

Original Article

Evaluation of skin safety of Venusia Acne Facewash for primary skin irritation using skin irritation test: Patch test in humans

Monil Gala¹ , Snehal Muchhala¹ , Seema Bhagat¹ , Arti Sanghvi¹, Bhavesh Kotak¹

¹Department of Medical Affairs, Dr. Reddy's Laboratories Ltd, Hyderabad, Telangana, India.



*Corresponding author:

Monil Gala,

Department of Medical Affairs,
Dr. Reddy's Laboratories Ltd,
Hyderabad, Telangana, India.

monil.yogesh@drreddys.com

Received: 11 December 2025

Accepted: 11 January 2026

Published: 10 March 2026

DOI

10.25259/CSDM_232_2025

Quick Response Code:



ABSTRACT

Objectives: Face washes are an effective adjuvant in routine skincare for the management of acne vulgaris. However, prior assessment of the skin irritant potential of such formulations is essential to mitigate the risk of adverse dermatological effects. Venusia Acne Facewash is a product formulated for acne-prone skin. This study aimed to evaluate the primary skin irritation potential of Venusia Acne Facewash using a 24-h occlusive patch test in healthy human volunteers, as per IS 4011: 2018 Methods of Test for Safety Evaluation of Cosmetics (Third Revision) guidelines.

Material and Methods: This was a monocentric, non-randomized, single-blinded, single-application, controlled study conducted on healthy adult subjects aged between 18 and 65 years, with Fitzpatrick skin types III to V and having apparently healthy skin on the test area. The test product (Venusia Acne Facewash, diluted 8% w/w), positive control (1% sodium lauryl sulfate), and negative control (0.9% isotonic saline) were applied occlusively on the upper back for 24 h. Skin reactions, including erythema/dryness/wrinkles and edema, were assessed 48 h post-application using the Draize scale. Combined mean irritation scores were calculated for each sample.

Results: A total of 26 subjects were enrolled, and 25 completed the study. One subject was discontinued due to unrelated systemic symptoms. Venusia Acne Facewash showed a combined mean irritation score of 1.08, classifying it as a non-irritant. The negative control showed no reaction (0.00), while the positive control showed a higher irritation score (3.04). All subjects showed complete recovery from any local reactions within 1 week.

Conclusion: Venusia Acne Facewash demonstrated good dermal tolerance and was classified as non-irritant under the test conditions. These findings support its dermal safety and safe use as part of a regular skincare regimen, particularly for individuals seeking a gentle cleansing formulation.

Keywords: Acne vulgaris, Erythema, Facewash, Edema, Skin irritation

INTRODUCTION

Acne vulgaris is a chronic inflammatory condition of the pilosebaceous unit, which includes the hair follicle, hair shaft, and sebaceous gland.^[1] It is the most common skin condition worldwide, affecting approximately 20.5% of the global population, with one in five adults (aged between 25 and 39 years) experiencing acne.^[2] In India, acne affects approximately 72% of both children and adolescents, while around 27% of cases are seen in adults, indicating a high prevalence in younger age groups.^[3,4] It is characterized by a variety of lesions ranging from non-inflammatory, superficial comedones (blackheads or whiteheads) to inflammatory, deeper lesions such as

This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-Share Alike 4.0 License, which allows others to remix, transform, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

©2026 Published by Scientific Scholar on behalf of CosmoDerma

papules, pustules, nodules, and cysts, often leading to scarring and hyperpigmentation.^[5]

In adult persistent acne, genetic and familial factors are primary contributors; poor hygiene can exacerbate acne.^[6-8] Therefore, incorporating mild, gentle, and effective cleansers such as face washes in a person's skincare regimen is an important component of acne management.

Harsh skincare products containing irritants such as sulfates, parabens, synthetic fragrances, or artificial colors can damage the skin barrier, leading to irritation, dryness, or allergic reactions such as contact dermatitis.^[9-11] In contrast, gentle, non-irritating facewashes enriched with vitamins, antioxidants, and hydrating ingredients help cleanse the skin effectively, without disrupting the skin's natural moisture barrier, making them valuable in acne management, especially for individuals with sensitive or acne-prone skin.^[12,13]

Given the widespread and frequent use of facewashes, especially on sensitive skin, these products must undergo rigorous safety and dermatological testing before commercialization, particularly to evaluate skin tolerability. Various testing methods (including patch test) are commonly used to assess skin irritation and evaluate the safety of personal care and cosmetic products.^[14,15] A suitable facewash should cleanse the skin without stripping away the lipids, proteins, and the beneficial microbiome that maintains the skin integrity.^[16]

Venusia Acne Facewash, developed by Dr. Reddy's Laboratories, is a cosmetic cleanser formulated for acne-prone skin. It contains active ingredients such as salicylic acid and glycolic acid, which provide exfoliating benefits.^[17,18] In addition, it contains aloe vera, which has been shown to suppress the hyperproliferation of *Propionibacterium acnes* and aid in acne improvement,^[19] and niacinamide, which exhibits anti-inflammatory properties, regulates sebum production, and supports skin barrier function.^[20] Considering its intended daily use on sensitive skin, it is critical to establish its dermal safety profile, despite its promising use in acne. This study aims to assess the dermal safety of Venusia Acne Facewash through a patch test, to determine its suitability as a daily cosmetic adjuvant for acne-prone skin.

MATERIAL AND METHODS

Study design

This was a monocentric, non-randomized, single-blinded, single-application, controlled trial conducted over a period of 10 days. This study was designed to evaluate the skin irritation potential of Venusia Acne Facewash using a patch

test in accordance with IS 4011: 2018 Methods of Test for Safety Evaluation of Cosmetics (Third Revision) guidelines.

Ethical approval

The study was approved by the Independent Ethics Committee of C.L.A.I.M.S. Pvt. Ltd (ECR/245/Indt/MH/2015/RR-22; approved on April 30, 2025). The trial is carried out in compliance with the protocol (Protocol No.: CL/013/0425/STU; Version No.: 1; dated April 21, 2025), Declaration of Helsinki, The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use E6 (R3) Guideline for Good Clinical Practice, Good Clinical Laboratory Practices, along with Bureau of Indian Standards and Indian Council of Medical Research guidelines concerning medical research in humans. This trial was registered with the Clinical Trial Registry of India (CTRI Registration No: CTRI/2025/05/087030).

Informed consent

The study, including potential risks and benefits, was explained to the subjects by the principal investigator (PI) before screening for the study. All subject queries were cleared by the PI. Those who agreed to participate provided their consent to participate in the trial.

Study subjects

Healthy male and female volunteers aged 18–65 years, with Fitzpatrick skin types III to V and having apparently healthy skin on the test area, were included in the study. Only individuals whom the PI deemed likely to comply fully with trial procedures were considered. Subjects were required to adhere to all protocol requirements, including avoiding intense ultraviolet exposure and water or sweat-inducing activities on the test site during the trial. Exclusion criteria included pregnancy or lactation, history of excessive sweating or participation in athletics, the presence of scars, tattoos, or excessive hair on the test site, and any dermatological conditions, hypersensitivity, or clinically significant systemic or cutaneous diseases that might interfere with trial outcomes. Individuals undergoing any medical treatment (topical or systemic) within the past month, or those currently involved in another clinical or cosmetic trial, were also excluded from the study.

Blinding procedure

This was an investigator-blinded study in which the samples were coded and labeled by C.L.A.I.M.S. Pvt. Ltd., ensuring that the investigator remained unaware of the product identity during evaluation.

Primary endpoint

The primary endpoint was to evaluate the occurrence and severity of skin irritation reactions (erythema, edema, dryness, and scaling/wrinkling), using the Draize scale.

Study product and controls

An 8% w/w aqueous dilution of Venusia Acne Facewash was prepared using distilled water. This concentration was selected in accordance with the IS 4011:2018 Methods of Test for Safety Evaluation of Cosmetics (Third Revision) guidelines, which recommend an 8% dilution for surfactant-based products, and to ensure subject safety during occluded patch application. Approximately 0.04 mL of the diluted product was absorbed onto filter papers and placed in the wells of the patch chambers. Positive control consisted of 1% sodium lauryl sulfate (SLS), and negative control was 0.9% isotonic saline solution, each similarly applied (0.04 mL) on separate sites using the same patch chamber method.

Application procedure

During screening visit 1, patch chambers containing the test product, positive control, and negative control were occlusively applied to designated areas on the subject's back, with an occlusion period of 24 h. In Visit 2 (24 h post-application), patches were removed. Visit 3 (48 h from initial application) involved clinical evaluation of the

test sites under standardized artificial daylight conditions. Subjects showing any visible reactions at 48 h were called for Visit 4 (1-week post-application) to confirm resolution of symptoms. Representative photographs were taken from 10 subjects for documentation. The brief chronology of events is depicted in Figure 1.

Evaluation and scoring

Skin reactions were assessed using the Draize scoring system, where erythema and dryness/wrinkling were scored on a scale of 0–4, with higher scores indicating increased severity. Edema was scored separately on the same 0–4 scale. A score of 0 indicated no reaction, while scores of 1 to 4 represented very slight-to-severe responses [Table 1].

Reactions were evaluated 24 h after patch removal (i.e., 48 h after application) to allow for the manifestation of any delayed irritation responses. For each sample (test product, positive control, and negative control), the Mean Irritation Score was calculated using the formula:

$$\text{Mean Score for Irritation} = \frac{\text{Total Score (Erythema + Oedema) for all subjects}}{\text{Total number of subjects}}$$

The resulting mean scores were then interpreted using the following classification criteria: up to 2.0/8.0 indicated a non-irritant, >2.0/8.0–4.0/8.0 indicated a mild irritant, and

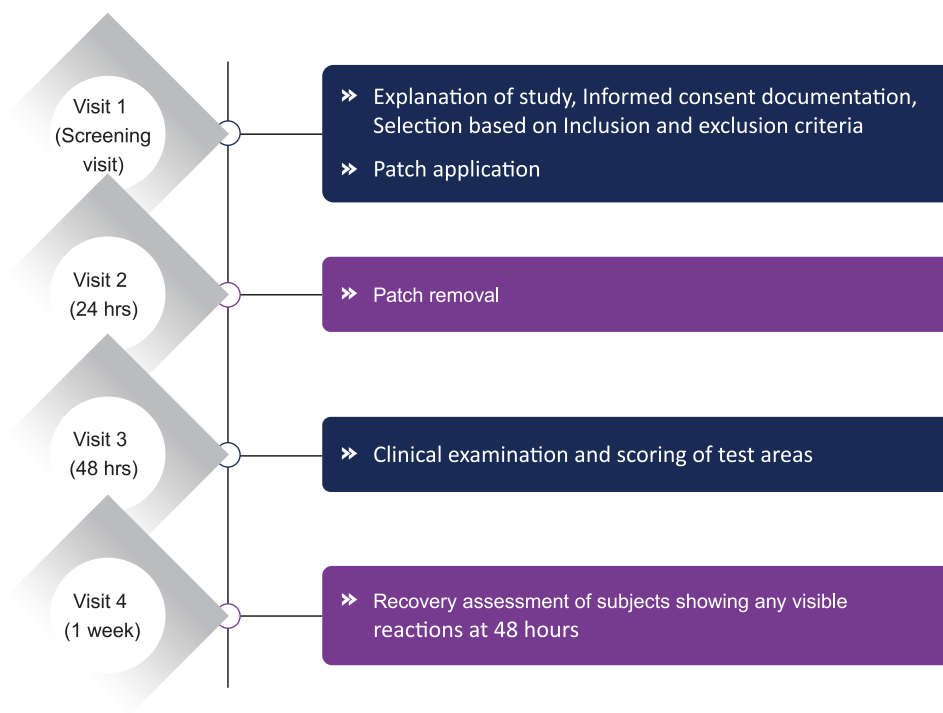


Figure 1: Flowchart of the study, explaining events in chronological order.

>4.0/8.0 classified the product as an irritant. Comparative analysis between the test product and controls was conducted to determine the irritation potential of the facewash.

Safety monitoring

All adverse events (AEs) and serious AEs were recorded and assessed by the PI for their potential relationship to the study product.

Statistical analysis

Data were recorded and presented in tabular form for descriptive interpretation. No formal statistical analysis was conducted.

RESULTS

Between June 11, 2025, and June 20, 2025, 26 subjects were recruited, wherein one subject dropped out due to unrelated systemic symptoms. Data were analyzed for 25 subjects [Figure 1].

Subject demographics

The age range of subjects was between 18 and 54 years, with an average age of 31.56 ± 12.15 years. Of the subjects, 13 (52%) were male, and 12 (48%) were female.

Skin irritation assessment and mean score analysis

The Venusia Acne Facewash showed a mean erythema score of 0.84, a mean edema score of 0.24, and a combined irritation score of 1.08, classifying it as a non-irritant based on the predefined category ($\leq 2.0/8.0$) [Table 2]. The negative control (0.9% isotonic saline) showed no irritation. The positive control (1% SLS) demonstrated higher irritancy, with a combined mean score of 3.04. A photographic representation of two subjects at the time of patch application and scoring is provided in Figure 2.

Safety assessment

No AEs related to the test product were reported. Fever, throat infection, and nausea were reported in one subject during the study, and sought medical treatment independently. The event was assessed by the investigator and deemed not related to the test product. The subject recovered but was discontinued from the study.

At the follow-up visit 4, all subjects were re-evaluated to confirm resolution of any skin reactions. All observed reactions had completely subsided by this visit.

Table 1: Draize scale for skin irritation scoring.

Score	Reaction
Erythema/dryness/wrinkles	
0	No reaction
1	Very slight erythema/dryness with shiny appearance
2	Slight erythema/dryness/wrinkles
3	Moderate erythema/dryness/wrinkles
4	Severe erythema/wrinkles/scales
Edema	
0	No reaction
1	Very slight edema
2	Slight edema
3	Moderate edema
4	Severe edema

Table 2: Combined mean scores of subjects at 48 h (visit 3).

Products	Mean score (A)	Mean score (O)	Mean score (A+O)	Irritancy assessment
Venusia Acne Facewash ($n=25$)	0.84	0.24	1.08	Non-Irritant
0.9% Isotonic Saline (Negative Control) ($n=25$)	0.00	0.00	0.00	Non irritant
1% SLS (Positive Control) ($n=25$)	1.96	1.08	3.04	Mildly irritant
Erythema/Dryness/Wrinkles=(A), Edema=O, Erythema/Dryness/Wrinkles+Edema=A + O. SLS: Sodium lauryl sulfate				

DISCUSSION

Many environmental pollutants, cosmetic residues, and skin lipids are not water-soluble and therefore cannot be effectively removed by rinsing with plain water alone.^[21] Cleansing plays a critical role in maintaining skin hygiene, particularly for individuals with acne-prone or sensitive skin.^[21] Cleansers function as surface-active agents that reduce surface tension, facilitating the removal of sebum, dirt, microbes, makeup, and desquamated skin cells.^[21,22] However, not all cleansers are equally skin-friendly. Traditional soap-based products often contain harsh surfactants that can disrupt the skin barrier, leading to irritation, dryness, erythema, or itching.^[22] While the choice of cleanser may be less critical for individuals with healthy skin, it becomes particularly important in dermatological conditions such as acne vulgaris, atopic dermatitis, rosacea, and sensitive skin syndromes.^[21]

Mild, moisturizing formulations are preferred, as they offer cleansing benefits while helping to maintain the skin's hydration and viscoelastic properties.^[22] For acne-prone skin,

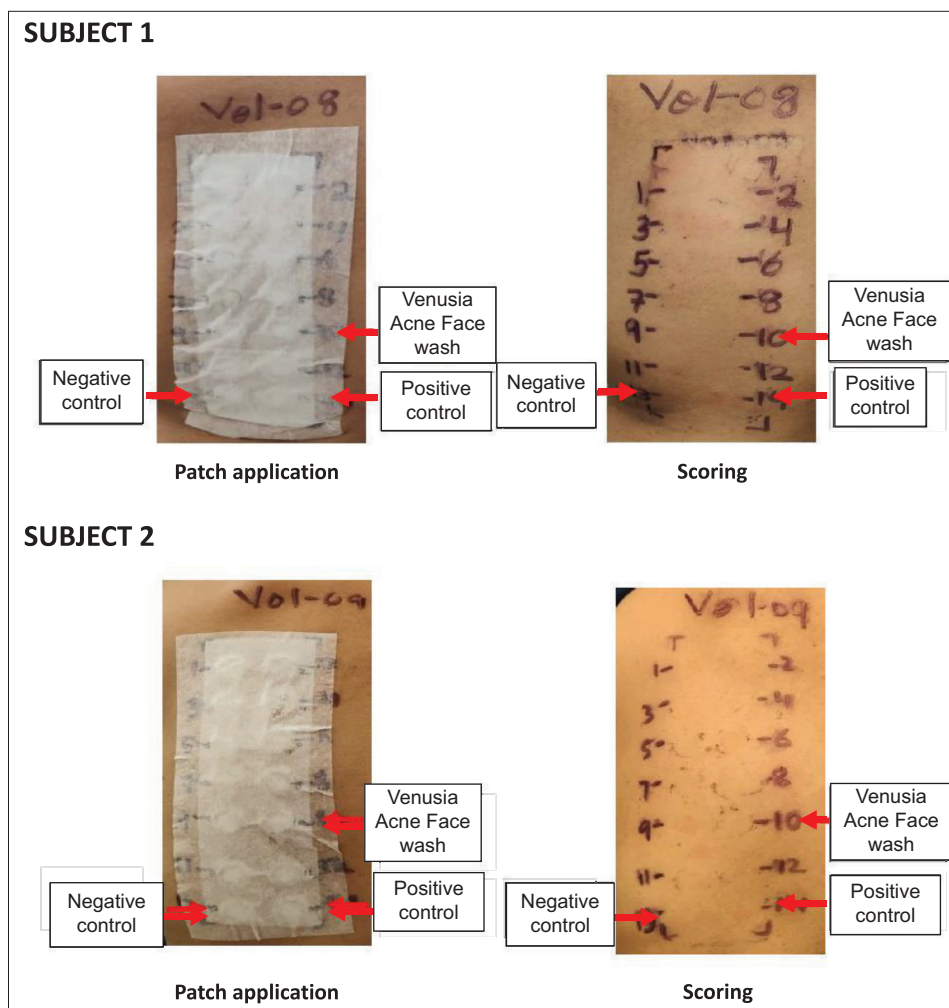


Figure 2: Representative photographs of subjects at the time of patch application and scoring.

the goal of cleansing is to gently eliminate surface debris, excess oil, and sweat without provoking inflammation or exacerbating skin dryness.^[21] Thus, products should be non-irritating, non-comedogenic, non-acnegenic, non-allergenic, and compatible with concurrent topical treatments.^[21]

Skin irritation is one of the most common local adverse effects associated with dermally applied personal care products.^[15] In addition to irritation, cosmetics can also cause allergic reactions and acneiform eruptions in sensitive individuals.^[15] Therefore, evaluating the irritation and sensitization potential of cosmetic formulations is an essential step in ensuring their safety before widespread use.^[15]

The current study evaluated the dermal safety and irritation potential of Venusia Acne Facewash using a standardized patch test in healthy adult volunteers. The results demonstrate that the product has a low irritation potential, with a mean irritation score of 1.08, thereby classifying it as non-irritant based on predefined criteria. This finding is clinically

relevant, especially considering the intended daily use of the product to maintain healthy skin, and may additionally benefit individuals with sensitive, acne-prone skin. The absence of any AEs related to the product further supports its tolerability and safety.

The favorable tolerability profile of Venusia Acne Facewash observed in this study may be attributed to its well-balanced formulation, combining therapeutic efficacy with skin barrier protection. The product contains a range of active ingredients commonly used in acne management, including salicylic acid, niacinamide, glycolic acid, and aloe vera. Salicylic acid provides comedolytic and exfoliating effects that help prevent pore blockages.^[23] Niacinamide complements this action by reducing inflammation, improving skin texture, and minimizing post-inflammatory hyperpigmentation.^[23] The formulation also includes zinc-pyrrolidone carboxylic acid (PCA), known for its sebum-regulating and anti-inflammatory properties, which can help reduce the number of inflammatory lesions in acne-prone skin.^[24,25]

Notably, the use of encapsulated salicylic acid may contribute to the low irritation observed in this study by enabling controlled release, thereby maintaining exfoliating and broad-spectrum antimicrobial activity while minimizing skin sensitivity. Additional components, such as glycolic acid, support exfoliation and improve skin texture.^[23] Hydrating and barrier-supporting agents, including allantoin, oat extract, aloe vera, and a hyaluronic acid–ceramide complex, play a crucial role in maintaining skin moisture levels and reducing transepidermal water loss, which are essential in minimizing irritation and supporting overall skin health. Importantly, the cleanser is formulated with mild, sulfate-free surfactants such as decyl glucoside, cocamidopropyl betaine, and sodium lauroyl sarcosinate. These agents are known for their gentle cleansing action and are less likely to disrupt the skin barrier compared to traditional soap-based surfactants. The inclusion of multivitamin beads containing Vitamins A, C, E, B3, and B5 further enhances the formulation by offering antioxidant protection and supporting skin repair processes. Together, these ingredients create a synergistic formulation that not only targets acne-related concerns but also promotes barrier integrity and reduces the risk of irritation, consistent with the non-irritant classification observed in this study. The clinical relevance of such a gentle formulation lies in its suitability for daily use across different skin types, including sensitive and acne-prone skin. By cleansing effectively without disrupting skin hydration, Venusia Acne Facewash demonstrates good overall tolerability, making it appropriate for regular use as part of an acne management regimen and for maintaining healthy skin.

This study has several strengths. It employed a standardized patch testing method in accordance with IS 4011: 2018 Methods of Test for Safety Evaluation of Cosmetics (Third Revision) guidelines, using both positive and negative controls, contributing to its methodological soundness. The use of human subjects, validated scoring systems, and photographic records enhanced the credibility and consistency of the results. Nonetheless, certain limitations should be acknowledged. The study population comprised healthy individuals under controlled conditions, which may limit generalizability. The small sample size, while adequate for initial safety assessment, also restricts generalizability. In addition, it did not evaluate potential skin reactions from repeated or long-term use, as this was a single-application study. Future studies, including human repeat insult patch tests or long-term trials in acne patients, are needed to confirm the product's safety and efficacy in routine use.

CONCLUSION

Venusia Acne Facewash was found to be non-irritating under controlled test conditions, with no adverse skin reactions or intolerance reported. These findings support its dermal safety and safe use as part of a regular skincare regimen. Further

clinical evaluation in the target population may help substantiate its suitability for routine use, particularly for individuals with acne-prone skin seeking a gentle cleansing formulation.

Acknowledgments: The authors thank the study subjects, principal investigators, and site (Site name: C.L.A.I.M.S. Pvt. Ltd.) staff.

Ethical approval: The research/study was approved by the Institutional Review Board at 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 participants' consent forms. In the form, the participants have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial Support and Sponsorship: The study was funded by Dr. Reddy's Laboratories Ltd., Hyderabad, Telangana, India.

Conflict of interest: All authors are employees of Dr. Reddy's Laboratories Ltd.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation: The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

REFERENCES

1. Tuchayi SM, Makrantonaki E, Ganceviciene R, Dessinioti C, Feldman SR, Zouboulis CC. Acne vulgaris. *Nat Rev Dis Primers* 2015;1:1-20.
2. Saurat JH, Halioua B, Baissac C, Cullell NP, Ben Hayoun Y, Aroman MS, et al. Epidemiology of acne and rosacea: A worldwide global study. *J Am Acad Dermatol* 2024;90:1016-8.
3. Sharma RK, Dogra S, Singh A, Kanwar AJ. Epidemiological patterns of acne vulgaris among adolescents in North India: A cross-sectional study and brief review of literature. *Indian J Paediatr Dermatol* 2017;18:196-201.
4. Budamakuntla L, Parasramani S, Dhoot D, Deshmukh G, Barkate H. Acne in Indian population: An epidemiological study evaluating multiple factors. *IP Indian J Clin Exp Dermatol* 2020;6:237-42.
5. Vasam M, Korutla S, Bohara RA. Acne vulgaris: A review of the pathophysiology, treatment, and recent nanotechnology based advances. *Biochem Biophys Rep* 2023;36:101578.
6. Goulden V, Mcgeown CH, Cunliffe WJ. The familial risk of adult acne: A comparison between first-degree relatives of affected and unaffected individuals. *Br J Dermatol* 1999;141:297-300.
7. Ogé LK, Broussard A, Marshall MD. Acne vulgaris: Diagnosis and treatment. *Am Fam Physician* 2019;100:475-84.
8. Lynn DD, Umari T, Dunnick CA, Dellavalle RP. The epidemiology of acne vulgaris in late adolescence. *Adolesc Health Med Ther* 2016;7:13-25.
9. Scheinman PL, Vocanson M, Thyssen JP, Johansen JD, Nixon RL, Dear K, et al. Contact dermatitis. *Nat Rev Dis Primers* 2021;7:38.

10. Held E. So moisturizers may cause trouble! *Int J Dermatol* 2001;40:12-3.
11. Goel S, Shetty VH, Eram H, Babu AM. Study of the clinical pattern of contact dermatitis over the face and its correlation with patch testing. *Int J Res Dermatol* 2019;5:350-6.
12. Yogesh HR, Gajjar T, Patel N, Kumawat R. Clinical study to assess efficacy and safety of purifying neem face wash in prevention and reduction of acne in healthy adults. *J Cosmet Dermatol* 2022;21:2849-58.
13. Shafaat K, Kumar P, Kumar A, Kumar S, Kumar A, Raj R, *et al.* A Comprehensive insights into face wash: Formulation, function, and applications. *Int Pharm Sci* 2025;18:135.
14. Jírová D, Basketter D, Liebsch M, Bendová H, Kejlová K, Marriott M, *et al.* Comparison of human skin irritation patch test data with *in vitro* skin irritation assays and animal data. *Contact Dermatitis* 2010;62:109-16.
15. Kose O, Erkekoglu P, Sabuncuoglu S, Kocer-Gumusel B. Evaluation of skin irritation potentials of different cosmetic products in Turkish market by reconstructed human epidermis model. *Regul Toxicol Pharmacol* 2018;98:268-73.
16. Levin J, Miller R. A guide to the ingredients and potential benefits of over-the-counter cleansers and moisturizers for rosacea patients. *J Clin Aesthet Dermatol* 2011;4:31-49.
17. Wiegmann D, Haddad L. Two is better than one: The combined effects of glycolic acid and salicylic acid on acne-related disorders. *J Cosmet Dermatol* 2020;19:2349-51.
18. Măgeruşan ŞE, Hancu G, Rusu A. A comprehensive bibliographic review concerning the efficacy of organic acids for chemical peels treating acne vulgaris. *Molecules* 2023;28:7219.
19. Pal S, Raj M, Singh M, Saurav K, Paliwal C, Saha S, *et al.* The effect of *Aloe vera* on skin and its commensals: Contribution of acemannan in curing acne caused by *Propionibacterium Acnes*. *Microorganisms* 2024;12:2070.
20. Kurokawa I, Kobayashi M, Nomura Y, Abe M, Kerob D, Dreno B. The role and benefits of dermocosmetics in acne management in Japan. *Dermatol Ther (Heidelb)* 2023;13:1423-33.
21. Mukhopadhyay P. Cleansers and their role in various dermatological disorders. *Indian J Dermatol* 2011;56:2-6.
22. Ananthapadmanabhan KP, Moore DJ, Subramanyan K, Misra M, Meyer F. Cleansing without compromise: The impact of cleansers on the skin barrier and the technology of mild cleansing. *Dermatol Ther* 2004;17:16-25.
23. Mysea MJ, Kusumawardani A, Murasmita A, Widhiati S. The relationship of over the counter (OTC) facial soap usage and acne risk in Sebelas Maret university medical students. *Berkala Ilmu Kesehatan Kulit dan Kelamin* 2024;36:191-5.
24. Andrade JP, Wagemaker TA, Mercurio DG, Maia Campos P. Benefits of a dermocosmetic formulation with vitamins B3 and a B6 derivative combined with zinc-PCA for mild inflammatory acne and acne-prone skin. *Biomed Biopharm Res* 2018;15:214-23.
25. Sitohang IB, Yahya YF, Simanungkalit R, Adi Winarni DR, Madjid A. Efficacy and tolerability of topical nicotinamide plus antibacterial adhesive agents and zinc-pyrrolidone carboxylic acid versus placebo as an adjuvant treatment for moderate acne vulgaris in Indonesia: A multicenter, double-blind, randomized, controlled trial. *J Clin Aesthet Dermatol* 2020;13:27-31.

How to cite this article: Gala M, Muchhala S, Bhagat S, Sanghvi A, Kotak B. Evaluation of skin safety of Venusia Acne Facewash for primary skin irritation using skin irritation test: Patch test in humans. *CosmoDerma*. 2026;6:27. doi: 10.25259/CSDM_232_2025