



# An Open Label, Single-Arm, Single Center Clinical Study to Assess Efficacy and Safety of the “Skin Rejuvenating SPF 30 Moisturizer” on Improving Skin Hydration, Barrier Function, UV Protection, Antioxidant Activity, and Reducing Skin Pigmentation in Adult Subjects

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## Abstract

**Background:** Moisturizers are skincare products that combine water-binding ingredients and emollients to hydrate and protect the skin. They are beneficial for various skin concerns such as dryness, roughness, aging signs, UV damage, melasma, sunspots, freckles, fine lines, and wrinkles. The objective of the study is to evaluate the effectiveness of moisturizer on improving skin hydration, barrier function, UV protection, antioxidant activity and reducing skin pigmentation in adult subjects. **Material & Methods:** The study assessed skin pigmentation using the 6-point Fitzpatrick scale at baseline, visit-03, visit-04 and visit-05. Skin hydration was measured with a corneometer at the same time points to assess the moisturizer efficacy. Transepidermal water loss was measured using a TEWA meter to evaluate the moisturizer's impact on improving skin barrier function. Antioxidant activity and UV protection were evaluated with a UV camera. Subject satisfaction was measured over 5-point Likert scale. **Results:** The study demonstrated that the moisturizer effectively improved skin tone and reduced tanning that resulted in clearer and fairer skin. Skin hydration significantly improved by 90.24% from baseline. TEWL showed an average reduction of 68.28% after 60 days of treatment, indicating improved skin barrier function. The moisturizer provided UV protection and increased antioxidant activity. Subject satisfaction was high, with 94% of participants reporting satisfaction. No SAE was reported. **Conclusion:** The Noemi Skin Rejuvenating SPF 30 Moisturizer effectively treated dry, rough, aging and UV damaged skin, melasma, sunspots, freckles, fine lines and wrinkles without any associated AEs. These findings highlighted the clinical significance and potential of the moisturizer.

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## INTRODUCTION

Skin care is a basic, daily activity performed by formal and informal caregivers from birth until end of life.<sup>[1]</sup> Skin, the largest organ of the body, functions as the necessary interface between the

internal and the external environment. Thus, it continuously protects the body from noxious stimuli, e.g., microorganisms, ultraviolet (UV) irradiation, allergens, and irritants. Its unique role and function are a direct result of its structure and makeup, particularly of the most

superficial part, the epidermis.<sup>[2]</sup> Moisturizer is a major component of basic daily skin care, particularly in presence of epidermal barrier alteration and reduced epidermal water content. It is an important part of a dermatologist's strategy to maintain skin health as well as treating various dermatoses which co-exist with skin dryness and are linked to impaired skin barrier function.<sup>[3]</sup> This term was developed by marketers, promoting its function to moisten the skin.<sup>[4]</sup> Moisturizer and emollient are often regarded as synonymous, even when occlusives and humectants are also part of it. Emollients are mostly made up of lipids and their components, which fill inter corneocyte cluster gaps to enhance skin hydration, smoothness, softness, flexibility. Water from deeper epidermal layers moves upward to hydrate stratum corneum cells and is then lost to evaporation. Epidermal water content is essential to prevent skin dryness and maintain elasticity.<sup>[4]</sup> Dry skin signs appear when corneocytes accumulate on skin surface (when stratum corneum has less than 10% water content) and lose its continuity. Moisturizers improve skin barrier repair, maintain skin's integrity and appearance by acting as humectants, emollients, and occlusives, each with its own mechanism of action.<sup>[5]</sup> The study was approved by the local ethics committee and written informed consent was obtained from all adult participants. The study was conducted in accordance with the Declaration of Helsinki.

The objective of this study to obtain an overview about the evidence of skin care activities for Dry & Rough Skin, Aging Skin, UV damaged, Melasma, Sunspots, Freckles, Fine Lines and Wrinkles with NOEMI Skin Rejuvenating SPF 30 Moisturizer. This

Nourishing Moisturizer made up with olive oil, shea butter and wheat germ oil where Olive Oil has strong moisturizing, photoprotective and toning effect on the skin.<sup>[1]</sup> Natural oils, such as olive oil and shea butter, have been used for skin care for centuries. Generation after generation has touted them for various moisturizing, protective, and antibacterial qualities.<sup>[6]</sup> Shea Butter has strong antioxidant and anti-inflammatory properties. Shea butter triterpenes, induce collagen deposition and enhance tissue repair.<sup>[7]</sup> Wheat Germ Oil and WGO, is a moisturizer with ceramides, to prevent skin aging and WGO, rich in linoleic acid, helps in skin protection and renovation.<sup>[8]</sup> Emollients blend used for Softening, Penetrating and Smoothing. It also has UVA & UVB shield and skin rejuvenators. Stearic acid is an emollient, for softening and smoothing the skin. RESICARE AE01 for soft and smooth skin feel with a glossy effect. Glyceryl Stearate, a fast-penetrating emollient creates a protective barrier Isopropyl myristate, a moisturizer that enhances skin penetration of drugs and BELSIL® PDM 20 an excellent emollient, imparts a very pleasant feel to the skin. UVA & UVB Shield contain Titanium dioxide & Zinc oxide are physical sun blockers, for UVB & UVA. Combination assures broad band UV protection,<sup>[9]</sup> Blended with 4 other organic UVA and UVB Blockers, Vit E, C & Coenzyme Q10. Skin Rejuvenators as Coenzyme Q10,<sup>[10,11]</sup> Cutaneous Antioxidant, 10 X levels in epidermis, Prevents Photoaging, Enhances Elastin, Reduces Melanin Reduces Wrinkles. Aging skin is functionally anaerobic, due to loss of mitochondrial function. Topical CoQ10 rapidly improves mitochondrial function in skin.<sup>[12]</sup> Long Acting Stable Vit C, Ascorbic Acid 2 Glucoside- AA2G. AA2G

absorption continues over 24 hours.<sup>[13]</sup> improves elastogenesis, scavenges ROS due to solar radiation.<sup>[13,14]</sup> Vit C acts directly on collagen biosynthesis and helps stabilization and cross-linking of type I and III collagen fibers.<sup>[15]</sup> AA2G limits melanogenesis, helps treat hyperpigmentation, melasma & sunspots.<sup>[15]</sup> Vitamin E, is moisturizing, photoprotective, antioxidant & antiaging.<sup>[16]</sup> It decreases expression lines, wrinkles & freckles induced by photoaging. In this moisturizer major actives are Coenzyme Q10, Ascorbic Acid 2 Glucoside, Vitamin E, Olive Oil, Wheat Germ Oil, Shea Butter, Zinc Oxide and Titanium Dioxide.

Emollients influence skin physiology and pathology by exerting many effects on skin barrier function, such as eicosanoid production, membrane fluidity, and cell signaling, improving skin repair, and permeability, playing important role for therapeutic benefits.<sup>[15]</sup> Emollients classification are Isopropyl palmitate, isostearyl alcohol, decyloleate Propylene glycol, octyl stearate, glyceryl stearate, cyclomethicone, octyl octanoate, isopropyl myristate.<sup>[3]</sup> Most moisturizers combine emollients, occlusives, and humectants. Occlusives and humectants combinations enhance skin's water-holding capacity. Furthermore, addition of certain emollients may improve esthetic quality and stability of moisturizer's active ingredients. When glycerol combines with occlusives, skin dryness will be synergistically alleviated. The predominant formulation is cosmetic emulsions, most are lotions (oil-in-water emulsions) or creams (water-in-oil emulsions).<sup>[3]</sup> Till date choosing, the right moisturizer is still a matter of trial and error. As

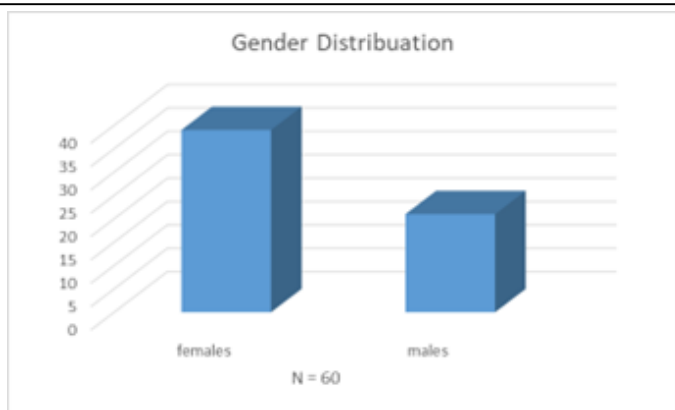
the population ages and we turn into an urbanized makeover worldwide, the need of moisturizers will be ever increasing. The key to future moisturizer therapy will be to tailor specific agents to specific dermatological needs. This review helps provide a fundamental understanding of the physiochemical and psychological effects of this Test Product.

### MATERIAL AND METHODS

This study was an open label, single-arm, single center clinical study to assess efficacy and safety of the product. The objective of this study was to evaluate the effectiveness of moisturizer on improving skin hydration, barrier function, UV protection, antioxidant activity, and reducing skin pigmentation in adult subjects. The study was conducted by qualified Investigator at single center in India and it was initiated after the written EC approval. After confirming eligibility criteria, 60 patients were enrolled in the study. All 60 subjects included in the study were healthy males and females with normal to dry skin types, aged between 20 and 45 years.

They actively completed their all visits from visit 01(screening visit) to last visit 05 (Evaluation phase/End of the study). The potential subjects will be screened as per the inclusion and exclusion criteria only after obtaining written informed consent from the subjects.

Out of 60, there were 39 females and 21 males enrolled in this clinical study. Shows in figure 1:



**Figure 1:** Gender Distribution

All 60 enrolled subjects were prescribed and dispensed study test product on enrolment visit and Subjects were instructed to use the test product on Day 01 (Visit 02: Enrollment) and All participants were instructed to apply approximately 2 grams of the test product on their entire face twice daily (morning and evening) for 60 days. Participants were asked to wash their hands and face before apply on face and not to use any soap or detergent or cosmetic product so that they would not affect moisture, TEWL and pH level. Hot beverages and spicy foods were not allowed during study time. Subjects were followed up on visit 03 [Evaluation Phase (Day 15 ± 02 Days)], visit 04 [Evaluation Phase (Day 30 ± 02 Days)], and visit 05 [Evaluation Phase and End of Study (Day 60 ± 02 Days)].

Assessment of Efficacy of the test product on skin pigmentation was done by using 6-point Fitzpatrick scale at baseline, visit 03, visit 04, and visit 05 to evaluate the reduction of skin pigments and hydration or moisture of the skin was measured through Corneometer at Visit 03, Visit 04, and Visit 05 to evaluate the nourishing moisturizers and emollients blend in the moisturizer. Also, the skin barrier function

assessed through transepidermal water loss (TEWL) using a TEWA meter to evaluate the effectiveness of the nourishing moisturizers and lotions blend in restoring/improving the skin barrier function. Evaluation was done over baseline, visit 03, visit 04, and visit 05.

To assess the UV protection and antioxidant activity of the human face, a UV camera was used. UV cameras are designed to capture images of the skin that show areas of pigmentation and damage caused by UV radiation. By comparing images taken before and after application of a product containing UV protection and antioxidants at visit 05, the effectiveness of the product in protecting the skin from UV damage and oxidative stress was assessed. Also, Satisfactory data was collected from the Subject by using the satisfaction scale after product usage at Visits 03, 04, and 05.

## RESULTS

All 60 enrolled participants completed the study and were included in the analysis. There were no serious adverse events reported during the study period. The test product was well-tolerated by all participants, with no significant adverse reactions reported.

### Efficacy Endpoints:

#### Skin pigmentation:

The objective of this study was to evaluate the effectiveness of the test product in reducing skin pigmentation. The degree of skin pigmentation was evaluated using a 6-point Fitzpatrick scale at baseline, visit 03, visit 04, and visit 05. 6-point Fitzpatrick scale shown in [Figure 2].



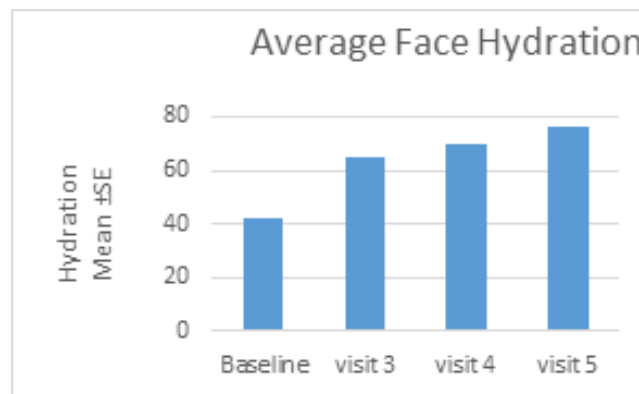
**Figure 2: The Fitzpatrick Scale**

Through this scale subjects measured their skin improvement in this study. Here, we calculated that how much population of the study fell under which criteria of Fitzpatrick scale from baseline to End of the study visit for test product and by using this data (table 01) we analysed the change in general tone of the patients. A diverse range of participants with varying skin tones were enrolled in the study, and they showed improvement in their skin tone by the end of the study visit from sun burn or skin tans. Additionally, the results demonstrated that participants with higher Fitzpatrick skin types (types 4 to 6) also showed improvement in their skin tone, indicating the effectiveness of the test product across a range of skin tones. The test product was found to be effective in removing tanning, resulting in clearer and fairer skin than before.

**Skin Moisturization:**

Skin hydration was measured using a corneometer at each study visit. The corneometer measured the amount of water present in the upper layer of the skin. The readings were recorded in arbitrary units (AU) and analyzed to evaluate the efficacy of the test product in improving skin hydration. The results of the skin moisture/hydration over each visit demonstrated in figure 03 that clearly represent a growth from baseline to end of the study visit. At the baseline, average skin hydration was 41 while it increased till 78 at the

end of the study visit with an 90.24% improvement from the initial level of the study.

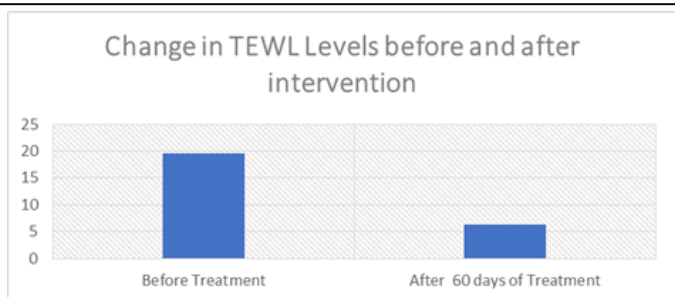


**Figure 3: Average Skin Hydration**

Study data shows that the maximum study population at the baseline visit is less than the average hydration scale. Figure 3 shows quite improvement in visit 3, 4 and 5 from baseline. Moisturizer helped to improve skin hydration by attracting and retaining moisture in the skin due the presence of vitamin E in the test product and helped to draw moisture to the skin and also help to lock in moisture and prevent water loss.

**Skin Barrier Function**

TEWA meter was used to measure transepidermal water loss (TEWL) to evaluate the effectiveness of the nourishing moisturizers and emollients blend in restoring/improving the skin barrier function. For the TEWL measurement, a probe was placed on the skin surface and a small amount of air was introduced to create a controlled environment. The meter then recorded the rate of water vapor diffusion from the skin surface. Three measurements were taken at each site, and the average value was calculated.



**Figure 4:** Change in TEWL level before and after 60 days of treatment

Figure 04 represented that subject condition improved after the intervention.

Table 2 illustrated a statistically significant association before treatment and after 60 days of treatment with 68.28% reduction in TEWL level from the baseline to the end of the study.

#### Antioxidant Activity and UV Protection:

The UV camera was used to assess the UV protection and antioxidant activity of the human face before and after the application of a test product at visit 05. The UV camera revealed a significant decrease in UV radiation on the face after the application of the test product. On average, the participants' faces showed a 25% reduction in UV radiation after application of the test product. In addition, the antioxidant activity of the test product was also evaluated using the UV camera. The test product showed a significant increase in antioxidant activity on the participants' faces. The results of the study demonstrate the effectiveness of the test product in providing UV protection and

increasing antioxidant activity on the human face.

#### Subject Satisfaction Scale

Subject Satisfaction was measured after product usage through 5-point likert scale on baseline, visit 03 and 05. Here, we analyzed the improvement in satisfaction of study subjects from baseline to end of study visit through scale.

Table 3 shows that there was a statistically significant difference between baseline and end of the study values with respect to 5-point likert scale. At baseline subjects were neutral about the product. But after completing half time period of study at visit 3 some of them getting better results that's why they were satisfied and extremely satisfied. At end of the study the results of Subject Satisfaction scale showed a good incline in approval. Also, it could be concluded that 94% Subjects satisfied with the product usage while rest 6% were either neutral or slightly satisfied.

#### Safety Results

Safety assessment includes the monitoring of adverse events (AEs) reported during the study, including serious adverse events (SAEs). There were only two adverse events reported, one in visit 2 (Itching) and second in visit 3 (redness). Further, no adverse event has any causal relationship with IMP. There was no serious adverse event reported during the study conduct.

**Table 1:** Change in skin pigmentation over the 6-Point Fitzpatrick scale at baseline, visit 03, 04 and 05

6-Point Fitzpatrick scale	Baseline (N=60)	Visit 03 (N=60)	Visit 04 (N=60)	Visit 05 (N=60)
Light Pale White	5 (8.33)	9(15.00)	12(20.00)	17 (28.33)



White, Fair	15(25.00)	16(26.67)	20(33.33)	25 (41.67)
Medium White to Olive	17(28.33)	16(26.67)	13(21.67)	11(18.33)
Olive, Moderate Brown	15(25.00)	13(21.67)	10(16.67)	6(10.00)
Brown, Dark Brown	8(13.33)	6(10.00)	5(8.33)	1(1.67)
Black, Very Dark Brown to black	0(0.00)	0(0.00)	0(0.00)	0(0.00)

**Table 2:** Change in TEWL level before and after 60 days of treatment

Analyzed Parameters	Skin Rejuvenating SPF 30 Moisturizer n = 60			
	Before Treatment	After 60 days of Treatment	$\Delta$	Wil coxon Test p
	Me $\pm$ Q	Me $\pm$ Q	Me $\pm$ Q	
TEWL (g/m <sup>2</sup> /h)	19.64 $\pm$ 2.215	6.23 $\pm$ 3.38	-13.41 $\pm$ -15.25	0.001

**Table 3:** Subject satisfaction measurement over baseline, visit 03 and 05

5-Point Likert Scale	Baseline n (%)	Visit-3 n (%)	Visit-5 n (%)
Not at all satisfied	0 (0)	0 (0)	0 (0)
Slightly Satisfied	0 (0)	0 (0)	2 (3)
Neutral	60 (100)	23 (39)	2 (3)
Satisfied	0 (0)	17 (28)	6 (10)
Very Satisfied	0 (0)	8 (13)	18 (30)
Extremely Satisfied	0 (0)	12 (20)	32 (54)

## DISCUSSION & CONCLUSIONS

Healthy skin appearance is essential as flawed presentation may result in reduced self-esteem.<sup>[17]</sup> Moisturizers are commonly used to reduce fine lines, smoothen and hydrate skin which may improve a patient's social life, psychological satisfaction and quality of life.<sup>[18]</sup> Moreover, either normal skin or dermatoses with dry skin symptoms may both gain optimal benefit from proper utilization of moisturizers. Impression of skin dryness consist of visible and tactile changes of the skin as well as alteration in skin's sensory components, which presents as dry skin symptoms. These symptoms include dryness feeling and discomforts; consist of tightness, pain, itch, stinging, and tingling.<sup>[19]</sup> Test product have several benefits aside from skin moistening. Some of the possible functions provided by moisturizers are as follows:

Nourishing by Olive Oil,<sup>[20]</sup> Shea Butter,<sup>[7]</sup> Wheat Germ Oil,<sup>[8]</sup> Emollients Blend for Softening, Penetrating, Smoothing, UVA & UVB shield protection of skin by Zinc Oxide,<sup>[9]</sup> Titanium Dioxide,<sup>[9]</sup> UV Filters Blend. Skin Rejuvenators with the use of Vitamin E,<sup>[16]</sup> Coenzyme Q10,<sup>[10,11]</sup> Vitamin C as AA2G.<sup>[13,14,15]</sup> The study data demonstrated the improvement in skin pigmentation, skin oxygen level, skin hydration, and reduction in transepidermal water loss (TEWL) level and UV damage. Additionally, subjects showed satisfaction over 5-point Likert scale in nourishing moisturizer. Based on the study results/ data, it can be concluded that the Noemi Skin Rejuvenating SPF 30 Moisturizer shows better efficacy results with no linked AEs with respect to the treatment of Dry & Rough Skin, Aging Skin, UV damaged skin, Melasma, Sunspots, Freckles,



Fine Lines and Wrinkles types of problem. However, the test product is clinically

significant and have affinity to improving such conditions.

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