

## EVALUATION OF SAFETY AND EFFICACY OF MOISTURIZING GEL CONTAINING CERASURGE ULTRA ON SKIN HYDRATION AND BARRIER FUNCTION: A 72 HOUR SINGLE-BLIND COMPARATIVE CLINICAL STUDY

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### ABSTRACT

Ceramides are essential lipid molecules that make skin strong, smooth, and healthy in both males and females by maintaining skin texture, hydration, and barrier integrity. They are essential for maintaining healthy, smooth, and resilient skin. Maintaining hydration and an intact barrier function is crucial for skin health to support overall dermal integrity, guard against environmental stresses and prevent water loss. Disruptions in these aspects can lead to dryness, irritation, and increased susceptibility to dermatological conditions. This study aimed to assess the safety and efficacy of a novel moisturizing gel formulation in enhancing skin moisturization and strengthening the water barrier function compared to an untreated control in healthy female volunteer with dry skin on the forearms. In comparison to an untreated control site, this study assessed the safety and effectiveness of a ceramide-based moisturizing gel containing CeraSurge Ultra in improving skin moisturization and barrier

function in 33 healthy Indian females (aged 18–40) with dry forearm skin. Over the course of 72 hours, a single application to a chosen forearm site was evaluated using corneometry (skin hydration), tewametry (trans-epidermal water loss, TEWL), dermatological examination, and subject self-evaluation. The findings contribute to understanding how targeted skincare

formulations can optimize skin physiology, offering potential benefits for daily skincare routines and therapeutic applications in managing dry skin conditions. This research underscores the importance of evidence-based skincare products in promoting long-term skin health and resilience.

**KEYWORDS:** Skin moisturization, Barrier function, Moisturizing gel, Dry skin, Clinical efficacy, Ceramide, CeraSurge Ultra.

## I. INTRODUCTION

The body's primary line of defense against environmental threats such as chemicals, pathogens, allergens, UV rays, and physical stressors is the skin.<sup>[1]</sup> To maintain optimal hydration and avoid transepidermal water loss (TEWL), the special architecture in skin controls water flux and retention, preventing desiccation and preserving skin homeostasis.<sup>[3]</sup> The intercellular lipid matrix, which is crucial for barrier integrity, is made up of roughly 50% ceramides, 25% cholesterol, and 15% free fatty acids arranged in highly ordered lamellar bilayers.<sup>[3,4]</sup> Because impairments can result in conditions like xerosis (dry skin), atopic dermatitis, irritant contact dermatitis, and increased sensitivity to environmental irritants and allergens, an optimal skin barrier function is crucial for overall skin health and quality of life.<sup>[2,5]</sup>

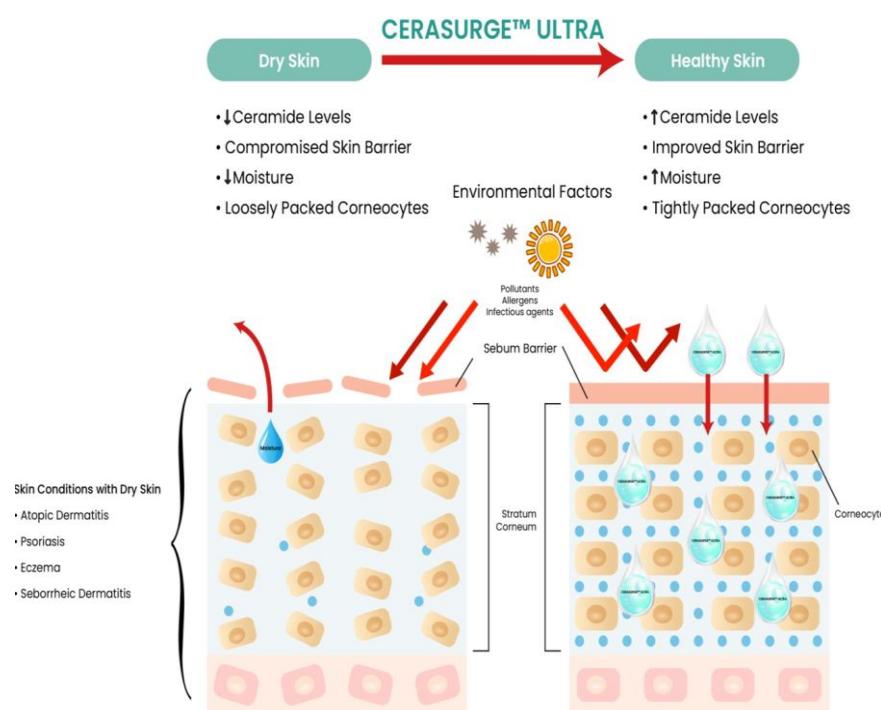
Moisturization plays a pivotal role in maintaining barrier function, as it not only replenishes water content in the stratum corneum but also supports the lipid matrix and the Natural Moisturizing Factors (NMFs) that fortify the barrier.<sup>[6]</sup> Ceramides are essential structural lipids that control keratinocyte differentiation and proliferation and preserve the integrity of intercellular lamellar membranes.<sup>[3]</sup> Skin hydration and ceramide content disruptions, which are frequently exacerbated by intrinsic factors such as aging and genetic predisposition, as well as extrinsic factors such as harsh climate conditions, frequent surfactant cleansing, and occupational exposures, can jeopardize barrier integrity.<sup>[7]</sup> A vicious loop of barrier dysfunction is created by this compromise, which increases trans-epidermal water loss (TEWL), impairs lipid organization, increases allergen and irritant penetration, and activates the inflammatory cascade.<sup>[1,2]</sup> Topical moisturizer development has evolved significantly in recent years to address these challenges, with modern formulations incorporating three functional categories: humectants (which attract and bind water), occlusives (substances that prevent water loss), and emollients (substances that smooth and soften the skin surface) to mimic and enhance the skin's natural barrier mechanisms.<sup>[7,8]</sup> Crucially, physiological lipids,

especially ceramides, are now included in sophisticated formulations to replenish stratum corneum lipids that are lacking and restore the original lamellar structure.<sup>[9]</sup> Clinical studies have convincingly demonstrated that using ceramide-containing moisturizers on a regular basis can improve barrier function by reducing permeability, TEWL, allergen penetration, promoting epidermal repair, and even modulating inflammatory responses.<sup>[10,11]</sup>

To demonstrate that emollient formulations, like gels, effectively treat pediatric eczema while maintaining high safety, Sykes et al. (2022)<sup>[12]</sup> carried out a comprehensive pragmatic randomized controlled trial. Furthermore, Chan and Visscher's (2025)<sup>[13]</sup> review of studies suggesting that lipid-based barrier repair therapy may prevent atopic dermatitis in high-risk infant populations emphasized the preventive potential of ceramide-enriched formulations. Even so, many commercially available products lack comprehensive comparative analysis using validated biophysical assessment techniques against untreated controls, particularly in short-term applications (24–72 hours) that replicate real-world initial use scenarios.<sup>[14,15]</sup> Moisturizing gel containing CeraSurge™ Ultra, is a next-generation, biocompatible moisturizing gel with a precisely tailored five-ceramide complex at a concentration that replicates the natural lipid lamellar structure of healthy human stratum corneum created to address this unmet clinical need.

Five distinct ceramide species were chosen for the formulation because of their established functions in barrier physiology: The most prevalent ceramide in human skin, ceramide NP, is essential for the development, maintenance, and repair of skin barriers.<sup>[10,16]</sup> Long hydrophobic chains seen in ceramide NS are crucial for preserving barrier function and lowering TEWL<sup>[17]</sup>; Ceramide AP, when combined with Ceramide NP, cholesterol, linoleic acid, and phyto-sphingosine, has been shown to significantly improve barrier function and hydration, especially in atopic skin conditions ; Ceramide EOP, which is crucial for the formation and stabilization of the lamellar sheets in stratum corneum, helps organize the lipid matrix architecture.<sup>[6]</sup> This dual-ceramide combination is especially crucial for barrier repair because it has been demonstrated that the ratio of Ceramide NS to Ceramide NP closely correlates with TEWL values and skin texture parameters.<sup>[18]</sup> The multifactorial nature of barrier dysfunction is addressed by including all five ceramides: Ceramide EOP promotes the formation of the critical long periodicity phase necessary for water impermeability, Ceramide AP and AS support structural stability and lipid organization, and Ceramide NP and NS provide immediate and sustained moisture retention.

This is especially crucial because ceramide depletion causes abnormal packing arrangements of intercellular lipids, which disrupt the stable structure of stratum corneum lipids and result in impaired barrier function, increased TEWL, and susceptibility to irritants and allergens.<sup>[19]</sup> This can be caused by intrinsic aging, genetic factors, or extrinsic damage from harsh surfactant-containing cleansers. Moisturizing gel containing CeraSurge™ Ultra, differs from traditional moisturizing gels with its therapeutic "leave-behind" effect that lasts well beyond the immediate post-application period, offers a lipid-replenishing approach that maintains barrier integrity while providing both rapid onset and sustained long-term effects by replicating the physiological ceramide profile and incorporating these five complementary ceramide species in a lightweight gel vehicle designed for rapid penetration.<sup>[20,21]</sup> The "Fig 1", schematically illustrates the transformation from compromised dry skin to restored healthy skin barrier achieved through the moisturizing gel containing CeraSurge™ Ultra five-ceramide mechanism of action.



**“Figure 1”: Mechanism of Action of moisturizing gel containing CeraSurge™ Ultra Five Ceramide-complex in Barrier Restoration.**

The moisturizing gel containing CeraSurge™ Ultra transforms dry skin characterized by decreased ceramide levels, compromised barrier function, reduced moisture and closely packed corneocytes (left panel) into healthy skin with increased ceramide level, improved barrier integrity, enhanced moisture retention and tightly packed corneocytes (right panel).

For the purpose to restore the organized lamellar structure necessary for defense against environmental stressors (pollutants, allergens, infectious agents) and stop trans-epidermal water loss, the five-ceramide complex (Ceramide EOP, NP, NS, AS, and AP) penetrates the stratum corneum at optimal concentrations. The multifactorial pathophysiology of barrier failure, which is frequently seen in diseases like psoriasis, eczema, atopic dermatitis, and seborrheic dermatitis, is addressed by this treatment strategy (left: Skin Conditions with Dry Skin).

The study employed validated biophysical measurement techniques, including corneometry, which measures stratum corneum hydration by capacitance, and tewametry, which measures barrier function by trans-epidermal water loss quantification. Numerous studies and a variety of populations have demonstrated the reliability and non-invasiveness of these techniques for assessing moisturizer efficacy.<sup>[14,15]</sup> By integrating these objective measurements with dermatological evaluation of clinical and functional signs, subject self-assessment of product acceptability, and perceived efficacy, this study provides a comprehensive, multifaceted assessment of the formulation's effect on skin physiology and user experience.<sup>[22]</sup> The comparative approach provides strong statistical power to detect treatment effects while lowering inter-individual variability by using untreated control sites on the same subjects.<sup>[12]</sup> Previous studies have demonstrated the intricate interactions between physical, chemical, and immunological elements in the regulation of the skin barrier and the urgent need for products that offer quantifiable, long-lasting advantages free from side effects.<sup>[1,5]</sup>

The primary objective of this research was to assess the safety and effectiveness of moisturizing gel containing CeraSurge<sup>TM</sup> Ultra, contains five-ceramide complex, in strengthening water barrier function (measured by tewametry) and improving skin moisturization (measured by corneometry) in comparison to untreated control sites over a 72-hour period after a single application in healthy female volunteers with dry forearm skin. Characterizing the temporal dynamics of hydration and barrier improvement over eight assessment time points (T+30 minutes, 4, 8, 12, 24, 48, and 72 hours), assessing user acceptability and perceived efficacy through structured questionnaires covering the two functional attributes (hydration, softness, radiance) and sensorial characteristics (non-sticky, ultra-lightweight, quick absorption, spreadability, non-oily feel) were secondary objectives. By providing rigorously validated, evidence-based skincare options for a variety of populations affected by barrier dysfunction and xerosis, an understanding of these dynamics

can help develop product development strategies for next-generation barrier-repair formulations, optimize application frequency recommendations based on evidence of sustained effects, and ultimately advance dermatological care.

## II. MATERIALS AND METHODS

The study was a single-center, controlled, in-vivo clinical study conducted at Mascot Spincontrol India Pvt. Ltd, Mumbai, India to evaluate the moisturization and barrier-repair benefits of single use of Moisturizing Gel containing CeraSurge™ Ultra over a period of 72 hours. The Declaration of Helsinki, ICH E6(R2) rules, ICMR ethical standards, and Good Clinical Practice (GCP) recommendations were all adhered to in this investigation. The test product was Moisturizing Gel containing CeraSurge™ Ultra, a liquid gel form supplied in a PET bottle. The product was applied once on site to randomized 3x3 cm<sup>2</sup> areas on the forearms, with one site treated whereas the other serving as an untreated control. In the randomized site, a disposable syringe or micropipette was used to dispense the test product onto a previously indicated region on the forearm. The product was then delicately dispersed using a finger pad for protection. The test site was then left exposed for a minimum of five minutes so that the substance could be absorbed onto the skin.

### The evaluations included

- Subject-Self Evaluation (SSE): Questionnaires assessing product efficacy (hydration, softness), physical characteristics (non-stickiness) acceptability (no itching) on a 4-point scale (1= Completely Agree to 4= Completely Disagree)
- Dermatological Evaluation: Assessment of clinical (erythema, oedema, dryness, scaling, peeling) and functional signs (itching, tingling) on a 0-3 scale (0=None to 3= Severe) by a registered dermatologist at all checkpoints.
- Corneometry: Measured skin capacitance Using corneometer CM 825 to evaluate hydration.
- Tewametry: Assessed TEWL Using Tewameter TM 300 to evaluate barrier function.

## INCLUSION AND EXCLUSION CRITERIA

### Inclusion Criteria

To be eligible to participate in the study, the subjects must meet all the inclusion requirements, unless otherwise noted:

- Indian Female subjects 18-40 years of age
- Healthy individuals with no infectious or evolutive pathology interfering with the study.

- Skin should be healthy on forearms (free of eczema, wounds, inflammatory scars)
- Dry skin specifically on forearms

### Exclusion Criteria

Subjects would be refrained from participating if the following criteria was met.

- Pregnant, breastfeeding or stopped breast feeding in the past three months.
- Refusal to sign the consent form
- Participation in any other study liable to interfere with the present study.
- Known diabetes, asthma, thyroid issues, epilepsy, or hypersensitivity.
- Chronic treatments (e.g. anti-inflammatories, anti-histamines, corticosteroids)
- Diagnosed allergy to cosmetic compounds.
- Surgery under general anesthesia (> 1 hour) in past 6 months.
- Changed in cosmetic habits in 14 days prior to study.
- Applied any cosmetic products 48 hours prior on the would be studied areas.
- Specifics: Commencing or ceasing hormonal therapy within the last three months; taking oral or local retinoids within the last six months; engaging in beauty treatments or participating in water activities within the last week; smoking, alcohol, caffeine, spicy foods, sports, wiping forearms, wearing jewelry on the wrist, being exposed to UV light, taking care of one's skin, applying a surfactant product to the forearms, or washing forearms.

### PROTOCOL

This single-blind comparison study was carried out for 72 hours following the application. Subjects were employed as their own reference for intra-group comparisons, but not inter-group (product vs control) analysis. Software was used to produce the treatment-site randomization.

- A randomized, prospective single blind comparative clinical trial was conducted at a single location to evaluate the efficacy, acceptability, and features of Moisturizing Gel containing CeraSurge™ Ultra (test product) to an untreated control site.
- The study comprised 33 healthy female subjects with sound forearm skin who were between the age group of 18-40.
- All of the designated forearm was examined. For every kinetics, the site to be tested was consistent. Using a gauge, the cutaneous marking at T0 was used to identify the location.
- The test product was applied once to one forearm site (3x3 cm<sup>2</sup>), with the other untreated

site acting as a control for 72 hours.

- Product attributes were evaluated at T+30 minutes, and efficacy and acceptability evaluations were carried out at T+4 hours, T+8 hours, T+12 hours, T+24 hours, T+48 hours and T+72 hours.
- Under the guidance of a Clinical Research Associate (CRA) at Spincontrol, subjects completed self-evaluation questionnaires that evaluated efficacy (changes in the condition), acceptability and product features (such as texture and ease of application).
- Safety was monitored using adverse events (such as skin irritation) that trial participants reported.
- Statistical analysis was performed using (software to be specified: SigmaStat 3.5 and PAST 4.03) at a significance level of  $p < 0.05$ . Paired t-tests were utilized for intra-group Wilcoxon test Using Shapiro-Wilk test at 1% (efficacy over time) and the Mann-Whitney U test for inter-group comparisons (treated vs untreated).

### III. RESULTS AND DISCUSSION

#### A. Dermatological Evaluations

According to the Dermatological Evaluation for Cosmetic Acceptability, Test Product A (Moisturizing Gel containing CeraSurge™ Ultra) did not exhibit any erythema, scaling, peeling, itching, or tingling at any point in time.

#### B. Corneometry

**Table 1:** The following table summarizes the mean and standard deviation of capacitance using a Corneometer.

		RAW VALUES								
		T0	T+30 minutes after product application	T+4 hours after product application	T+8 hours after product application	T+12 hours after product application	T+24 hours after product application	T+48 hours after product application	T+72 hours after product application	
Capacitance	Product A	N Mean Standard deviation Significant at 5% (T0 vs Tn) p= Test	33 24.90 3.17 4.63	33 55.58 5.18	33 50.90 4.38	33 46.13 3.30	33 40.41 3.13	33 30.35 3.24	33 28.62 3.15	33 27.37
	Untreated Control	N Mean Standard deviation Significant at 5% (T0 vs Tn) p= Test	33 24.89 3.30 3.31	33 24.94 3.32	33 24.95 3.33	33 24.94 3.31	33 24.95 3.33	33 24.93 3.36	33 24.95 3.33	

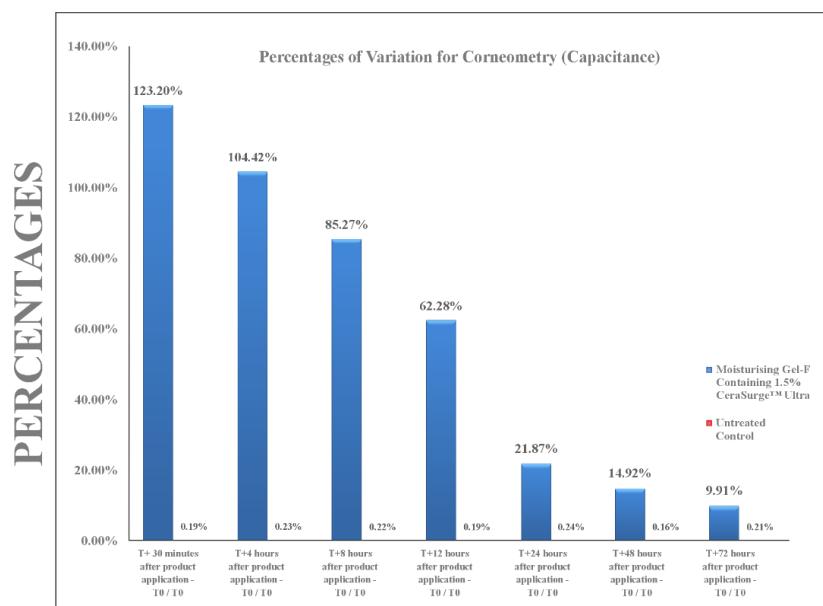
Yes: Significant difference in favor of the product  
No: No significant difference  
Yes\*: Significant difference in disfavor of the product

**Table 2:** The following table presents the mean and the standard deviation of the evolutions (Tn-T0).

			EVOLUTION OF THE PARAMETERS (Tn-T0)						
Capacitance	Product A	Mean	T+ 30 minutes after product application - T0	T+4 hours after product application - T0	T+8 hours after product application - T0	T+12 hours after product application - T0	T+24 hours after product application - T0	T+48 hours after product application - T0	T+72 hours after product application - T0
		Standard deviation	5.03	5.68	4.49	3.50	2.29	2.31	2.03
Capacitance	Untreated Control	Mean	0.05	0.06	0.06	0.05	0.06	0.04	0.05
		Standard deviation	0.19	0.20	0.20	0.19	0.20	0.21	0.20

**Table 3:** The following table summarizes the average percentages of variations (Tn-T0)/T0.

			Percentages of Variation* for Capacitance						
Capacitance	Product A	Mean	T+ 30 minutes after product application - T0 / T0	T+4 hours after product application - T0 / T0	T+8 hours after product application - T0 / T0	T+12 hours after product application - T0 / T0	T+24 hours after product application - T0 / T0	T+48 hours after product application - T0 / T0	T+72 hours after product application - T0 / T0
		Untreated Control	Mean	0.19%	0.23%	0.22%	0.19%	0.24%	0.16%
Capacitance	Product A	Mean	123.20%	104.42%	85.27%	62.28%	21.87%	14.92%	9.91%
	Untreated Control	Mean	0.19%	0.23%	0.22%	0.19%	0.24%	0.16%	0.21%



**Figure 2:** Graphical representation of the statistical analysis.

**Table 4:** The following table presents the statistical results on the comparison of the studied parameters.

		COMPARISON FROM THE DIFFERENCES (Tn-T0)						
		T+ 30 minutes after product application	T+4 hours after product application	T+8 hours after product application	T+12 hours after product application	T+24 hours after product application	T+48 hours after product application	T+72 hours after product application
Capacitance	Significant at 5 % p= Test	Yes <0.001 Student t test (two-tailed)	Yes <0.001 Rank Sum Test	Yes <0.001 Rank Sum Test	Yes <0.001 Rank Sum Test			

Yes: Significant difference in favor of the product

No: No significant difference

Yes\*: Significant difference in disfavor of the product

### C. Tewametry

**Table 5:** The following table summarizes the mean and standard deviation of capacitance using a Tewameter.

		RAW VALUES							
		T0	T+ 30 minutes after product application	T+4 hours after product application	T+8 hours after product application	T+12 hours after product application	T+24 hours after product application	T+48 hours after product application	T+72 hours after product application
TEWAMETRY- (g/h/m <sup>2</sup> )	Product A	N	33	33	33	33	33	33	33
		Mean	12.18	8.14	8.83	9.54	9.89	10.53	11.17
		Standard deviation	1.25	0.65	1.18	1.07	1.22	1.25	1.25
	Untreated Control	Significant at 5 % (T0 vs Tn) p= Test		Yes <0.001 Student Paired t-test	Yes <0.001 Student Paired t-test	Yes <0.001 Student Paired t-test	Yes <0.001 Wilcoxon	Yes <0.001 Student Paired t-test	Yes <0.001 Wilcoxon
		N	33	33	33	33	33	33	33
		Mean	12.15	12.12	12.12	12.12	12.13	12.12	12.13
		Standard deviation	1.20	1.18	1.18	1.19	1.19	1.18	1.18
		Significant at 5 % (T0 vs Tn) p= Test		No 1.43E-01 Wilcoxon	No 1.07E-01 Wilcoxon	No 2.30E-01 Student Paired t-test	No 2.64E-01 Student Paired t-test	No 5.96E-01 Wilcoxon	No 1.94E-01 Student Paired t-test

Yes: Significant difference in favor of the product

No: No significant difference

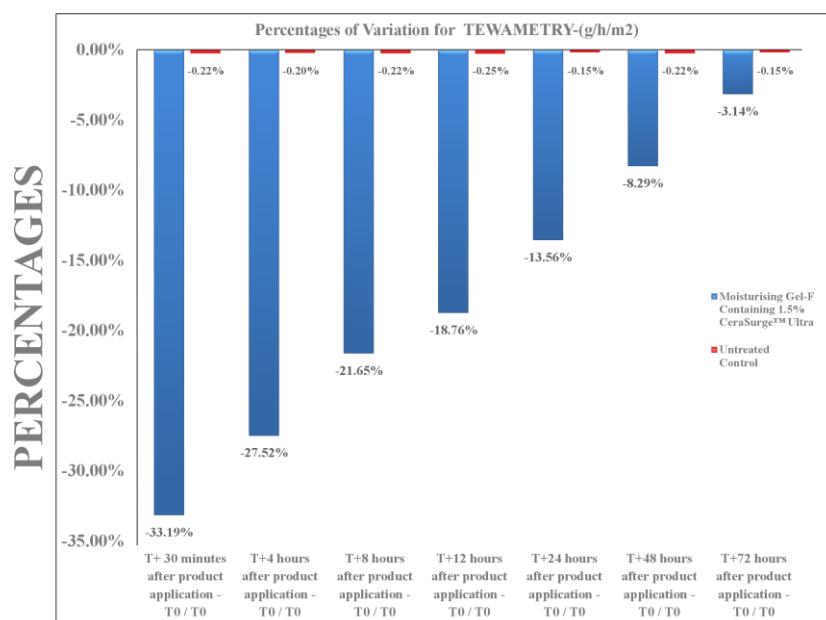
Yes\*: Significant difference in disfavor of the product

**Table 6:** The following table presents the mean and the standard deviation of the evolutions (Tn-T0).

			EVOLUTION OF THE PARAMETERS (Tn-T0)						
TEWAMETRY - (g/h/m <sup>2</sup> )	Product A	Mean	T+ 30 minutes after product application - T0	T+4 hours after product application - T0	T+8 hours after product application - T0	T+12 hours after product application - T0	T+24 hours after product application - T0	T+48 hours after product application - T0	T+72 hours after product application - T0
		Standard deviation	1.14	0.82	1.29	0.67	0.58	0.70	0.24
	Untreated Control	Mean	-0.03	-0.02	-0.03	-0.03	-0.02	-0.03	-0.02
		Standard deviation	0.12	0.09	0.13	0.15	0.12	0.12	0.10

**Table 7:** The following table summarizes the average percentages of variations (Tn-T0)/T0.

			Percentages of Variation* for TEWAMETRY- (g/h/m <sup>2</sup> )						
TEWAMETRY- (g/h/m <sup>2</sup> )	Product A	Mean	T+ 30 minutes after product application - T0 / T0	T+4 hours after product application - T0 / T0	T+8 hours after product application - T0 / T0	T+12 hours after product application - T0 / T0	T+24 hours after product application - T0 / T0	T+48 hours after product application - T0 / T0	T+72 hours after product application - T0 / T0
		Standard deviation	1.14	0.82	1.29	0.67	0.58	0.70	0.24
	Untreated Control	Mean	-33.19%	-27.52%	-21.65%	-18.76%	-13.56%	-8.29%	-3.14%
		Standard deviation	0.22%	0.20%	0.22%	0.25%	0.15%	0.22%	0.15%



**Figure 3:** Graphical representation of the statistical analysis.

**Table 8:** The following table presents the statistical results on the comparison of the studied parameters.

		COMPARISON FROM THE DIFFERENCES (Tn-T0)						
		T+ 30 minutes after product application	T+4 hours after product application	T+8 hours after product application	T+12 hours after product application	T+24 hours after product application	T+48 hours after product application	T+72 hours after product application
TEWAMETRY. (g/h/m <sup>2</sup> )	Significant at 5 %	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	p=	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Test	Student t test (two-tailed)	Student t test (two-tailed)	Student t test (two-tailed)	Student t test (two-tailed)	Student t test (two-tailed)	Student t test (two-tailed)	Student t test (two-tailed)

Yes: Significant difference in favor of the product

No: No significant difference

Yes\*: Significant difference in disfavor of the product

The Moisturizing Gel containing CeraSurge™ Ultra, comprises of five-ceramide complex (Ceramide EOP, NP, NS, AS, and AP) greatly enhances skin hydration and strengthens barrier function, with measurable effects lasting up to 72 hours after a single application, according to the results of this clinical trial. Significant increases in skin capacitance were found by corneometry tests, with an impressive 123.20% increase at 30 minutes after application and a gradual decline to 9.91% at 72 hours (all  $p < 0.001$  compared to baseline), indicating persistent water retention in the stratum corneum.<sup>[14,23]</sup> This swift hydration onset coincides with the dual mode of action characteristic of advanced gel formulations: immediate humectant-driven water binding paired with rapid penetration of the ceramide complex into the stratum corneum.<sup>[17,22]</sup>

The combined action of Ceramide EOP and Ceramide NP results in hydration effects that are greater than those of separate ceramides, according to PubMed study, which supports the reported magnitude of capacitance increases.<sup>[19]</sup> Importantly, the five-ceramide formulation employed in CeraSurge™ Ultra provides a distinct advantage over a currently marketed alternative. Most commercial ceramide-based moisturizers contain substantially fewer ceramide species while certain comparable formulations contain only three essential ceramides. Other competitive brands launched a triple ceramide formulation with glycerin and niacinamide, still falling short of the all encompassing five ceramide complex approach. Research demonstrates that multiple ceramides acting synergistically produce superior results compared to single or limited ceramide formulations. One seminal study comprising of ceramides working synergistically enhanced skin hydration after four weeks and maximum

TEWL reduction substantially out performing single-ceramide emulsions. This synergistic activity lends support to the biomimetic hypothesis that mimicking the natural stratum corneum lipid complexity with a complete ceramide profile results in better barrier repair over formulations with inadequate ceramide representation.

Tewametry results supported these conclusions by showing significant improvements in barrier function, with TEWL reductions of 33.19% at 30 minutes and maintaining a statistically significant 3.14% reduction at 72 hours (all  $p < 0.001$ ), while untreated control sites showed little variation.<sup>[10,25]</sup> In line with recent research showing that ceramide-based formulations replenish depleted intercellular lipids, thereby restoring the ordered lamellar bilayer structure necessary for water impermeability, this progressive decrease in water efflux indicates true enhancement of epidermal cohesiveness and structural resilience.<sup>[9,13]</sup> All five ceramide species are included to address multifactorial barrier dysfunction: Ceramide EOP helps form the critical long periodicity phase that causes water impermeability, Ceramide AP and AS support lipid layer organization, and Ceramide NP and NS provide hydrophobic chains necessary for lowering TEWL.<sup>[16,18]</sup> Because the biomimetic composition closely mimics the physiological ceramide profile of healthy human stratum corneum, the sustained efficacy at 72 hours (3.14% TEWL reduction, 9.91% capacitance increase) suggests long-lasting therapeutic benefits that represent true barrier repair rather than superficial occlusion.<sup>[20,26]</sup>

Subject self-evaluation data and extensive dermatological assessments largely supported the objective biophysical measurements, indicating great safety and high concordance between measured physiological improvements and reported advantages. Throughout the 72-hour study period, no adverse events occurred (0/33 subjects), and no clinical signs (erythema, oedema, dryness, scaling, peeling) or functional signs (itching, tingling) were observed at any time point, yielding a 100% tolerability rate consistent with the established safety profile of physiological lipid-based barrier repair moisturizers.<sup>[12,27]</sup> Subject self-evaluation revealed universal early acceptance, with 100% of subjects (33/33) reporting complete agreement at 30 minutes regarding hydration, softness, and non-sticky texture, indicating the immediate sensory impact of the lightweight gel vehicle—a critical determinant of long-term adherence given that up to 40% of patients discontinue moisturizers due to unpleasant sensory attributes.<sup>[28,29]</sup> The sustained high agreement rates for hydration (100% at T+30min through T+8h, 85% at T+12h, 73% at T+24h) paralleled corneometry findings, indicating that

subjects could accurately perceive gradual decline in stratum corneum water content, while consistent 100% agreement on non-irritancy parameters across all time points confirmed dermatological findings.<sup>[30,31]</sup>

Despite robust findings demonstrating efficacy and safety, several limitations should be acknowledged. The homogeneous study population (healthy Indian females aged 18–39 years with dry forearm skin) restricts generalizability to male subjects, pediatric and elderly populations, various ethnic groups, and clinical populations with active dermatological conditions like atopic dermatitis or psoriasis.<sup>[14,32]</sup> The 72-hour evaluation period effectively characterizes acute effects, but it does not address long-term cumulative benefits with repeated daily application. Future studies should use longer durations (4–12 weeks) with repeated applications to determine cumulative benefits and the best frequency of application, perform head-to-head comparative trials against competing ceramide formulations and standard-of-care treatments, and assess efficacy in disease populations, especially utilizing evidence that lipid-based barrier repair may prevent atopic dermatitis in high-risk populations.<sup>[13]</sup>

According to these results, Moisturizing Gel containing CeraSurge™ Ultra as a clinically effective, non-irritant therapeutic modality for xerosis management that successfully integrates biomimetic composition (five-ceramide complex replicating physiological profiles), rapid onset (123.20% capacitance increase at 30 minutes), sustained efficacy (measurable benefits at 72 hours), universal tolerability (zero adverse events), and superior cosmetic acceptability (100% subject satisfaction).<sup>[11,15]</sup> This gel formulation represents a significant advancement in topical barrier repair therapy, with potential applications in constitutional dry skin, occupational/environmental barrier compromise, age-related barrier decline, and preventive care in populations predisposed to barrier dysfunction, while contributing to the evidence base supporting non-invasive biophysical methodologies (corneometry and tewametry) as reliable tools for assessing moisturizer efficacy and support.<sup>[1,7]</sup>

## CONCLUSION

The Moisturizing Gel containing CeraSurge™ Ultra is an evidence-based option for managing dry skin due to its rapid hydration onset (123.20% increase in skin capacitance at 30 minutes,  $p < 0.001$ ), sustained benefits (9.91% increase,  $p < 0.001$ ), and improvement of barrier function through a 33.19% reduction in TEWL at 30 minutes sustained at 3.14% at 72

hours (all  $p < 0.001$ ), demonstrating statistical superiority versus control at all time points ( $p < 0.001$ ). With 100% study completion and zero adverse events (0/33 individuals), the formulation showed an outstanding safety profile.

There were no symptoms of irritation in any of the eight tests, and the subjects unanimously accepted the lack of irritation. It was perfect for daytime use because of its non-sticky, lightweight, and rapidly absorbing cosmetic properties. Clinical Moisturizing Gel containing CeraSurge™ Ultra addresses two needs in dermatological care: measurable physiological barrier repair supported by objective biophysical data and cosmetic elegance promoting adherence. It also suggests a favorable dosing interval that may reduce application frequency compared to standard moisturizers. Future studies can include long-term efficacy and safety studies (4-12 weeks), head-to-head trials against conventional treatments, studies in disease populations (atopic dermatitis, eczema, ichthyosis, and senile xerosis), physiological analyses using confocal microscopy, lipidomic and transcriptomics, diverse population studies across ages, genders, and ethnicities, real-world effectiveness under various conditions, prevention trials. Overall, this research supports the idea that barrier-repair moisturizers containing ceramides are essential for strengthening skin resilience and developing preventative measures.

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#### **V. CONFLICT OF INTEREST**

The authors declare no conflicts of interest.

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