.

**New eruptions have been observed for closed, open & total comedons after 42 days for the test product B.*

Date: 03/12/2025

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