



RESEARCH ARTICLE

IMMUNOLOGY OF VERDURA INTENSE MOISTURIZING LOTION

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ABSTRACT

Specialty cosmetic formulations are meant for certain unique benefits that are linked closely with therapeutic effect and hence such formulations require high level of safety considerations. The cosmetic formulations meant for dry skin in Psoriasis, dry eczema, Atopic dermatitis, Ichthyosis vulgaris type conditions need to be very safe as the skin of these patients is very sensitive. More over the Psoriasis, Atopic dermatitis, eczema are auto immune diseases and the products for these should not have the potential for irritancy. The current study was done on human subjects to check the skin irritancy nature and potential for skin irritancy by skin irritancy test and skin sensitization test. Results are presented in the article.

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INTRODUCTION

Specialty cosmetic formulations are meant for certain unique benefits that are linked closely with therapeutic effect and hence such formulations require high level of safety considerations. The 'leave on' formulations like skin creams, lotions etc., meant for dry skin in Psoriasis, dry eczema, Atopic dermatitis, Ichthyosis vulgaris patients should not possess both primary skin irritant potentials and potentials to cause skin sensitization reaction (hypo-allergenic). Primary skin irritant reaction is non-immunological response of the skin to any irritants which is not concentration dependent skin manifestation. On the contrary, the skin sensitization reaction is completely immunological in nature. For a product to trigger skin sensitization reaction the skin requires sufficient exposure to such products and that may vary from people to people. The immunological responsiveness does vary between individuals and therefore minimum exposure time is inevitable for such products to ascertain the hypo-allergenic nature of the specialty cosmetic formulations. The present study reports the 'near perfect safety profile' of Verdura intense moisturizing lotion of Dr.JRK's research and pharmaceuticals Pvt Ltd. Verdura intense moisturizing lotion is carefully formulated with select Siddha herbal ingredients to give the supreme benefit of moisturization. The Verdura intense moisturizing lotion is specially formulated for patients who suffer from dry skin in

Psoriasis, dry eczema, Atopic dermatitis, Ichthyosis vulgaris type conditions. The present study highlights the absolute safe nature of Verdura intense moisturizing lotion which is essential for considering its utility value for dry skin in Psoriasis, dry eczema, Atopic dermatitis, Ichthyosis vulgaris type conditions. The above safe nature of Verdura intense moisturizing lotion was established by primary skin irritancy test and hypo-allergenic test in human volunteers. Findings are discussed in the article.

MATERIALS AND METHODS

Both the primary skin irritancy study and skin sensitization study were done in healthy human volunteers. The studies were done by a very reputed CRO in Chennai, Quest life sciences. The studies were done strictly in accordance with all ethical norms to be followed in studies that involve human volunteers.

Protocol employed for Primary skin irritancy test (Safety Evaluation of Bathing Bars and Toilet Soaps - Methods of Test, 2001)

In brief, 24 healthy volunteers were empaneled in the study after obtaining the consent and following rigorous inclusion-exclusion criteria. 20 µl of the undiluted sample was loaded into Finn chamber and was then fixed in the volar forearm region. Adjacent to it, another Finn chamber filled with 20 µl of 3% SLS was also fixed. Both Finn chambers were covered

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with Millipore tape and allowed to remain in contact with a skin for 24 hours. After 24 hours Finn chamber was removed and the irritant responses such as dryness, wrinkle formation, formation of oedema and erythema. Extent of the skin response to the product was compared with 3% SLS and scoring was done by using draize scale given below

already established that Verdura intense moisturizing lotion is effective in offering the sustained moisturizing benefit which is inevitable for extreme dry skin conditions. The above studies clearly substantiate the therapeutic efficacy of the product. (Amruthavalli and Gayathri Rajagopal, 2016) Antigens or irritants can trigger the inflammatory responses in various auto

Draize scale

| Score for erythema, dryness and wrinkling | Reaction | Score for oedema | Reaction |
|---|---|------------------|----------------------|
| 0 | No reaction | 0 | No reaction |
| 1 | Very slightly erythema, dryness and wrinkling | 1 | Very slightly Oedema |
| 2 | slight erythema, dryness And wrinkling | 2 | slightly Oedema |
| 3 | Moderate erythema, dryness and wrinkling | 3 | Moderate Oedema |
| 4 | Severe erythema, dryness and wrinkling | 4 | Severe oedema |

Table 1. Primary Skin irritancy test of Verdura intense moisturizing lotion

| Sample | Draize scale Score (Average of 24 subjects) | | | |
|-------------------------------------|---|-------|---------|-----------|
| | Erythema | Odema | Dryness | Wrinkling |
| SLS 3% | 4 | 4 | 4 | 4 |
| Verdura intense moisturizing lotion | 0 | 0 | 0 | 0 |

Table 2. Skin sensitization study (Hypo-allergenic)

| Response | Draize scale Score (Average of 24 subjects) | | | | | | | | | | |
|-----------|---|----|----|----|-----|-----|-----|-----|-----|-----|-----|
| | V2 | V4 | V6 | V8 | V10 | V12 | V14 | V16 | V18 | V20 | V22 |
| Wrinkling | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Erythema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Odema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dryness | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Protocol employed for Primary skin sensitization test ([http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/antest/\(5\)_chapter_3/4._skin_sensitisation_\(final\)_1_en.pdf](http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/antest/(5)_chapter_3/4._skin_sensitisation_(final)_1_en.pdf))

Repeat open patch test was done to assess the hypo-allergenic nature of the product. In brief, induction phase was followed for three weeks by continuously fixing the patch and reading the results on subsequent days (Fixing on Monday, reading on Tuesday, fixing on Wednesday, reading on Thursday, fixing on Friday and reading on Saturday and same procedure was repeated for subsequent three weeks). After induction phase, a period of rest was followed for 2 weeks and then challenging was done both at the site of test (done earlier) and on contralateral site. After 24 and 48 hours the skin was examined for any response using Draize scale followed for primary skin irritancy test.

RESULTS

3% SLS produced visible irritant reaction whereas Verdura intense moisturizing lotion did not produce any skin irritant reaction Table 1. The hypo-allergenic study has clearly shown that Verdura intense moisturizing lotion does not possess skin sensitization property (hypo-allergenic) Table-2.

DISCUSSION

The present study has clearly revealed that Verdura intense moisturizing lotion is absolutely safe with reference to the tests such as primary skin irritancy and skin sensitization. We have

immune conditions such as Psoriasis, Eczema and Atopic dermatitis. Therefore, the product meant for these conditions must be hypo-allergenic and non-irritant. The Psoriatic patients do suffer from severe dryness of the skin and rapid turnover of immature undifferentiated stratum corneum cells resulting in increased trans-epidermal water loss and affecting the functional integrity of cutaneous tissue. Such impaired skin requires super specialty moisturizing cream. All the above properties of Verdura intense moisturizing lotion collectively makes the product a 'wonderful drug' although it is a cosmetic formulation. In other words, the Verdura intense moisturizing lotion is a product i.e both a cosmetic and a drug (USFDA). The hypo-allergenic nature of Verdura intense moisturizing lotion reveals the non-immunological effect which is extremely essential for dry skin in Psoriasis, dry eczema, Atopic dermatitis, Ichthyosis vulgaris patients. Therefore, every product for these patients must be free from any irritant potential as well as allergenic property. Any small immune elicitation may trigger or worsen the clinical manifestation. The present study has undoubtedly established that Verdura intense moisturizing lotion is not only safe but also effective in managing the dryness.

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