

Formulation and Evaluation of Topical Formula Gel for Dermatitis and Inflammations

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ABSTRACT

Skin allergy is a widespread skin problem at the level of different ages, and it occurs when an irritant comes into contact with the skin, and immune system believes it is under attack, so it overreacts and sends antibodies to help fight invaders. Oral corticosteroids are used to treat the symptoms caused by all kinds of allergic reactions. Long-term use may cause many side effects, such as white water on the eyes, brittleness, weak bones, and stomach ulcers and an increase in blood sugar (glucose) and growth retardation for children. Oral corticosteroids may also worsen high blood pressure. This study has the advantage of designing and testing new topical formulas with standard kinetics and efficacy properties by combining tocopherol with glycolate in addition to antihistamines (phenylephrine hydrochloride and diphenhydramine) to form a Noder formula for the treatment of hypersensitivity. The current study was formulated to manufacture the Noder formula which was submitted to extensive investigations and analyzes by four important models. The results showed that the Noder formula has the ideal physical properties and the absorption is higher than the commercial formula and it has stability for a period of 24 months. The therapeutic efficiency in reducing the degree of redness and sensitivity was 60% compared to 56% in the commercial formula, as well as the clinical safety parameters are better from its comparison of general results, there is a significant increase in absorptivity, efficacy, safety, and consistency of the formula Noder compared to the commercial formula.

Keywords: Noder formula, Skin allergy, Tochoferol, Urticaria.

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INTRODUCTION

Allergies and hypersensitivity are common and multi-dimensional problems that appear in various forms such as asthma, rhinitis, drug and food allergies, and hypersensitivity to insects, eczema, urticaria and angioedema.^{1,2} However, the complexity of allergic and hypersensitivity states is not only limited to the clinical presentation itself, but also to its chronic chronology which has a significant impact on patients' quality of life and health care costs. Among the diseases of allergies is skin allergy, which is immunological or nervous overstimulation that causes itching, redness or thickening, and human infections, and it is on several types, including acquired nervousness and primary immunology such as urticaria and chemical sensitivity, and from it acquired such as contact allergy and eczema.^{3,4} These injuries include a large number of people, acute or chronic. Skin allergies are characterized by itching, redness, swelling, pain, and sometimes skin ulcers. Symptoms may be part of a general or drug allergy,

such as penicillin allergy, and pollen is used by many oral, intravenous, and muscular ointments to treat skin allergies such as antihistamines. Oral and muscular as well as steroids are used in allergy to eczema and allergic shock.⁵

MATERIAL AND METHOD

Materials

Cloxacillin -(Taufkirchen, Germany), Tetracycline , milk powder, catechol , Hydroxypropyl methylcellulose hydroxypropyl methylcellulose (HPMC)-Humilin-USA-1 kg powder , Tochoferol were purchased from Merck Life Science Pvt Ltd., India , glycolate (Sigma-aldrich-Germany) polyphenol oxidase (Mumbi)

Instruments

Centrifuge Drucker diagnostic-California, USA Cecil, UV/V spectrophotometer-UK- CE 1021 Staurt , mechanical stirrer-UK, HPLC system-Conquer Scientific-USA5975C /

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6890N, light microscope Germany-Zeit,s UV sterilizer-Bio-Rad Berkeley California Dialyzing catheter Alpha Germany Brucker Somatco, dissecting set-62148, 5 remote thermometer-Seek Thermal USA -Mini prep cell,-, US151, sonicator-BioLogics-USA-150VT, sonicator-BioLogics-USA-150VT ,computerized thermographic melting point analyzer Seek-thermal-USA, Computerized, pH meter-Prime bioscience-Malaysia Model APP 071, Ball viscometer Indiamart-India.

Preparation of the Noder gel Formula

Gels are usually formed from the liquid phase, which is condensed or thickened with other components. Substances such as antioxidants, stabilizers, and antimicrobial preservatives are used as additives in the formulation of gels and the organic phase:

HPMC K4M is prepared in water in a mechanical or magnetic mixer vessel at a speed of 200 rev/min for 5 minutes at 25°C. Then the mixture is heated to 60°C for one minute with continuous mixing, then add 10 g of glycol, 5 g of tocopherol, and 5 g of diphenhydramide in a hydrochloric acid.

HPMC is widely used in gels and ointments as a good excipient, as they are non-toxic and non-irritating substances. While polypropylene, it acts as a moisturizer and also speeds up the passage or entry of drugs through the skin.



Figure 1: Shows the ratio of time of dissolution or fading of the formula Noder, compared with the commercial formula.

Pharmacological Testing and Evaluation of Noder Topical Formula

Table 1: Types of comprehensive evaluation of topical formula

Standards measured	Methods and test device	Evaluation types of topical noder formula
Color, odor, consistency PH, Peroxide value viscosity, appearance	Viscometer, sensitive balance, densimeter, TLC, microscope, HPLC , FTIR, UV	1-evaluation physical and pharmacokinetic features
Effectiveand metamorphic concentrations	HPLC, UV, TLC	. evaluation of2- Stability
Concentration of active and dispersed active ingredient	HPLC, UV/Vis	Pharmacokinetics andabsorption evaluation3-
Redness, itching, swelling of the skin and skin pains	Image processor, local	4. -evaluation Safety
General cost	The relative cost of treatment And the cost of work	-evaluation of 5 Feasibility

Table 2: Results General pharmacokinetic properties of the topical formula Noder:

A) The general pharmaceutical test	The result	Statistics
1. color	Transparency40%	+/- 5%
2. Odor	Odorless	
3. Appearance	Opacity 60%	+/- 3%
4. Homogeneity	Homogeneous sediment free	
5. Micibility	5 folds water miscible	
6. Grittiness	No particles under the microscope	
7. Consistency	Emulsifying gel	
8. Swelling	No swelling after 3 months	
9. Aging	No aging before 36 months if cealed	
10. Thixotropy	80% flattening after 24 hours	
11. Dryness rate	No dryness at 25 C for 30 days	
12. Dye absorption	Continuous phase appeared red amaranth	
13. Moisture absorption	No significant moisture absorption	
14. Rheology	Easily flow	
15. Structure	Gel plus oil	
16. Syneresis	Minimal	

Table 3: Results of the pharmacokinetic properties of the topical formula noder

B) The objective pharmaceutical test of Noder formula	The results	Statistics
1. Viscosity	89 cps centipoise	1-/+
2. Density	1.005	0.001-/+
3. Spreadability	Score 2 moderately spreadable	
4. Extrudability test	Score 2 moderately good	
5. Microbial count	No microorganism per g	
6. pH value	7.4	0.1-/+
7. Acidity value	0.73	0.01-/+
8. Peroxide value	ME/1000g = 6	0.2-/+
9. Partition coefficient	40% hydrophobicity coefficient	
10. Solubility studies	Soluble in propylene glycol at 37C	
11. Saponification value	233	2-/+
12. Conductivity	6 A/V	0.1-/+

Table 4: Results of diagnosing the topical formula with infrared and gel spectroscopy

C) Band documentation tests	The results	Comment
1. FTIR	10% alcohol shift as a difference in gel structure before and 36 months after production of the formula Noder	Used to assess the alcohol shift as an indicator of percentage of reactive conversion of the standard formula throughout a given
2. Electrophoresis	Identical bands of gel with the standard	
3. TLC	For the active ingredient showed a homogenous band identical	

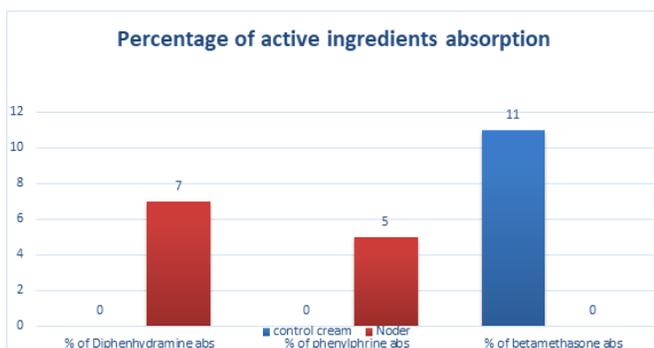


Figure 2: evaluation of gel absorption and active substances in Noder gel while following the physical properties of the formula.

Pharmacokinetics Findings of Bioequivalence Study

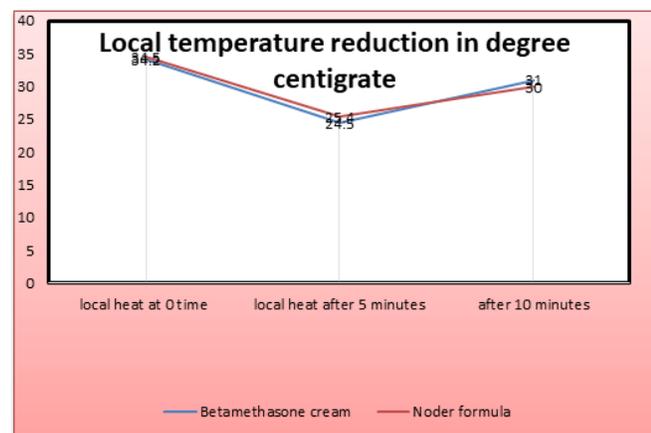


Figure 3: Shows the effect of the lowering temperatures of the formula Noder compared to the commercial formulas

The Result of Biosafety

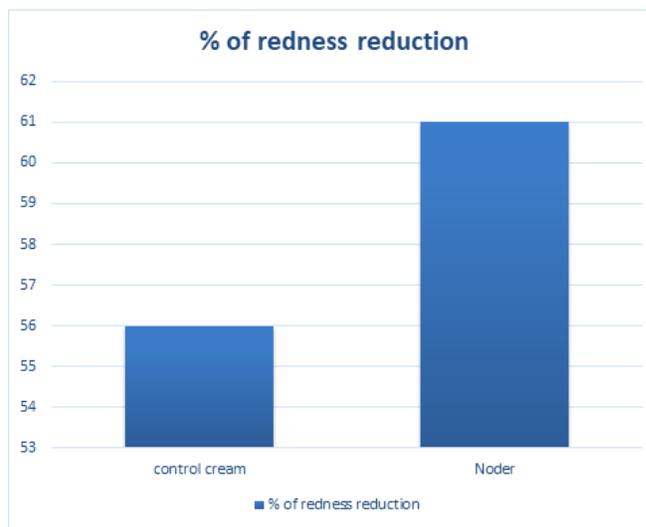


Figure 4: Shows the percentage reduction of the redness of the localized formula Noder compared to the commercial formula

THE RESULTS

Results of the pharmaceutical properties of Noder formula

DISCUSSION

Atopic dermatitis (AD) is a chronically relapsing inflammatory disease; AD is characterized by intensely pruritic skin and occurs quite often in children.⁶ This is associated with increased production of IgE and/or altered pharmacological reactivity.⁷ The characteristic symptoms of AD include skin dryness, erythema, oozing, and it is occasionally followed by

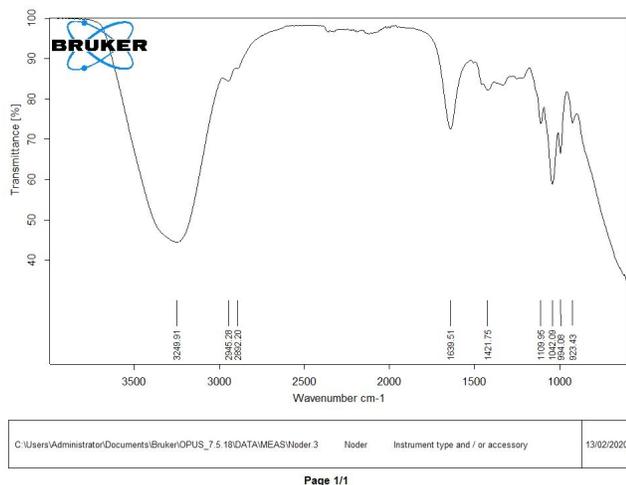


Figure 5: FTIR spectroscopy

crusting of the skin in untreated patients. Pruritus and skin itching are the most annoying symptoms and are responsible for much of the disease burden for patients and their families.⁸ Therefore, the main goal of the management of AD patients is based on the use of topical anti-inflammatory preparations along with optimum hydration of the skin. However, some patients may require phototherapy or systemic treatment in severe cases.^{9,10}

The physical stability was assessed by observing change in odour, colour, physical appearance, viscosity and droplet size of gel and chemical stability was evaluated by determination of pH and drug content (Table 2). The gel formulations exposed to different stability conditions were found to be homogenous with no change in color intensity or odor throughout the study period.

Visual inspection of all prepared formulations showed no phase separation after storage for 3 months. In addition, there were no significant changes in the viscosity or rheological parameters after storage. FTIR spectroscopy shows the infrared Fourier spectrum of the infrared formula Noder as it is used to check the purity of the components of the infrared formula and to follow its non-transformation as an indication of stability and estimate the shelf life. The results show the multiple hydroxyl components of the gel polymer at 3200 and 1030 cm⁻¹, and the infrared Fourier spectrum is used to evaluate the stability of the active substances. The spectrum

shows an indication of the presence of CN and CO components of the cloxacillin content in Noder to assess and compare its ability to preserve the active substances.

CONCLUSION

In this study, components of the formulation showed physical stability, the Noder gel showed better activity as compared to marketed formulation owing to the characteristics such as permeability enhancing components, improved skin retention and targeted drug delivery. The overall results elucidated that Noder gel could be a successful carrier system for the treatment of acute dermatitis.

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