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# DO A SOAP NEED SO MUCH – YES IT IS MEANT FOR PSORIASIS

Cosmetology

***Amruthavalli G.V** Dr.JRK's Research and Pharmaceuticals Pvt Ltd,11, Perumal koil street, Kunrathur-600069. *Corresponding Author

**Aruna.V** Dr.JRK's Research and Pharmaceuticals Pvt Ltd,11, Perumal koil street, Kunrathur-600069.

**Gayathri Rajagopal** Dr.JRK's Research and Pharmaceuticals Pvt Ltd,11, Perumal koil street, Kunrathur-600069.

## 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 Psoriasis type conditions need to be very safe as the skin of psoriatic patients is very sensitive. More over the Psoriasis is an auto immune disease and the products for these should not have the potential for irritancy. Cleansing products i.e soaps should be much more gentle and safe for psoriatic skin. 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.

## KEYWORDS

Psoriasis, Dermal Safety, skin irritation test, Skin sensitization test, hypo-allergenic

### 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 'wash off' formulations like bathing bars, Shampoo, face wash etc., meant for Psoriasis 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 must be sufficiently exposed to such products and exposure time 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 skin fresh of Dr.JRK's research and pharmaceuticals Pvt Ltd. Verdura skin fresh is carefully formulated with select Siddha herbal ingredients to give the supreme benefit of moisturization and nourishment. The Verdura skin fresh is specially formulated for patients who suffer from Psoriasis and extreme dry skin conditions.

The present study highlights the absolute safe nature of Verdura skin fresh which is essential for considering its utility value for Psoriasis.

The above safe nature of Verdura skin fresh 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 (12 Male and 12 Non-pregnant females) were empaneled in the study after obtaining the consent and following rigorous inclusion-exclusion criteria. 20µL of 3% solution was applied on the forearm for half an hour to dry and subsequently the surface was washed and porous tape was fixed adjacent to positive control at a distance of 2.5 cm.

Adjacent to it, another Finn chamber filled with 20 µl of 3% SLS was also fixed. Finn chamber 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, formation of oedema and erythema were recorded.

Extent of the skin response to the product was compared with 3% SLS and scoring was done by using draize scale given below

| 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. (Ref)

Verdura skin fresh intense moisturizer bar were applied as open patch on the skin. 20 µL of solution was applied directly on forearm and was allowed to stay for half an hour. Subsequently the surface was washed and a porous tape was fixed to demarcate the location.

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.

The patch application and assessment were performed in the following days:

| Description | * | # | * | # | * | # | * | # | * | # | * |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Visit | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| Day | 1 | 2 | 3 | 4 | 5 | 6 | 8 | 9 | 10 | 11 | 12 |
| Description | # | * | # | * | # | * | # | * | # | * | # |

| Visit | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Day | 13 | 15 | 16 | 17 | 18 | 19 | 20 | 22 | 23 | 35 | 36 |

* - Patch Application
# - Patch Removal and assessment for skin reaction

## STATISTICAL ANALYSIS

The reaction score for erythema, dryness, wrinkling and oedema was found to be "0" in all the subjects. As the scores were "0" statistical analysis was not performed.

## Result

3% SLS produced visible irritant reaction whereas Verdura skin fresh did not produce any skin irritant reaction Table 1.

**Table-1: Primary Skin irritancy test of Verdura skin fresh**

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

The hypo-allergenic study has clearly shown that Verdura skin fresh does not possess skin sensitization property (hypo-allergenic) Table-2.

**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 |

## Discussion

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

We have already established that Verdura skin fresh 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 skin fresh.

The above findings clearly indicate the brilliant formulation chemical engineering followed in formulating Verdura skin fresh as it is meant for Psoriatic patients. One of the pathophysiology of Psoriasis states that any antigens or irritants can trigger the inflammatory responses in Psoriasis. Therefore, the product meant for Psoriasis 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 cornium cells resulting in increased trans-epidermal water loss and affecting the functional integrity of cutaneous tissue.[6] Such impaired skin requires super fatted mild and gentle soap which also can give cleansing. It gives the much needed moisturization benefit to the psoriatic skin.

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

The hypo-allergenic nature of Verdura skin fresh reveals the non-immunological effect which is extremely essential for Psoriatic patients. Therefore, every product for Psoriatic 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. The present study has undoubtedly established that Verdura skin fresh is not only safe for Psoriatic patients but also effective in managing the dryness.

## REFERENCES

1. IS 13424 (2001): Safety Evaluation of Bathing Bars and Toilet Soaps - Methods of Test [CHD 25: Soaps and other Surface Active Agents].
2. http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/antest/(5) chapter 3/4. skin sensitisation (final) (1) en.pdf.
3. Amruthavalli G.V, Aruna.V, Gayathri Rajagopal. Safety evaluation of skin fresh Intense moisturizer bar. Journal of Applied cosmetology.34,9-13(Jan - June 2016).
4. Indian Council of Medical Research (ICMR): Ethical guidelines for medical research on human Subjects 2006.
5. "Good Clinical Practices for clinical research in India" guidelines – Schedule Y (Amended version 2014)
6. Psoriasis: A comprehensive review. International journal of pharmacy & life sciences Ashwin B. Kuchekar1 *, Rohini R. Pujari2 et.al. Int. J. of Pharm. & Life Sci. (IJPLS), Vol. 2, Issue 6: June: 2011, 857-877.