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Original Research Article

Assessment of primary skin irritation potential of Venusia cleanser: a human patch test study

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ABSTRACT

Background: This study aimed to evaluate the skin irritation potential of Venusia Cleanser using a standardized human patch test, with particularly in individuals with sensitive skin.
Methods: A monocentric, single-blind, controlled study was conducted in accordance with IS 4011: 2018 Methods of Test for Safety Evaluation of Cosmetics (Third Revision) and ICH-GCP guidelines. Healthy adults aged 18–65 years were enrolled, with 50% having sensitive skin based on the lactic acid sting test. Venusia Cleanser (8% dilution), 0.9% saline (negative control), and 1% sodium lauryl sulfate (SLS, positive control) were applied on the upper back for 24 hrs using a patch test. Patches were applied at Visit 1 and removed after 24 hrs at Visit 2. Draize scoring was done at 48 hours, with a 1-week follow-up to confirm recovery.
Results: Of the 26 participants, 25 completed the study (mean age 31.6 years; 13 males, 12 females; 13 with sensitive skin). At 48 hours, Venusia Cleanser (8% dilution) demonstrated a mean irritation score of 1.12, well below the IS 4011:2018 threshold of 2.0, confirming its non-irritancy. The positive control (1% SLS) showed marked irritancy (mean score 3.04), while saline (mean score 0.00) produced no reaction. No delayed reactions occurred, and the formulation was well tolerated in both the sensitive and normal skin groups.
Conclusions: Venusia Cleanser was demonstrated to be safe, well-tolerated, and non-irritant for sensitive skin. These findings reinforce its suitability for daily-use cleansers, particularly for gentle cleansing that helps maintain skin barrier integrity while minimizing irritation risk.

Keywords: Human patch test, Non-irritant cleanser, Sensitive skin dermal safety, Topical formulation

INTRODUCTION

The skin, the body's largest organ, serves as a critical barrier against chemical, microbial, and physical insults while helping to maintain hydration and overall homeostasis.[1] The integrity of this barrier depends heavily on the stratum corneum (SC) and its lipid matrix.[2] As many environmental contaminants and cosmetics are insoluble in water, simply washing the skin with water would not be enough to get rid of them.[3] Cleansing is a cornerstone of skin care and is necessary for removing sebum, dirt, sweat, and microbial contaminants, and controlling odor. However, inappropriate cleansers on contact with SC can strip skin of its essential lipids and proteins, leading to irritation, barrier damage, and worsening of skin conditions.[4,5] Skin cleansers are available as soap-based or synthetic detergents (Syndets). Usually, soaps tend to fall in the alkaline pH range, and syndets usually belong to the mildly acidic and neutral pH range group. Harsh alkaline soaps induce unfavorable changes to the skin barrier, such as itching, dryness, cracking, inflammation, and roughness. This leads to skin

becoming dehydrated and more prone to irritation and sensitivity.[6] Syndets, on the other hand, are a better choice, are preferred due to their skin-friendly pH, they result in a very low skin barrier disruption.[7] Additionally, while creating a cleanser, special attention needs to be given to the vulnerable skin categories, such as sensitive skin and infant skin, as their skin differs from general adult skin.[8] Hence, modern formulations have shifted toward mild, pH-balanced, syndet-based cleansers, often enriched with emollients and humectants to reduce surfactant-induced barrier disruption.[5]

Cleansers and moisturizers, like the ones comprising ceramides, support a healthy skin barrier and have been widely utilized to prevent adverse reactions caused by any topical or systemic treatments, strengthening treatment adherence and enhancing patient results.[9]

The importance of safety validation is amplified in the Indian context, where skin phototypes IV–V predominate and climatic factors such as heat, humidity, and pollution, which may contribute to sensitive skin, leading to more dryness and itching.[10,11] It is estimated that approximately 1-5.4% of the population is sensitive to cosmetic ingredients. Nearly 80% of the reactions arise in patients between 20-60 years and are observed more commonly in females and nearly 5200 substances are recognized as allergens, which may result in allergic contact dermatitis (ACD).[12,13]

ACD usually results from the overreaction of our immune system to certain allergens.[14] Patch testing serves as a potential diagnostic tool and is an imperative method to identify allergens causing ACD.[15] It is generally utilized to generate a miniature eczematous response by placing allergens under occlusion on undamaged patient skin, which is considered to be allergic.[16] Hence, against this backdrop, the present study was designed to evaluate the irritation potential of Venusia Cleanser using a standardized human patch test IS 4011: 2018 Methods of Test for Safety Evaluation of Cosmetics (Third Revision) guidelines, focusing on its tolerability in individuals.

METHODS

Participant informed consent

Before screening, the study details, potential risks, and benefits were explained to participants by the investigator in a language they understood. All participant queries were addressed. Individuals who were willing to participate provided written informed consent before undergoing any study-related procedures.

Study design and population

This was a monocentric, single-blinded, controlled clinical study conducted in Mumbai, India. The study was carried out at Clinical Aesthetics and Investigative Management Service Private Limited (C.L.A.I.M.S. Pvt. Ltd), located at 27 MIDC Commercial Premises, 5th Floor, 17th Road, MIDC, Andheri East, Mumbai 400093. The trial was conducted over a defined period, from 11 June 2025 to 20 June 2025. Healthy volunteers (aged 18–65 years) were enrolled with an equal representation of men and women where possible.

To ensure real-world relevance, 50% of participants were selected with sensitive skin, identified using the lactic acid sting test, while the remainder had normal skin. Only participants with healthy skin at the test site and Fitzpatrick skin phototypes III–V were included, reflecting the predominant Indian skin types. Exclusion criteria included pregnancy or lactation, dermatological conditions, known cosmetic allergies, scars, tattoos, or excessive hair at the test site, chronic illnesses, and any ongoing systemic or topical medication use that could interfere with outcomes. Participants were instructed to avoid sun exposure, swimming, sauna, or strenuous activity that could alter skin reactions during the study.

Investigational products

Test product: Venusia Cleanser (evaluated at 8% w/w dilution in distilled water). The active ingredients of the test product include sodium cocoyl isothionate, allantoin, niacinamide, hydrosella, provitamin B5, oatmeal extract, triple ceramide with hyaluronic Acid (HA).

Negative control: 0.9% isotonic saline solution.

Positive control: 1% sodium lauryl sulfate (SLS), a well-established skin irritant used as a benchmark for sensitivity testing. Approximately 0.04 ml of each solution was applied on filter papers secured within occlusive patch chambers.

Patch preparation and application

Patches were applied on the back for 24 hours and then removed. At 48 hours, the application sites were examined and scored under standardized lighting. Local reactions such as, erythema, dryness, oedema, and wrinkling were graded using the Draize scale (0–4-point scale). This approach ensured standardized evaluation of irritation potential, while the inclusion of saline and SLS controls validated both the sensitivity and specificity of the model.

Follow-up schedule

Visit 1 (baseline): Consent taking, medical history, screening, and patch application.

Visit 2 (24 hours): Patch removal.

Visit 3 (48 hours): Clinical examination and grading of test areas.

Visit 4 (1 week): Confirming recovery of the patients who had experienced reactions.

Endpoint and scoring

Table 1 illustrates the Draize scale used to evaluate skin irritation. The primary endpoint was the mean irritation score for each product, calculated as:

Mean irritation score=

$$\frac{\textbf{Total (erythema + oedema) score across participants}}{\textbf{Number of participants}}$$

Table 1: Draize scale for skin irritation evaluation.

Evaluation of skin irritation reactions (erythema, oedema, dryness, scaling wrinkling)		
Scores	**Erythema/dryness/wrinkling**	**Oedema**
0	No reaction	No reaction
1	Very slight erythema/dryness with shiny appearance	Very slight
2	Slight	Slight
3	Moderate	Moderate
4	Severe	Severe

Interpretation followed IS 4011:2018 methods of test for safety evaluation of cosmetics (third revision) guidelines:

≤2.0/8.0=non-irritant, 2.0–4.0/8.0=Mildly irritant, 4.0/8.0=Irritant.

Sample size and statistical analysis

The study enrolled a total of 26 participants, with 25 completing all study procedures and one participant discontinuing prematurely. The sample size met the minimum requirement of 24 subjects as stipulated by IS 4011:2018 Guidelines (Third Revision) for safety evaluation of cosmetics. The study was descriptive in nature. Positive and negative controls confirmed assay validity, allowing interpretation of the test product's irritancy potential with clinical confidence.

Ethical considerations

The study protocol was reviewed and approved on 30 April 2025 by the Independent Ethics Committee (Re-Registration number: ECR/245/Indt/MH/2015/RR-22), C.L.A.I.M.S. Pvt. Ltd., Mumbai, India. The trial adhered to the Bureau of Indian Standards IS 4011:2018 Methods of Test for Safety Evaluation of Cosmetics (Third Revision) guidelines, ICMR guidelines (2017), ICH-GCP (E6 R3,2016), Good Clinical Laboratory Practices (GCLP), and the Declaration of Helsinki (Brazil, 2013). All participants provided written informed consent prior to study-related procedures.

RESULTS

Demographic characteristics

Of 26 participants enrolled, 25 completed the study; one participant discontinued due to an adverse event deemed unrelated to the test product. Participants ranged in age from 18 to 54 years, with a mean age of 31.56±12.15 years. The study population comprised 13 males and 12 females. Based on skin type, 13 participants were categorized as having sensitive skin and 12 as having normal skin. Table 2 outlines the demographic and other baseline characteristics of the study population.

Table 2: Demographic and other baseline characteristics.

Parameters	Value
Total no. of participants	25
Age (years)	
Mean	31.56
Standard deviation (SD)	12.15
Range	18-54
Sex	
Male	13
Female	12
Skin type	
Sensitive skin	13
Normal skin	12

Irritation assessment

At 48 hours (Visit 3), skin irritation was assessed using oedema (O) and erythema/dryness/wrinkles (A) scores. The combined mean scores (A+O) for each product are shown in Table 3 and illustrated in Figure 1.

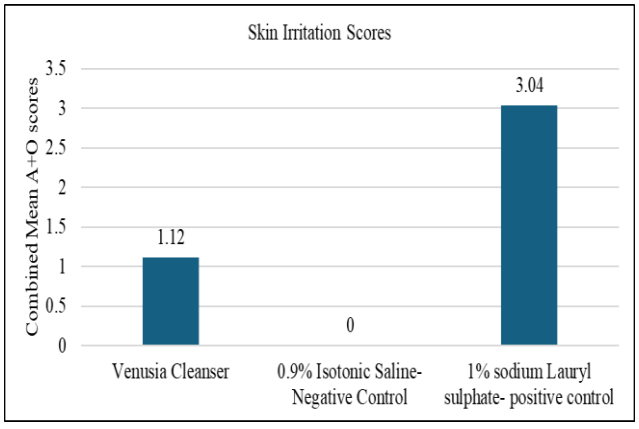

Figure 1: Skin irritation scores of test product, positive, and negative controls.

The test product, Venusia Cleanser (8% dilution), had an average score of 1.12, indicating it is non-irritating. The negative control (0.9% isotonic saline) showed a score of 0.00, confirming no irritation. The positive control (1%

sodium lauryl sulfate) exhibited a significantly higher combined mean score of 3.04, indicating its irritant potential. These findings confirm the study design's sensitivity and specificity, showing that the test product was well-tolerated, and no delayed reactions were observed at the 1-week follow-up.

Table 3: Combined mean skin irritation scores of participants recorded at visit 3 (48 hours).

Products	Sample size	Mean score(A)	Mean score(O)	Mean score	Irritancy assessment
Venusia cleanser	25	0.76	0.36	1.12	Non-irritant
0.9% isotonic saline-negative control	25	0.00	0.00	0.00	Non-irritant
1% sodium lauryl sulfate- positive control	25	1.96	1.08	3.04	Mildly-irritant

*Oedema= O, *Erythema/Dryness/Wrinkles =(A), *Erythema/Dryness/Wrinkles+Oedema= A+O

Adverse events

One participant experienced fever, throat infection, and nausea. They recovered after treatment but were discontinued from the study. The event was unrelated to the test product.

DISCUSSION

In this study, Venusia Cleanser (8% w/w dilution) demonstrated a non-irritant profile, with a mean irritation score of 1.12, which was well below the IS 4011: 2018 Methods of Test for Safety Evaluation of Cosmetics (Third Revision) guidelines threshold of 2.0. The positive control, 1% sodium lauryl sulfate (SLS), produced significant irritation (mean score 3.04), whereas saline caused no reaction, thereby confirming the validity and sensitivity of the assay. Importantly, both sensitive and non-sensitive skin subgroups tolerated the formulation without irritation, and no delayed irritation reactions were observed at the 1-week follow-up, underscoring its short-term safety across different skin types.

Chan et al showed that SLS-free aqueous cream had a reduced irritancy potential, compared to SLS-based formulation, along with the ability to maintain the trans epidermal water loss (TEWL), thus preserving hydration and skin integrity. These findings are consistent with broader evidence demonstrating the reduced irritancy of syndet-based formulations compared with traditional surfactant systems.[17]

Similarly, Aramaki et al confirmed that SLS-induced irritation is dose- and time-dependent, supporting its role as a benchmark irritant in patch testing.[18] The alignment of our data with the established literature strengthens the reliability of the study outcomes.

These results have direct clinical and consumer significance. In contrast, Venusia Cleanser, formulated with mild surfactant systems and a barrier-supportive base, demonstrated safety even in volunteers with sensitive skin under occlusive conditions, which are more rigorous than typical daily use. This study provides evidence supporting the cleanser as a safe, low-irritant option for daily hygiene.

A study by Hawkins et al also supported the daily use of cleansers, which significantly improved skin hydration, reduced dryness and sensitivity, and enhanced overall skin appearance in subjects, highlighting that daily cleansing is essential for maintaining healthy skin.[19]

One of the active ingredients of this test product, sodium cocoyl isethionate (SCI), is utilized as a key surfactant component in mild, syndet cleansing bars. SCI is less harmful to the skin barrier than soaps and surfactants like sodium dodecyl sulfate (SDS), according to in vitro and in vivo research studies.[20]

Among the other ingredients of this test product, colloidal oatmeal has several benefits. It has antioxidant, anti-inflammatory, a good hydrating, cleansing, and buffering agent. It is also anti-fungal, soothing, with anti-itch properties.[21] Other active ingredients include allantoin, niacinamide, triple ceramide with hyaluronic acid, hydrosella, and provitamin B5. Allantoin is a skin-soothing agent that has eczema-reducing properties.[22]

Dextrorotatory isomer of panthenol (provitamin B5), dexpanthenol, is biologically active.[23] According to studies conducted by Peltier et al, daily application of dexpanthenol-containing liquid cleanser (DCLC) for 4 weeks resulted in a good hydrating effect without altering the skin pH or skin barrier integrity, along with being a good emollient.[24] Hyaluronic acid is a compound that helps to maintain skin firmness and elasticity. It also helps in hydration and ceramide 3 helps in barrier repair.[22,25]

Niacinamide has antipruritic, photoprotective, antimicrobial, vasoactive, and lightening properties at a suitable bioavailability.[26] Hydrosella, containing rosella (Hibiscus sabdariffa L.), is a rich source of flavonoids, astaxanthin, known antioxidants that suppress matrix metalloproteinase-1, prevent collagen breakdown, and minimize ultraviolet-induced damage.[27]

From a consumer perspective, tolerability is as important as efficacy. The most effective formulations can also be ineffective if they trigger irritation. Irritation is a leading cause of product discontinuation, especially among users with sensitive skin. This makes the balance between cleansing power and barrier protection a critical differentiator.

A cleanser that balances effective cleansing with barrier protection by replenishing lost skin lipids and proteins, and enhances adherence to long-term skincare regimens, improving the overall dermatological outcomes.[5] Such adherence is imperative to achieve sustained dermatological benefits. Through this study, the non-irritant profile of Venusia Cleanser was demonstrated which positions Venusia Cleanser as a well-tolerated alternative to harsher face washes in both preventive and therapeutic skincare routines.

Strengths and limitations

The key strengths of this study include the inclusion of both sensitive and non-sensitive populations, adherence to international guidelines, and the use of validated positive and negative controls, which together enhance the reliability and generalizability of the findings. The limitations of this study include a relatively small sample size, a single-center design, and an evaluation restricted to acute irritation following a single application. The cumulative irritation and sensitization potential were not assessed, and the cleanser was not tested in populations with active dermatological conditions. Future research using Human Repeated Insult Patch Tests (HRIPT), multicenter trials, and real-world use studies would further substantiate its long-term safety and consumer applicability.

CONCLUSION

Based on standardized dermatological testing IS 4011: 2018 Methods of Test for Safety Evaluation of Cosmetics (Third Revision) guidelines, the Venusia Cleanser demonstrated a non-irritant profile in both sensitive and normal skin populations. The results confirm the suitability of this product as a safe, well-tolerated daily use cleanser that preserves skin barrier integrity while minimizing irritation risk. These findings provide tolerability data for Venusia Cleanser, particularly for individuals requiring both daily and long-term, low-irritancy, barrier-friendly cleansing regimens, including those with chronic dermatological conditions or sensitive skin.

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