

Dermal Safety of Verdura mela Gain Cream

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Abstract

Skin of vitiligo patients is sensitive. Vitiligo patients need safe cosmetic preparations. Cosmetic preparations linked with therapeutic benefits are highly desired. Autoimmune causes predilect vitiligo. The cosmetic preparation should be safe and should not cause irritant reaction and allergic response. Present study reports the hypo-allergenic and nonirritant property of Verudra mela gain cream.

Keywords: Vitiligo, dermal safety, skin irritation test, skin sensitization test, hypo-allergenic, hypo-pigmentation

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INTRODUCTION

For unique benefits, speciality cosmetics are desired as these cosmetics also have therapeutic benefit, and in simple sense they are cosmetic and also drugs; and such products need detailed safety evaluation.

The 'leave on' formulations like skin creams, lotions etc., meant for vitiligo patients should not possess both primary skin irritant potentials and potentials to cause skin sensitization reaction (hypo-allergenic).

The most common safety required for the dermatological products are primary skin irritancy tests and hypo-allergenic tests. The first one is non-immunological response of the skin to any irritants. This reaction does not depend on the concentration, whereas, 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. Individual variations are quite common therefore clinical trial in human being is essential to establish their safety.

The present study reports the 'near perfect safety profile' of Verdura mela gain cream of Dr. JRK's Research and Pharmaceuticals Pvt. Ltd. Verdura mela gain cream is carefully formulated with select Siddha herbal ingredients to give the supreme benefit of anti-

oxidant, increase in tyrosinase and melanin synthesis and also offers sun protection. The Verdura mela gain cream is specially formulated for patients who suffer from vitiligo.

The present study highlights the absolute safe nature of Verdura mela gain cream which is essential for considering its utility value for vitiligo.

The above safe nature of Verdura mela gain cream 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 [1]

In brief, 24 healthy volunteers were empanelled 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 with Millipore tape and allowed to remain in contact with a skin for 24 h.

After 24 h, Finn chamber was removed and the irritant responses such as dryness, wrinkle formation, formation of oedema and erythema were noted.

Extent of the skin response to the product was compared with 3% SLS and scoring was done by using Draize scale given below in Table 1:

Table 1: 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 |

Protocol Employed for Primary Skin Sensitization Test [2]

For determining the hypo-allergenic nature of the product repeat open patch test was done.

The study was done by having an induction phase followed by 3 week patch fixing 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 h, the skin was examined for any response using Draize scale followed for primary skin irritancy test.

RESULT

3% SLS produced visible irritant reaction, whereas Verdura mela gain cream did not produce any skin irritant reaction (Table 2).

Table 2: Primary Skin Irritancy Test of Verdura mela Gain Cream.

| Sample | Draize Scale Score (Average of 24 subjects) | | | |
|-------------------------|--|--------|---------|-----------|
| | Erythema | Oedema | Dryness | Wrinkling |
| SLS 3% | 4 | 4 | 4 | 4 |
| Verdura mela gain cream | 0 | 0 | 0 | 0 |

The hypo-allergenic study has clearly shown that Verdura mela gain cream does not possess skin sensitization property (hypo-allergenic) Table 3.

Table 3: 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 |
| Oedema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dryness | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

DISCUSSION

The present study has clearly revealed that Verdura mela gain cream is absolutely safe with reference to the tests such as primary skin irritancy and skin sensitization.

We have already established that Verdura mela gain cream does not have any cytotoxic effect on fibroblasts and does not hydrolyze or coagulate zein protein [3]. The above findings clearly substantiate the absolute safe nature of Verdura mela gain cream.

The above findings clearly indicate the brilliant formulation chemical engineering followed in formulating Verdura mela gain cream as it is meant for vitiligo patients. One of the pathophysiology of vitiligo states that any antigens or irritants can trigger the destruction of melanocytes in vitiligo. Therefore, the product meant for vitiligo must be hypo-allergenic and non-irritant.

We have already established that Verdura mela gain cream scavenges free radicles, that was established by DPPH, NO inhibition and increases tyrosinase and melanin synthesis [4]. It offers sun protection to the vitiliginous skin [5].

All the above properties of Verdura mela gain cream collectively make the product a 'wonderful drug', although it is a cosmetic formulation. In other words, the Verdura mela gain cream is a product i.e. both a cosmetic and a drug (USFDA).

The hypo-allergenic nature of Verdura mela gain cream reveals the non-immunological effect which is extremely essential for vitiligo patients. Therefore, every product for vitiligo patients must be free from any irritant potential as well as allergenic property. Any small immune elicitation may trigger or worsen the clinical manifestation of vitiligo. Verdura mela gain cream does not have any such properties as revealed by present study which was conducted in healthy patients.

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