

Original Article

# A prospective, double-blinded, within-subject, site-randomized study to evaluate skin compatibility and non-comedogenic profile of Venusia acne facewash when applied topically under an occluded patch to the skin

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## ABSTRACT

**Objectives:** Acne vulgaris is a common inflammatory skin disorder influenced by factors such as sebum production, microbial colonization, and the use of comedogenic topical products, which can promote microcomedone formation. Considering the potential role of facial cleansers in triggering or worsening acne, this study aims to evaluate the skin compatibility and non-comedogenic profile of Venusia acne facewash under occluded skin conditions compared to control products, to assess its dermatological safety for acne-prone skin.

**Material and Methods:** This was a prospective, randomized, double-blinded, positive- and negative-controlled, within-subject, site-randomized study. Healthy male and female subjects with follicular orifices on the upper back region were enrolled in this study. The test product (Venusia acne facewash), positive control (coconut oil), and negative control (glycerine) were applied occlusively on the three marked sites. Follicular biopsy by the cyanoacrylate method was performed for each site at baseline and at the end of the study. The product was applied and occluded using a patch after 2 h of the biopsy on alternate days over a period of approximately 1 month (24 visits). Microcomedones were graded using a four-point grading scale: 0 = non-comedogenic; 1 = presence of small microcomedones; 2 = moderately sized microcomedones; and 3 = large, globoid microcomedones present throughout the entire field.

**Results:** A total of 30 subjects were enrolled, of whom 29 completed the study and were included in the data analysis. The majority of the subjects enrolled were female (58.6%). The mean comedogenic grade for the coconut oil (positive control) and glycerine (negative control) was 2.07 and 0.76, respectively. The method was validated by the significant difference ( $P = 0.001$ ) between the positive and negative controls. The mean comedogenic grade in Venusia acne facewash was 1.00, significantly ( $P = 0.001$ ) less than the positive control. One subject reported an adverse event (AE) not related to the study product and was discontinued from the study. No serious AEs were reported in any of the study subjects.

**Conclusion:** Venusia acne facewash is a non-comedogenic and well-tolerated formulation specifically designed for acne-prone skin. It offers cleansing without exacerbating acne or inducing dryness and irritation. Venusia acne facewash can be used as an everyday, gentle cleanser to promote clearer, healthier, and balanced skin in individuals with acne.

**Keywords:** Acne vulgaris, Facewash, Microcomedones, Non-comedogenic, Occluded patch test

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## INTRODUCTION

Acne vulgaris is one of the most common skin disorders worldwide, with its prevalence increasing from 8,563.4 to 9,790.5 cases per 100,000 population between 1990 and 2021.<sup>[1,2]</sup> During the same period, the disability-adjusted life years (DALYs) rose from 183.7 to 210.1/100,000 population.<sup>[2]</sup> India reported the highest burden in 2021, with 30.7 million prevalent cases and 0.66 million DALYs.<sup>[2]</sup> A 2024 study further indicated that facial acne affected 48.5% of Indian adolescents and adults.<sup>[3]</sup> Mostly, it affects areas rich in sebaceous glands, particularly the face, back, and chest.<sup>[4]</sup> Beyond its dermatological manifestations, moderate to severe acne is associated with social withdrawal, anxiety, depression, and reduced quality of life.<sup>[5]</sup> Clinically, acne vulgaris is a chronic inflammatory disorder of the sebaceous follicles, presenting with inflammatory papules, pustules, nodules, cysts in severe cases, and a spectrum of lesions such as open and closed comedones.<sup>[4,5]</sup> Comedone formation begins when excessive keratinization and shedding of follicular cells block the pilosebaceous unit, often aggravated by comedogenic substances.<sup>[6]</sup> This blockage produces invisible microcomedones, which gradually evolve into visible comedones and may be accompanied by inflammatory papules or pustules.<sup>[6]</sup> Partial obstruction of follicles results in open comedones or “blackheads,” whereas complete obstruction leads to closed comedones or “whiteheads.”<sup>[6]</sup>

Acne results from multiple factors, including follicular hyperproliferation, genetics, hormonal changes, increased sebum production driven by androgens, microbial colonization by *Propionibacterium acnes* and *Staphylococcus epidermidis*, and cosmetic usage.<sup>[4,7]</sup> Frequent use of cosmetics containing comedogenic substances such as lanolin, isopropyl myristate, oleic acid, and stearyl alcohol can trigger or worsen acne by promoting microcomedone formation.<sup>[6,8]</sup> As reported by a survey of approximately 6400 participants in India, 35% associated acne with excessive cosmetic use.<sup>[9]</sup> Most patients were seen with Grade II acne (47%), with papules (51%) and pustules (44%), with blackheads and whiteheads observed across all types of acne lesions.<sup>[9]</sup> Hyperpigmentation and scarring, reported in 35% and 29% of patients, respectively, were considered indicators of acne severity.<sup>[9]</sup>

Moisturizers and cleansers are among the most common supportive measures in acne management.<sup>[9]</sup> Cleanser is a facial care product designed to remove makeup, dead skin cells, oil, dirt, and other pollutants, thereby unclogging pores and preventing acne.<sup>[7]</sup> Comedogenic ingredients in facial cleansers have been independently associated with a 2.49-fold higher risk of acne compared to non-comedogenic formulations.<sup>[10]</sup> A recent study found lauric and stearic acids as the most prevalent comedogenic ingredients, with 61.7% of individuals with acne reporting the use of cleansers

containing these compounds.<sup>[10]</sup> Experts recommend using non-comedogenic, gentle cleansers to minimize irritation and protect the skin barrier.<sup>[11]</sup> Non-comedogenic products minimize the risk of comedone development and improve skin dryness and hydration,<sup>[11,12]</sup> making their evaluation essential for proper acne management.

Considering this, assessing the comedogenic potential of topical products, like face washes, is critical for individuals with acne-prone skin. The present study aims to evaluate skin compatibility and non-comedogenic profile of Venusia acne facewash when applied topically under occluded skin patches compared to control products. The findings will provide evidence of the product's dermatological safety and inform both clinical recommendations and consumer use in acne-prone populations.

## MATERIAL AND METHODS

### Study design and setting

This was a prospective, randomized, double-blinded, positive- and negative-controlled, within-subject, site-randomized study to evaluate the skin compatibility and non-comedogenic profile of the test product (Venusia acne facewash). The Independent Ethics Committee of Clinical and Aesthetic Investigate Management Services (C.L.A.I.M.S.) reviewed and approved this monocentric clinical study protocol along with associated study documents (Re-Registration number: ECR/245/Indt/MH/2015/RR-22; Date of approval: April 30, 2025; Protocol No.: CL/014/0425/STU). The trial is carried out in compliance with the Protocol, Bureau of Indian standards (IS 4011: 2018 Methods of Test for Safety Evaluation of Cosmetics [Third Revision] guidelines), Indian Council for Medical Research guidelines (2017), the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use E6 (R3) Guideline for Good Clinical Practice (2016), Good Clinical Laboratory practices, and the Declaration of Helsinki. A voluntary, written, and signed informed consent was obtained from all subjects before any study-related procedures. The study was registered at the clinical trials registry of India (CTRI/2025/05/086182; dt. May 02, 2025).

### Study procedure

The duration of the study was approximately 1 month, comprising 24 visits. Subjects who provided informed consent and met the eligibility criteria were enrolled in the study. Each subject completed twelve consecutive patch applications, with the patch applied at Visit 1, removed at Visit 2, and reapplied at Visit 3. This sequence of visits continued until all scheduled patch applications were completed. Three sites (3 × 3 cm<sup>2</sup> each) were marked on the upper back of each subject, with the test product (Venusia acne facewash) along

with a positive control (coconut oil, due to its comedogenic potential) and a negative control (glycerine, being non-comedogenic), applied to separate sites in the same subject according to randomization. Initially, follicular biopsies of all 3 sites were performed using 1–2 drops of cyanoacrylate liquid adhesive to a glass microscope slide, gently placing it on the marked zones, and allowing the cyanoacrylate to set for 30–60 s. The slide was gently removed to obtain a follicular biopsy specimen. Product application was then performed according to randomization on pre-marked 3 × 3 cm<sup>2</sup> zones, approximately 2 h after the follicular biopsy. The applied areas were occluded using patch chambers (2×2 cm<sup>2</sup> patches), and approximately 0.025 mL of the diluted test product and controls were applied to the marked zones on the upper back of each subject by clinical research associates. On the final day of the study, approximately 2 h after the removal of the last patch, a follicular biopsy was performed for all subjects. Figure 1 provides a diagrammatic overview of the study procedure.

### Study subjects

Study subjects included healthy men and/or women aged 18–55 years with prominent follicular orifices on the upper back. Subjects who were willing to avoid ultraviolet (UV) exposure (sun or artificial UV), water contact (e.g., swimming), or activities that may cause sweating (such as exercise, sauna), who had healthy skin test areas and were ready to wear loose cotton clothes, were enrolled in the study. Pregnant or lactating women, volunteers who had a job involving contact with water/perspiration, and those with scars, tattoos, or dermatological infections/pathologies on the study area, were excluded from the study. In addition, subjects with hypersensitivity, allergy antecedent, cutaneous

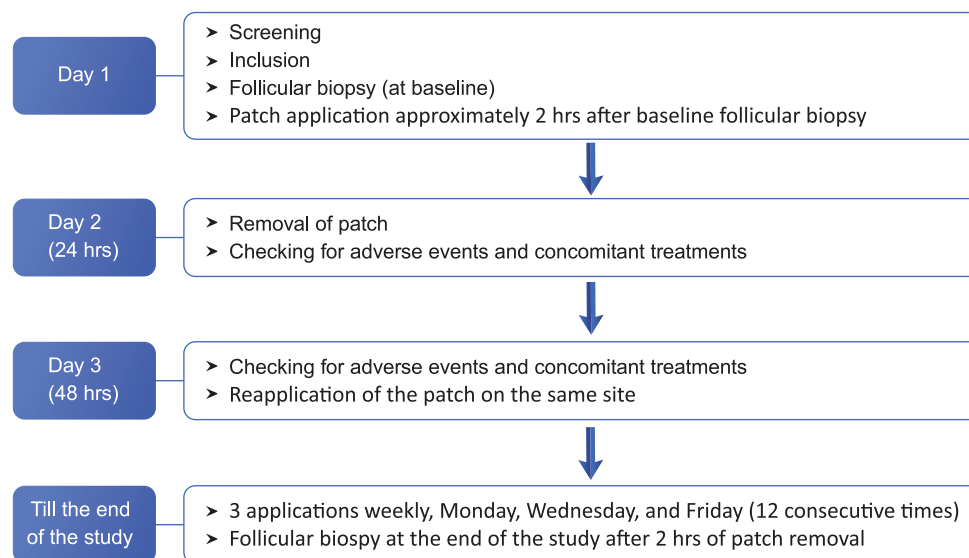
or systemic disease, those receiving any medical treatment that could interfere with the study performance, or those participating in another clinical study within 30 days before screening were excluded.

### Randomization and blinding

Randomization was carried out according to the marked sites where the test product and controls were applied. Products were coded by C.L.A.I.M.S. Pvt. Ltd., and block randomization was performed using a randomization sheet. Blinding was maintained across the different marked sites (site 1, site 2, and site 3), with product application performed by the study staff according to randomization, while evaluations were conducted by the investigator. Double blinding was maintained throughout the study, ensuring that neither the subjects nor the investigator was aware of the allocation of the test product or controls.

### Study products

The test product used in this study was Venusia acne facewash, manufactured by Helios Pharmaceuticals. It contains active ingredients including salicylic acid, glycolic acid, multivitamins, niacinamide, zinc-pyrrolidone carboxylic acid (PCA), oat extract, aloe vera, hyaluronic acid, and ceramides. Coconut oil and glycerine were used as positive and negative controls, respectively. The test and control products were applied to designated marked zones on the upper back and covered with occlusive patches. Patch application and removal were performed 12 times throughout the study.



**Figure 1:** Overview of the study procedure.

## Study outcome and assessment

The primary outcome was assessed by grading microcomedones using light microscopy. The Principal Investigator evaluated the biopsy slides and graded the comedones using the grading scale previously used in similar studies [Table 1].<sup>[8,13]</sup>

## Sample size

No formal sample size calculation was carried out, as this study was conducted as a safety evaluation in accordance with regulatory guidance. As per the IS 4011:2018 methods of test for safety evaluation of cosmetics (Third Revision) guidelines,<sup>[14]</sup> a sample size of 24 subjects is typically recommended for such evaluations. Considering the possibility of subject dropouts, a total of 30 healthy subjects were enrolled in the study.

## Statistical methods and data analysis

All scores were averaged and recorded. Statistical analysis performed using the Statistical Package for the Social Sciences version 30.00. All the *P*-values are reported based on the two-sided significance tests, and statistical analyses were interpreted at a 95% level of significance using the Mann-Whitney U-test. Statistical comparisons included the mean comedone grades of the positive control versus the negative control for method validation, as well as the mean comedone grades between the test product and the positive control.

## RESULTS

### Demographics and other baseline characteristics

Between July 15, 2025, and August 14, 2025, 30 healthy male and female subjects were enrolled, of whom one subject discontinued due to an adverse event (AE). Hence, the data analysis was performed for 29 subjects. The mean (standard deviation [SD]) age of the subjects was 32.45 (11.77) years, and the majority were female (17 subjects; 58.6%).

### Individual subject comedone grading data

The comedone grading data of all subjects are presented in Table 2. A total of 11 (37.9%) subjects remained non-

Scale	Definition
0	No comedones
1	Small microcomedones
2	Moderately sized microcomedones over most of the field
3	Large globoid microcomedones over the entire field

comedogenic (grade 0) after using Venusia acne facewash. However, only 3 (10.3%) subjects developed large globoid microcomedones (grade 3) after using the test product.

## Statistical comparison of mean comedone grades

Validation of the positive and negative control methods was performed by evaluating the comedogenic potential of both controls. The mean (SD) comedone grade was 0.76 (0.58) for the negative control (glycerine). Although some subjects exhibited grade 1 microcomedones, the overall comedogenic grade remained minimal and was significantly less compared to 2.07 (0.84) for the positive control (coconut oil) [Table 2]. Similarly, the comedogenic potential of the test product was assessed with respect to the positive control. The mean (SD) comedone grade for Venusia acne facewash (test product) was 1.00 (1.00), also significantly lower than 2.07 (0.84) for the positive control (coconut oil) [Table 2]. Figure 2 illustrates the mean comedone grades for the positive and negative controls along with the test product. Figure 3 presents photographic representations of subjects with different comedone grades following the application of test and control products.

## AEs

A subject reported one AE, an accidental head injury of moderate severity (not related to the study product) during the study. The subject received treatment, and the AE was resolved; however, the subject was subsequently discontinued from the study. No AEs related to the test product, nor any serious AEs, were reported among study subjects.

## DISCUSSION

Acne vulgaris is a highly prevalent skin problem that affects nearly all individuals at least once during their lifetime.<sup>[7]</sup> Acne causes significant dermatological and psychological burdens, requiring timely intervention

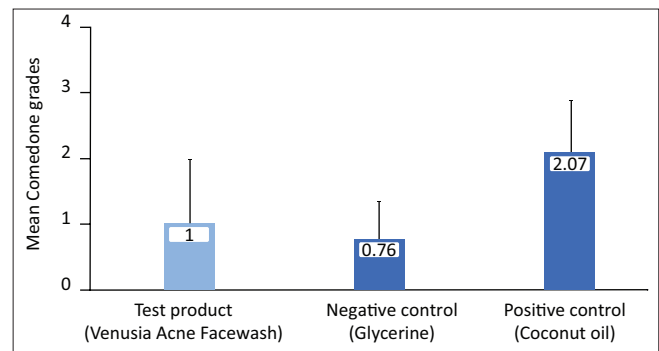
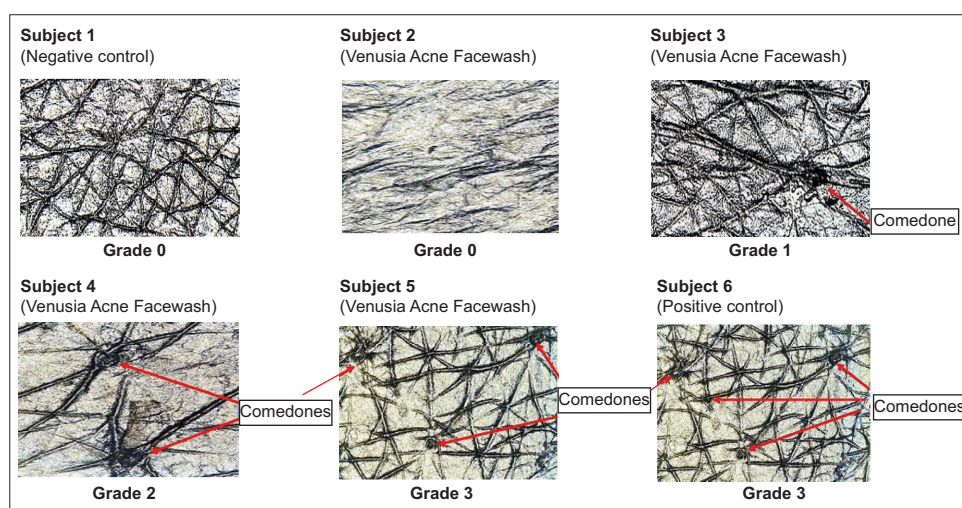


Figure 2: Mean comedone grades between test product (Venusia acne facewash) versus positive (coconut oil) and negative (glycerine) controls, with error bars representing standard deviation.

**Table 2:** Comedone grading with different products (N=29).

Grades	Venusia acne facewash (N=29) n (%)	Glycerine (N=29) n (%)	Coconut Oil (N=29) n (%)
Grade 0 (Non-comedogenic)	11 (37.9)	9 (31.0)	0 (0.0)
Grade 1 (Small microcomedones)	10 (34.5)	18 (62.0)	9 (31.0)
Grade 2 (Moderate-sized microcomedones over most of the field)	5 (17.2)	2 (6.9)	9 (31.0)
Grade 3 (Large globoid microcomedones over the entire field)	3 (10.3)	0 (0.0)	11 (37.9)
Mean comedones grade	1.00	0.76	2.07
P-value*	0.001	0.001	

\*P-value computed using the Mann–Whitney U-test versus positive control (coconut oil), N: Total number of subjects, n: Number of subjects



**Figure 3:** Representative photographs of subjects' comedone grades after application of test product (Venusia acne facewash), positive (coconut oil), and negative (glycerine) controls.

through careful selection of anti-acne agents and a consistent cleansing routine to maintain clear, healthy skin.<sup>[15,16]</sup> The accumulation of dirt, oil, cosmetic residue, and pollutants on the face can clog pores and lead to inflammation, pimples, blackheads, whiteheads, and more serious acne lesions.<sup>[15]</sup> Unlike regular soap or water, facewash is specially formulated to cleanse skin without depleting its natural oils, leaving the skin smooth and refreshed.<sup>[15]</sup> Many such products offer additional antimicrobial, anti-inflammatory, and anti-acne benefits.<sup>[15]</sup> However, some commercial facewashes contain harsh chemicals and synthetic additives that may irritate sensitive skin or exacerbate existing conditions.<sup>[15]</sup>

Given these considerations, the selection of non-comedogenic formulations is essential, particularly for acne-prone individuals. Non-comedogenic products are formulated to avoid clogging pores, thereby reducing the chances of comedone formation and acne breakouts.<sup>[17]</sup> Oil-free, non-comedogenic formulations effectively cleanse the skin and remove excess sebum while maintaining clear, healthy, and radiant skin, making them suitable for daily use across all skin types.<sup>[17]</sup>

The current study evaluated the comedogenic potential of Venusia acne facewash using occluded patch application under controlled conditions. Human subjects with comedone-prone skin were selected, in accordance with current regulations prohibiting animal testing, which favor human-based methods for comedogenicity assessment.<sup>[18]</sup> Comedogenicity was assessed after the application of the test product by grading microcomedones on biopsy slides using light microscopy, with the grading scale adapted from previous studies.<sup>[8,13]</sup> The test was performed on the upper back of 29 subjects with prominent follicular orifices, an important inclusion criterion consistent with previous comedogenic studies involving small cohorts.<sup>[8,18]</sup> Patch testing was conducted to assess the potential of the test product to cause primary skin irritation or allergic reactions, thereby evaluating its safety.<sup>[19]</sup>

For comparison, this study employed both positive control (coconut oil) and negative control (glycerine) for comparative assessment. While coconut oil has been used extensively for skin care, several studies have demonstrated its high

comedogenic potential<sup>[13,20]</sup> and lack of significant antibacterial activity, making it unsuitable for acne-prone skin.<sup>[21]</sup> Animal models such as rabbit ear assays have also shown that coconut oil induces microcomedone formation, which may worsen acne in susceptible individuals.<sup>[6]</sup> In contrast, glycerine is a well-known humectant with non-comedogenic and non-occlusive properties,<sup>[22]</sup> making it an ideal negative control.

In our findings, application of coconut oil resulted in significantly higher mean comedone grades compared to both glycerine and Venusia acne face wash ( $P = 0.001$ ). Notably, only 10.3% of subjects in the Venusia acne facewash group developed grade 3 comedones, compared to 37.9% in the coconut oil group. Moreover, 37.9% of subjects using Venusia acne facewash exhibited a non-comedogenic response (grade 0) compared to 31.0% subjects in the negative control group. Furthermore, no AEs related to the study product, nor any serious AEs, were observed throughout the study period. These findings indicate that Venusia acne facewash is non-comedogenic and has a favorable safety and tolerability profile.

These findings align with previous research emphasizing the importance of gentle cleansing in acne management. Over-washing, vigorous scrubbing, or using harsh soaps can irritate the skin and worsen acne.<sup>[23,24]</sup> Conversely, mild and consistent cleansing can help manage acne effectively. Gentle cleansing has been shown to improve therapeutic outcomes, reduce non-inflammatory lesions, and prevent an increase in acne lesions.<sup>[24,25]</sup> Choi *et al.* (2006) reported that twice-daily face washing with a gentle cleanser significantly improved open comedones and reduced total non-inflammatory lesions.<sup>[26]</sup>

Venusia acne facewash is a gentle cleanser formulated for acne-prone skin, combining salicylic and glycolic acid for exfoliation and acne control.<sup>[27,28]</sup> Enriched with niacinamide, zinc PCA, and allantoin, it helps calm irritation and regulate oil.<sup>[27,29,30]</sup> A complex of hyaluronic acid and ceramide restores hydration, while aloe vera extract, oat extract, and sodium lauroyl sarcosinate provide soothing, antioxidant, and mild cleansing benefits, leaving the skin clear, smooth, and refreshed.<sup>[27,30-32]</sup>

Studies support the efficacy and tolerability of similar multi-active cleansers. Cao and Ai (2024) reported that a cleanser containing sodium lauroyl sarcosinate, niacinamide, gluconolactone, ceramides, salicylic acid, and hyaluronic acid significantly improved open and closed comedones, reduced total inflammatory and non-inflammatory lesions (all  $P < 0.05$ ), reduced sebum production, and showed excellent tolerance in sensitive skin.<sup>[27]</sup> Similarly, Pal (2025) found that a niacinamide, hyaluronic acid, and a ceramide complex-based cleanser increased hydration by 42% ( $P < 0.01$ ), reduced transepidermal water loss by 28% ( $P < 0.05$ ), and decreased dryness and irritation scores by 65% and 58%, respectively, with 90% of participants reporting improved softness and comfort.<sup>[30]</sup> Kumari *et al.* (2023) also demonstrated that glycolic acid, aloe vera, and

vitamin E-based cleanser reduced acne, spots, and post-inflammatory hyperpigmentation (all  $P < 0.01$ ) without AEs, while enhancing skin radiance.<sup>[31]</sup>

This study has several strengths, including its prospective, randomized, double-blind design with positive and negative controls, and use of human subjects, allowing direct clinical relevance. The within-subject comparison of test and control treatments in this study minimized inter-individual variability and allowed for more reliable assessment of product effects, thereby enhancing the robustness and internal validity of the results. However, limitations include a small sample size and short study duration. Future multi-center studies with larger, more diverse populations are needed to further establish the generalizability of these findings.

## CONCLUSION

Venusia acne facewash is a non-comedogenic, well-tolerated formulation suitable for acne-prone skin. It offers cleansing without exacerbating acne or inducing dryness and irritation. It serves as a gentle cleansing option that helps reduce comedone formation and supports acne management. Venusia acne facewash can be used as an everyday cleanser to promote clearer, healthier, and more balanced skin, making it a suitable choice for individuals seeking a gentle solution for acne care.

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**Ethical approval:** The research/study was approved by the Independent Ethics Committee of C.L.A.I.M.S., number ECR/245/Indt/MH/2015/RR-22, dated April 30, 2025.

**Declaration of patient consent:** The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given consent for clinical information to be reported in the journal. The patient understand that the patient's names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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