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Evaluation of the comedogenic effect and safety assessment of skin lightening face serum in Indian subjects

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Introduction

- Acne cosmetica is a chronic inflammatory condition of the pilo-sebaceous follicle[1].
- It is estimated that the prevalence of the disease ranges from 1-12% in adult males and 12-17% in adult females[1]. Further, it is characterized by pimple-like breakouts caused by the use of pore-clogging cosmetics
- Cosmetics that can trigger acne cosmetica include sunscreens, topical creams and gels, moisturizers, lotions, and sprays[1]
- Comedogenicity is an essential consideration in the development of topical skin care products.
- The objective of this study was to evaluate the comedogenic effect of skin-lightening face serum in healthy Indian females

Methods

- This was a prospective, non-comparative, open-label single-centre study (CTRI/2025/01/079296) including healthy female subjects

- **Key inclusion criteria**: Healthy Indian female subjects, between 18-35 years of age, having mild to moderate acne and oily or mixed skin type on the face, as assessed by a dermatologist. Additionally, subjects having healthy skin on the studied anatomic unit (e.g., free of eczema, wounds, and inflammatory scars).

- **Key exclusion criteria:**
  - Have a chronic skin condition that may affect the test area (except for studies on specific skin conditions)
  - Pregnant, breastfeeding, or stopped breastfeeding in the last 3 months
  - Have uncontrolled thyroid problems, epilepsy, asthma, or insulin-dependent diabetes
  - On established chronic medications, including: Aspirin or Aspirin-based products, anti-inflammatory drugs, antihistamines, corticosteroids (except for Paracetamol)

- **Application:** Test product was applied to the face once daily in the morning for 28 days.
- **Primary endpoint:** Percent reduction in total number of lesions assessed by dermatologist at day 14-and-28
- **Secondary endpoints:**
  - Percent reduction in sebum assessed through sebumetry
  - Percent panel agreement on comedogenic effect from the self-evaluation questionnaire (SSE),
  - Study-related adverse events (AEs) and serious adverse events (SAEs) reported by the dermatologist and subject
  - Self-evaluation questionnaire (SSE) scores for comedogenic effect
  - Cosmetic appeal at day 14-and-28

Results

- Of the 36 subjects enrolled in the study, 35 subjects (mean age: 23.9±5.3 years) completed the study.
- Baseline total number of lesions count (mean ± SD) was 9.29 ± 5.11. Forehead sebum content at baseline was 205.97 ± 29.67 µg/cm^2
- **Percentage change in total number of lesions:** Total number of lesions reduced by 16.62% and 34.46% from baseline to day 14 and 28, respectively ($p<0.001$ for all) (Figure 1)
- A significant reduction in closed comedones by 18.55% and 38.01%, and total retentional lesions by 18.37% and 37.55% from baseline to day 14 and 28, respectively
- **Percentage change in sebum value:** The anti-sebum effect of the product is demonstrated as there was a significant reduction of 17.74% and 36.66% in sebum value at day 14 and 28, respectively, compared to baseline ($p<0.001$ for both) (Figure 2)
- **Patient-reported SSE responses indicate that all subjects (100%) agreed that the test product**:
  - Did not produce comedones/acne/pimples, make skin oily, or cause any itching/irritation/burning sensation after 14 and 28 days of application
  - Had an appealing colour, fragrance, and quickly absorbed into the face after application
- No study-related AEs and SAEs were reported by the dermatologist and subjects

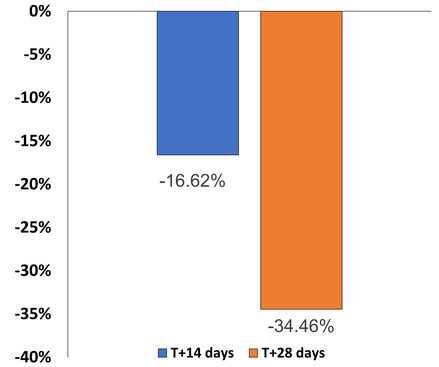

Figure 1: Percentage decrease in Total Number of Lesions

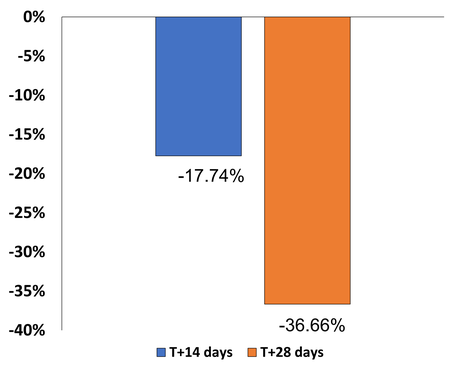

Figure 2: Percentage decrease in Forehead Sebum as assessed by Sebumetry

Conclusions

In this comedogenicity study, the test product, skin lightening face serum, was dermatologically tested and found to be non-comedogenic, well-tolerated, and cosmetically acceptable, demonstrating significant reductions in lesion count and sebum production over 28 days without any adverse effects.

References

1. Sharma K, *et al*. Review on acne cosmetica with management by vishaghan Mahakashay and lodhradi lepa. *Wjpmr.* 2018;4(11):105-109.

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