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FORMULATION AND EVALUATION OF HERBAL ANTI CRACKING CREAM FROM SHOREA ROBUSTA, ARECA CATECHU AND LITHARGE

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ABSTRACT

Objectives: Skin disorders are a common health condition that affects people of all ages, from newborns to the elderly, and inflicts injury in a variety of ways. If the cracks in the heels are severe, they can be uncomfortable and bleed when a person stands up. So, the basic purpose of preparing an anti-cracking moisturizing cream is to provide soothing and moisturizing effects on the xerotic skin of heels. The main objective of our research is to prepare a herbal anti-cracking cream that contains herbal ingredients that have strong healing properties for cracked and bleeding heels. **Methods:** This anti-cracking cream contains Herbal ingredients that are Raal safed, Katha safed and Murdar sang. It also contains oleic acid, urea, lanolin, mineral oil, and salicylic acid and the method used was emulsion type. **Results:** The color of the Cream is brown, the odor is pleasant, smooth appearance, pH of the cream was found to be 6.5, with excellent spread ability, and safe to use for the skin. **Conclusion:** Anticracking cream with moisturizing characteristics is made to treat diabetes complications such as diabetic neuropathy, diabetic foot ulceration, and other foot issues. All ingredients which are used in the formulation are effective in treating wound healing. After evaluating several criteria for anti-cracking cream, it was discovered that all results were within acceptable limits.

Keywords: Foot care, Moisturizing cream, Anti-cracking cream, Xerotic skin, Diabetic patients.

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INTRODUCTION

Human skin is a complex organ with multiple functions. One of its main functions is to act as a waterproof surface, limiting the loss of water from deep tissues and preventing harmful chemicals from entering the body. Loss of the skin barrier can lead to dry skin and a tendency for various diseases, including illnesses, sensitivity, and allergies **[1]**. Injury to the peripheral sympathetic nerves can lead to perspiration dysfunction, which exemplifies dry skin on the feet, which may lead to calluses and/or cracking, and ultimately foot ulcers **[2]**.

In diabetic neuropathy, the severity of the injury can involve the sensory, motor, and autonomic nerves of the affected limb. As a result of motor neuropathy, muscle atrophy, and foot deformity are observed, and biomechanics of the foot are altered leading to changes in pressure distribution of the foot and ultimately leading to ulceration. Diabetes mellitus is a disease of metabolic dysregulation, mostly due to abnormal metabolism of glucose, and leads to long-term complications. The complications which are associated with diabetic patients are retinopathy, nephropathy, and neuropathy and they are more prone to these complications **[3]**. The number of effects of diabetes in older people is rather considerable, and this is the case with complications as well. Peripheral disorders like neuropathy, ulcers, and in the worst cases amputation negatively affect older individuals with diabetes. The impact of systemic toxicity of drugs is decreased by treating acute or chronic inflammatory reactions and thus the best and most efficient way of drug delivery is through the skin. For this purpose, the use of Cream formulations provides efficient penetration through all skin layers. Water in oil(W/O) can be used to enhance the cutaneous absorption of pharmaceutical substances and increase the penetration through skin layers **[4]**.

Semisolid Dosage Forms including Cream formulations are Gold Standard vehicles for Topical drug delivery systems. Cream Formulations are defined as, multiple phase systems especially

sensitive to instability processes **[5].**

Creams are prepared to apply to the skin and mucous membrane. Their consistency depends on whether the Emulsion is water in oil or oil in water and the Nature of solids in the internal phase **[6]**. Creams are also used to treat cracked heals in diabetic patients. The activity of Creams for treating feet fissures in diabetic patients was confirmed because if these fissures are left untreated, bacteria can enter and lead to infections and further complications **[7].** Splits or cracks occur as a result of xerosis and anhidrosis/dehydration which usually forms callus around the rim of the heel and skin becomes discolored or yellowish or dark brown in color **[8]**. There are a lot of environmental factors to which human skin is exposed in daily routine life and is also exposed to many unhygienic things that have undesirable and deleterious effects on skin integrity causing the skin to be dry, dehydrated, wrinkles, fissures, and in the end sepsis. Diabetic patients are more prone to experience all these symptoms because of damage to nerves in the feet from **[9]**.

The proneness to infection and discomfort due to dry skin (Xerosis) in diabetic patients is a very common problem seen clinically which causes flaking, scaling, and itching. Simple interventions and wearing of appropriate shoes can play an important role in improving foot health and minimizing falls in older women **[10, 11].** So, a formulation was made to guide clinicians with the best formulation with moisturizing properties, anti-cracking and antiseptic properties, and also with pain reliving effect to treat foot xerosis of diabetic patients which can also protect underlying tissues of the infection from physical damage. For this purpose, topical moisturizer is the best choice that can improve skin conditions and manage xerosis. These emollients fill the gaps and fissures in the skin replenish its essential proteins and make it smooth by improving skin texture. An ideal moisturizer is effective with both an occlusive and humectant to get more hydrating effects **[12]**. Aims and objectives of anti-cracking moisturizing creams are to provide a soothing effect and moisturizing effect on the xerotic skin of heels. Herbal ingredients are added in the cream which have strong healing properties for cracked and bleeding heels. Along with skin cleansing properties used for dressing wounds. The prepared formulation can used for anhidrosis that may or may not present with hyperkeratosis as keratolytic agents are used in it which removes the dead skin **[13]**. Cracks, rashes, and xerosis occur on the skin due to excess loss of moisture from the skin especially when it is exposed more to the dry atmosphere. Medicated creams are used topically to treat and prevent this **[14]**.

The ICPA Research Center provided all of the chemicals and instruments required in the development and standardization of herbal Crack Cream. Cream is made by separating the ingredients for the oil and aqueous phases. All quality control criteria were determined, including organoleptic characteristics such as color, odor, and taste of the cream, as well as physicochemical parameters such as viscosity, pH, bulk density, and room temperature of the cream **[15]**. Herbal Crack Cream was made using a standard emulsion type cream-making procedure. All quality assurance parameters, such as Work on organoleptic factors such as color, odor, and taste of cream were carried out, as well as physiochemical parameters of Cream were determined. Herbal Crack Cream had excellent squeezing-out action and was stable at 25°C, 30°C, and 40°C, according to the results [1**6**].

MATERIALS AND METHODS

Chemicals

Some ingredients of the formulation such as urea, lanolin, salicylic acid, mineral oil, and spearmint oil were provided by Akhter Saeed College of Pharmaceutical Sciences while other herbal ingredients Shorea robusta (Raal safed), Areca catechu (Katha safed) and Litharge (Murdar sang) were purchased from market.

Pre-formulation Studies

Pre-formulation studies are done so that characteristics of active substances and excipients can be determined which can affect formulation, its performance, and process design. In this physical and chemical properties of drugs are determined to develop a dosage form that is stable, safe, and effective for use. For that purpose, the compatibility of different ingredients with each other is checked and the physicochemical parameters of new drug substances are established. Various trials have been done to prepare a cream that exhibits the parameters of a successful pharmaceutical formulation and the cream with better stability and consistency is selected.

Formulation of Anti-cracking Cream

Anti-cracking cream is prepared by making two separate phases.

Preparation of Phase A

For the preparation of phase A, Chemical ingredients of the cream Raal safed, Katha safed and Murder sang were taken and triturated in pestle and mortar to a fine powder and passed from a sieve no 10 to get a fine powder. After that added the weighed amount of salicylic acid, urea, and any preservative in it and mixed it uniformly.

Preparation of Phase B

For the preparation of phase B, the weighed amount

Table 1: Composition of formulation (F1-F3) of anti-cracking and moisturizing cream.

Ingredients	F1	F2	F3
Lanolin	7g	6g	5g
Urea	2g	2g	2g
Mineral oil	3g	2g	5g
Salicylic acid	3g	2g	2g
Oleic acid	3g	2g	5g
Sodium benzoate	-	1g	1g
Spearmint oil	-	3-5 drops	3-5 drops
Raal safed	6g	4g	4g
Katha safed	6g	4g	4g
Murdar sang	6g	4g	4g

Where, F1, F2 and F3 are 1st, 2nd and 3rd formulation respectively

Table 2: Evaluation of anti-cracking and moisturizing cream.

Evaluation parameters	F1	F2	F3
Colour	Brown	Brown	Brown
Odor	Unpleasant	Pleasant	Pleasant
Appearance	Gritty	Smooth	Smooth
pH determination	-	6.4	6.5
Thermal stability	Stable	Stable	Unstable at higher temperatures
Spreadability	Gritty	Excellent	Excellent
Sensitivity and irritability test	No irritation	No irritation	No irritation
Washability	Easily washable	Easily washable	Easily washable

of lanolin was taken and melt it over a water bath. Mixed it with mineral oil and oleic acid. After that phase B was added into phase A in the pestle and mortar slowly by continuously mixing until a cracking sound appears. Now added 3-5 drops of spearmint oil, mixed it well and pack in a close tight container **[17-24]**. The actual composition of cream is given in **Table 1**.

Evaluation of Anti-cracking Cream

To evaluate the prepared formulation following tests were performed (**Table 2**).

Organoleptic Evaluation

For organoleptic evaluation parameters such as colour, appearance, and Odor were carried out which helped in the visual identification of cream **[25]**.

Physicochemical parameters

Determination of pH

A solution was prepared from the cream by weighing 1g of cream and dissolved in 10 ml of water. When a proper solution was prepared pH was determined potentiometrically by using a pH meter. The apparatus was calibrated first using buffers of 4, 9, and 7 pH **[13]**.

Thermal stability

Thermal stability of the prepared formulation was measured at different temperatures i.e. 20˚C, 30˚C and 40˚C **[26]**.

Characteristics

Spreadability

Spreadability was determined by taking 1g of anti-crack cream and placing it on a circle glass plate of 1cm diameter another glass plate was placed on it and a certain weight was applied on the upper plate for 5 min. Spread ability is measured by the spread of cream uniformly and there should be no lumps or unmixed particles. The average of three readings was determined **[25]**.

Sensitivity and irritation test

The prepared formulation was applied to the 1cm skin of feet that area is exposed to the sun for about 4-5 minutes **[25]**.

Washability

A small amount of prepared cream was applied to the skin and placed under running water **[25]**.

RESULTS

Organoleptic evaluation

The physical properties of the prepared anti-crack cream were observed by its colour, Odor, and appearance. The colour of the cream is brown and the Odor is pleasant and it is smooth cream.

Determination of pH

The pH of the cream measured by immersing a pH meter into the solution of cream was found to be 6.5 which is a little acidic in nature

Thermal Stability

All three formulations were stable at 25˚C and 30˚C and there was no breaking or separation in the phases of cream at these temperatures but there was a change in color of the formulation when exposed to higher temperature 40-50˚C. so it is required to place the cream in a cool and dry place.

Spreadability

In the first formulation, grittiness was observed due to herbal ingredients so, this problem is resolved in 2nd and 3rd formulation by sieving them in sieve no 10. In two cream formulations (F2, F3), there was no hard and sharp-edged particles were observed so these formulations were smooth and had homogeneity and fineness with excellent spreadability **[25]**.

Sensitivity and irritability

There was no inflammation, edema, redness, or irritancy observed by all three formulations during irritancy and sensitivity testing. So, these anti-crack cream formulations are safe to use for the skin.

Washability

Washability was determined by applying a small amount of cream on the skin and placing it under running water. The washability of these formulations is not easily washable with the running water and there was stickiness on the skin.

DISCUSSION

Skin diseases are very common in diabetic patients like diabetic foot cracks and fissures. If these fissures are very deep in the heels of the foot, they become painful hurting a person while standing up and even sometimes bleed which is more dangerous for diabetic patients as they are more prone to suffer from bacterial infections and dehydration. So, its treatment is of prime importance. The purpose of preparing this formulation is to moisturize the xerotic foot it can heal the wounds due to cracking of heels and relieve its pain **[27].**

For this purpose, an anti-crack cream with moisturizing properties was prepared to get rid of these complications like ulceration of diabetic foot and other foot cracking issues. In this formulation, some herbal ingredients that are useful for skin's wound healing and some other ingredients like urea, lanolin, oleic acid, mineral acid, etc were added with a preservative and a fragrance agent. When the formulation is prepared some evaluation tests are performed to check its stability, spreadability, pH, sensitivity, irritation etc **[28].**

Anti-cracking moisturizing cream was prepared by the general method of preparation of cream i.e. emulsion type. Prepared moisturizing cream has a brown to light brown & greyish-yellow colour. All formulations had a pleasant Odor and smooth texture. The pH of the prepared formulation was determined to be 6.5 for the 3rd formulation and 7.2 and 6.4 for the F1 and F2 respectively. F2 and F3 were a little acidic while F1 was neutral. Thermal stability was measured which showed that all the formulations were stable at temperatures up to 30˚C but F3 becomes unstable at very high temperatures i.e. 40-50˚C.

The spreadability of the first formulation was not good as it had bigger particles in it but in other two formulations F2 and F3, this issue was resolved and their spreadability was excellent due to the absence of hard- and sharp-edged particles. Sensitivity and irritability tests were performed by applying a small amount of cream on the skin and all the formulations showed no irritation, inflammation, redness, edema etc so it is safe for use. At last washability test was performed by exposing it to running water. The washability of first cream formulation F1 was not easily washable because of high quantity of a herbal ingredient katha safed so its quantity was lowered in second and third formulation that showed a better result of washability **[28].**

After assessment of various parameters of the anti-cracking cream, it was observed that all findings were within range. The spreadability of F1 was not very good but that of F2 and F3 was greater than F1. Among all the formulations F2 was better as F1 has grittiness in it and F3 has shown thermal instability at higher temperatures due to which it changes its colour. So F2 was selected as an optimized formulation based on the result of spreadability and appearance.

CONCLUSION

Diabetes problems in the elderly are a big health concern. Foot problems such as neuropathy, ulcers, and eventually amputation are a significant hardship for diabetics in their later years **[29].** Dosage via semisolid Topical medication delivery systems use a variety of forms, including cream formulations. Heel fissures are splits or divisions in the skin around your heels that are an annoyance because heavy layers of dead skin cells accumulate. Fissures arise as a result of a lack of moisturizing, dryness, and poor foot care. As a result, a formulation is created to assist clinicians in selecting the best formulation with moisturizing properties, anti-cracking and antiseptic properties, as well as a pain-relieving effect, to treat diabetic foot xerosis while also protecting the infection's underlying tissues from physical damage. The cream contains herbal elements that have significant healing qualities for cracked and bleeding heels. In addition to its skin-cleaning properties, it's also used to treat wounds. Some herbal elements that aid in skin wound healing, as well as other ingredients such as urea, lanolin, oleic acid, mineral acid, and others, were combined with a preservative

and a fragrance agent in this formulation. When the formulation is ready, it is put through a series of tests to determine its stability, spreadability, pH, sensitivity, and irritation, among other things. After assessing many criteria for anti-cracking cream, it was revealed that all of the results were satisfactory and the formulation was safe to use **[30].**

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