

Effect of Plant- Based Paraben Free Venusia Max Cream on Skin Hydration in Healthy Individuals with Dry Skin

Keywords: Plant-based moisturizer; Paraben free moisturizer; Skin hydration; Transepidermal water loss; Moisture meter; Vapometer

Abstract

Objective: Skin hydration is the crucial indicator in both pathological skin diseases and in cosmetic field for maintaining proper skin barrier function. Present study evaluated test product (Venusia Max cream-paraben free) for its skin surface hydration and Trans-Epidermal Water Loss (TEWL) in healthy women compared to the control site as well as the initial state.

Materials and Methods: Thirty healthy women of mean age 34.17 years were enrolled in randomized, evaluator-blinded, comparative study conducted in January 2020. The primary end points were the skin hydration and TEWL, evaluated and compared to the control site and baseline reading (0 hour) at 4 hours, 10 hours, 24 hours and 36 hours after test product application on the volar surface of the forearm using Moisture Meter SC and Vapo Meter device in standardized conditions.

Results: Skin hydration was measured as mean skin hydration readings (MMSC) was significantly increased at all time points after the application of test product as compared to the control site ($p < 0.001$; Student's 't' test). Further, the MMSC value at the test product site demonstrated a significant increase of 92%, 48% and 34% at 10, 24, and 36 hours respectively when compared to the baseline (0 hour) data ($p < 0.001$). Besides, a significant reduction in TEWL values at the test product site was observed at all the time periods ($p < 0.001$) as compared to the control site. Similarly, as compared to the baseline data, a significant decrease of 17.1%, 15.7%, 10.3% and 5.6% was observed in TEWL values at 4, 10, 24 and 36 hours respectively after the application of test product ($p < 0.001$). No adverse effects were reported due to the test product.

Conclusion: Venusia Max cream is a plant-based paraben free moisturizer which improved skin hydration and reduced moisture loss providing a long lasting effect.

Introduction

Skin is the largest organ of the human body [1]. Healthy skin ensures the proper functioning of the stratum corneum (SC) [2]. SC and its insoluble lipid layer primarily have water retention property and act as a natural moisturizer; and physical barrier against chemical, microbial and mechanical stress [3,4]. When water content of the skin is below 10%, then the visible appearance of dry and flaky skin is observed [5]. Skin dryness primarily increases with age as it alters the SC's keratinization processes and lipid contents [6]. Other than age, the moisture level of the skin also depends on multiple factors such as body sites, gender, geographical distribution, ethnicity, temperature, humidity, seasons, ultraviolet (UV) radiation exposure, cigarette smoke, smog, and diurnal variations [3,7]. Together these factors contribute to dry skin and other age-related manifestations.

Worldwide, about 75% of young individuals use moisturizer creams daily [8]. Moisturizers should satisfy four essential requirements for users that include softer and smoother skin,



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Monil YN Gala^{1*}, Snehal Sameer M¹, Sujeet Narayan C¹, Rahul Rathod R¹, Mane A¹, Pandit S¹, Alok Ranjan S² and Anup Avijit C²

¹Department of Medical Affairs, Dr Reddy's Laboratories, India

²Department of FR and D, Dr Reddy's Laboratories, India

*Address for Correspondence

Dr. Monil YN Gala, MBBS, MD (Pharmacology), Medical Advisor, Department of Medical Affairs, Dr Reddy's Laboratories, India; Tel: 9004117134; Email: monil.yogesh@drreddys.com

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increased skin hydration, improved skin appearance and possibly deliver the components to the skin's surface. All the commercially available moisturizers can make skin soft and smooth; however, the better ones are long-lasting [1]. The moisturizers can be of distinct types depending on their mechanism of action, such as occlusives, humectants, emollients, and protein rejuvenators [9]. Commercially available moisturizers often use different constituents of each of these four classes to provide favorable results. One of the significant challenges in both the cosmetic and pharmaceutical industry is to increase moisture level of the skin, promoting a healthy and smooth appearance [10]. Currently, there are various commercially available moisturizing creams which claim to be suitable for dry skin treatment, but they are associated with number of adverse effects [4,7,11,12]. Venusia Max Cream (Paraben free) here after referred to as test product, is a type of plant-based humectants moisturizer and does not contain any animal product. It consists of soluble low molecular weight hygroscopic substances having water-attracting properties from the dermis into the epidermis [1]. The main ingredients of this cream are glycerin and aloe butter, both having skin moisturizing properties [13-16]. Moreover, glycerin has the ability to absorb and retain water, and diffuse through the human skin [17,18]. The present study evaluated our test product for its skin hydration property and safety.

Methodology

Study design and setting

This was a randomized, evaluator-blinded, comparative study conducted in January 2020 in Maharashtra, India. Informed consent was obtained from each participant before performing any study related procedure. The study was approved by the Institutional Ethics Committee and conducted in compliance with protocol and principles of the Declaration of Helsinki [19], good clinical practice (GCP) and schedule Y guidelines.

Healthy females aged between 18-55 year shaving dry type skin

(Moisture Meter SC reading < 20) with no prior history of allergies, skin disorder, cutaneous disease which would lead to dry skin and cutaneous conditions involving the test site such as scars, moles and papules were included in this study. Pregnant or lactating mothers and females with any chronic illness (eczema, dermatitis, psoriasis, etc.,) or any medical treatment either systemic or topical that may interfere with the performance of study treatment (past one month or presently) were excluded.

Study plan and outcomes

The study was conducted to evaluate skin hydration after application of test product (Venusia Max Cream-Paraben free, Batch number- ZD9043, India vide reference number NL-COS/2021/15, Dr. Reddy's Laboratories Ltd.) on the volar forearm compared to the initial site and control site (no product applied) over the duration of 36 hours. Two sites (test product site and control site) of 2 x 2 cm² size were marked on each participant's volar forearm, which were randomly allocated to test product and control. Before marking the sites, forearm of each participant was cleaned with alcohol swab and allowed to acclimatize for the duration of 1 hour. Humidity at 40-60% and temperature at 20-22°C was maintained throughout the study.

The study outcomes were hydration and Trans epidermal water loss (TEWL) measured using Moisture Meter SC (MMSC) [20] and Vapometer [21], respectively. Baseline skin hydration and TEWL measurements were taken from the test and control sites using MMSC and Vapometer, followed by an application of 0.03g of test product on the test site by massaging for 30 seconds and no product application was done at the control site. Later, MMSC and Vapometer measurements were taken at 4, 10, 24 and 36 hours, respectively. Participants were retained at the study center for the entire study duration. Safety outcome was evaluated through clinical examination of the skin for any adverse reaction after test product application.

Statistical Methods

No formal calculation for sample size was performed. Statistical analysis was carried out using IBM SPSS 10.0 version (IBM Corporation, New York, USA). Quantitative variables were represented as mean \pm standard deviation (SD). Test of significance for mean differences of continuous variables like MMSC and

Vapometer readings were estimated by Student 't' test.

Results

A total of 30 women were enrolled in the study. The mean (SD) age of the recruited participants was 34.17 (10.91) years (range: 18-54 years). All the participants completed the study. MMSC 21 and mean TEWL value was assessed between the control vs test site and the baseline vs different time points.

Evaluation of skin hydration

At baseline (0 hour), the MMSC value at the control site (11.91 \pm 2.19) and test product site (12.29 \pm 2.53) were similar ($p > 0.05$). Figure 1 illustrates the comparison of control and test product site at different time points.

MMSC values at the test site increased significantly by 92.7%, 48.8%, and 34.3% at time periods of 10, 24 and 36 hours as compared to the baseline data ($n = 30$; $p < 0.001$), respectively. The maximum and statistically significant increase in MMSC value was observed at the end of 4 hours for test site ($p < 0.001$). Furthermore, a statistically significant increase was observed in MMSC values of test site at all the time periods (4, 10, 24 and 36 hours) as compared to their MMSC value at 0 hour (baseline) ($p < 0.001$). Also, significant increase was observed in mean MMSC value at 10, 24 and 36 hours as compared to control site ($p < 0.001$) indicating improved skin hydration after the application of test product.

Measurement of trans epidermal water loss

At baseline (0 hour), no significant difference in the mean TEWL value at control site and the test product site was observed ($n=30$; $p > 0.05$).

At the test site, a significant decrease of 17.1%, 15.7%, 10.3% and 5.6% was observed in TEWL values at time periods of 4, 10, 24 and 36 hours as compared to the baseline data ($n = 30$; $p < 0.001$). Compared to the control site, a significant reduction in TEWL values at the test site was observed at all the time periods (4, 10, 24 and 36 hours) ($p < 0.001$) indicating reduced water loss after the application of test product at all time periods (Figure 2).

Safety/adverse events

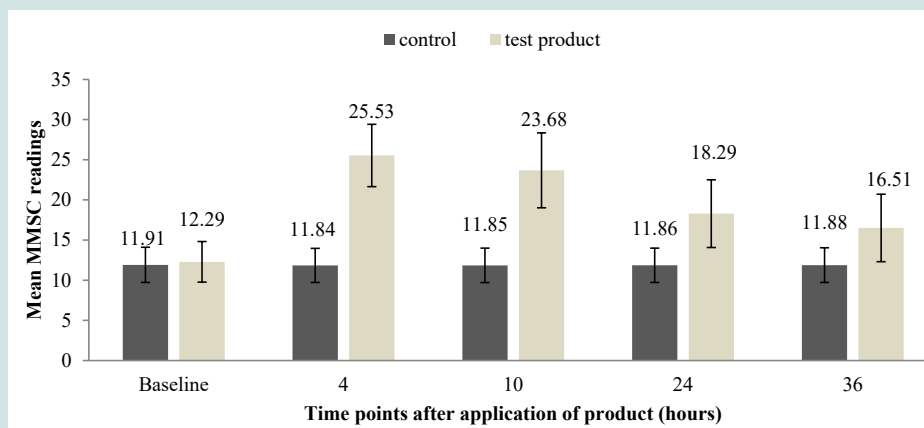


Figure 1: Comparison of change in mean MMSC readings among the control and test site at different time points.

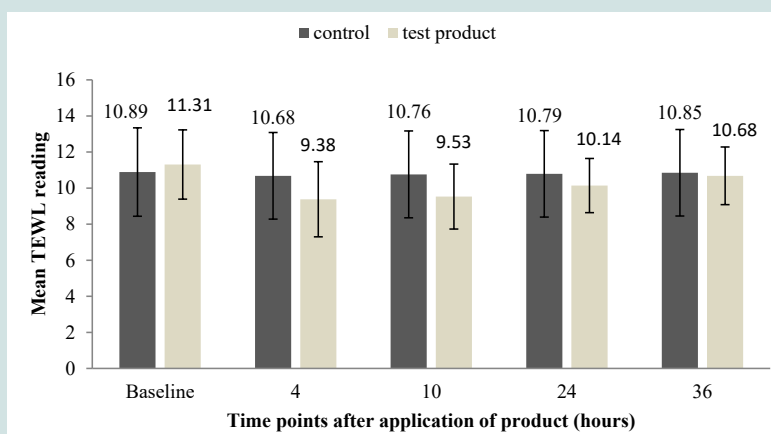


Figure 2: Comparison of change in mean TEWL readings among the control and test site at different time points

No product related adverse effects were reported during the study period.

Discussion

Dryness and sensitivity of the skin are caused by the hypofunction of the skin barrier [22,23]. Dry skin is usually observed in skin diseases like ichthyosis, psoriasis, asteatotic eczema, atopic dermatitis/eczema and irritant contact dermatitis [24,25]. Factors like exposure to low-to-humid air, over washing, UV radiation, use of harsh detergent and age could affect dry skin [26,27]. An ideal moisturizing cream should be cosmetically safe and acceptable, offering adequate long lasting hydration to the skin, fragrance free and should be non-sensitizing [2].

Moisturizing creams treat dry skin through four steps: high water content reduced TEWL, repairing the skin barrier, and restoring the ability to attract, hold, and redistribute water of lipid barriers [28]. Previous studies have shown that skin hydration treatment is effective for dry skin [6,7,29,30]. Therefore, we evaluated the skin hydration condition of the participants using the test product. Primarily, the skin hydration study was conducted for 36 hours at different time points using Moisture Meter. This instrument measures skin hydration which is related to the electrical properties of skin layers. The water content of the skin is proportionate to the measured capacitance. High water content in the skin corresponds to a higher reading in the Moisture Meter [20]. The readings obtained were classified into three ranges: dry skin (< 20), normal skin (20-40) and well-hydrated skin (> 40) [31]. We found that the readings obtained were in the range of normal skin at the end of 4 and 10 hours after the application of the cream as compared to the baseline where it was in the dry skin category. Further, at the end of 10 hours, the test product site demonstrated a 92.7% significant increase in MMSC values compared to the baseline; thus, indicating a long lasting skin hydration.

Medically relevant skin products increase skin hydration by delaying water loss from the skin surface [1]. Preventing excessive TEWL maintains adequate moisture content and hence a healthy skin barrier [5]. Therefore, the TEWL value was calculated from the increase in relative humidity (RH %), using VapoMeter, where the lower the VapoMeter value lesser will be the moisture loss [32].

Recent studies have demonstrated that TEWL is a significant factor in skin dryness [1,8,32,33]. The present study demonstrated that the TEWL readings decreased at 4 and 10 hours after application of the test product. At 4 hours, the mean TEWL showed a prominent and significant reduction of 17.1% compared to the baseline. However, by the end of 24 hours, the TEWL readings increased and were maintained till the end of the study. Hence, it can improve skin hydration and maintain it in the normal skin category for 10 hours.

However, the current study has inherent limitation associated as this study was carried out for a period of 36 hours where the participants are likely to adhere to the protocol. Future, long-term studies in a larger sample size might help clarify the role of our test product in skin hydration. Nevertheless, the test product did not pose any adverse effects on participants. In addition, this cream is paraben-free. Paraben is considered the most common allergen and can permeate through the skin and accumulate leading to an increased risk of sensitization and paraben allergy [8].

Conclusion

Venusia Max cream is a plant-based paraben free moisturizer providing long lasting skin hydration and is suitable for individuals with dry skin.

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