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Frozen Safety and Fasten Efficacy- Verdura Mela Pro Cream



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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 the high level of safety considerations. The cosmetic formulations meant for Psoriasis and Vitiligo type conditions need to be very safe as the skin of psoriatic & Vitiligo patients is very sensitive. Moreover, the Psoriasis & Vitiligo are autoimmune 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 the high level of safety considerations. The 'leave on' formulations like skin creams, lotions etc., meant for Psoriasis & Vitiligo patients should not possess both primary skin irritant potentials and potential to cause skin sensitization reaction (hypo-allergenic). Primary skin irritant reaction is a 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 mela pro cream of Dr. JRK's research and Pharmaceuticals Pvt Ltd. Verdura mela pro cream is carefully formulated with select Siddha herbal ingredient i.e. *Psoralea corylifolia* to increase the goodness of the Sun in the treatment of Psoriasis & Vitiligo conditions. The Verdura mela pro cream is specially formulated for patients who suffer from Psoriasis & Vitiligo. The present study highlights the absolute safe nature of Verdura mela pro cream, which is essential for considering its utility value for Psoriasis and Vitiligo. The above safe nature of Verdura mela pro cream was established by primary skin irritancy test and hypoallergenic 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 empaneled in the study after obtaining the consent and following rigorous inclusion-exclusion criteria. 20µl 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 hours.

After 24 hours Finn chamber was removed and the irritant responses such as dryness, wrinkle formation, the formation of edema 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 table no 1

Table no 1: Table showing 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]

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 the 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 the test (done

earlier) and on contralateral site. After 24 and 48 hours, the skin was examined for any response using Draize scale followed by primary skin irritancy test.

RESULTS

3% SLS produced visible irritant reaction whereas Verdura mela pro cream did not produce any skin irritant reaction Table 2.

Table-2: Primary Skin irritancy test of Verdura mela pro cream

Sample	Draize scale Score (Average of 24 subjects)			
	Erythema	Odema	Dryness	Wrinkling
SLS 3%	4	4	4	4
Verdura mela pro cream	0	0	0	0

The hypo-allergenic study has clearly shown that Verdura mela pro 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
Odema	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 pro cream is absolutely safe with reference to the tests such as primary skin irritancy and skin sensitization.

We have already established that Verdura mela pro cream is able to increase the sun benefit required for Psoriasis and Vitiligo treatment in our earlier study. [3] The above findings clearly substantiate the absolute therapeutic benefit of Verdura mela pro cream.

One of the pathophysiologies of Psoriasis and Vitiligo conditions states that any antigens or irritants can trigger the inflammatory responses in Psoriasis and melanocytes destruction in

Vitiligo. Therefore, the product meant for Psoriasis and Vitiligo must be hypo-allergenic and non-irritant.

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

The hypo-allergenic nature of Verdura mela pro cream reveals the non-immunological effect which is extremely essential for Psoriatic and Vitiligo patients. Therefore, every product for Psoriatic and 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 Psoriasis & Vitiligo. The present study has undoubtedly established that Verdura mela pro cream is safe for Psoriatic and Vitiligo patients.

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