Development and Evaluation of a bioactive polyherbal dermal formulation enriched with Niacinamide, Vitamin E and saffron extract

1.Hafiz Muhammad Umar Saleem (Corresponding author)
Department of Pharmaceutical Sciences
Madina College of Pharmacy
The university of Faisalabad
Email: umarchisti9107@gmail.com

2.Dr Aamna Habib
Department of Pharmaceutical Sciences
Madina College of Pharmacy
The university of Faisalabad
Email: aamnahabib.PHARM@tuf.edu.pk

3.Misbah Rasool
Department of Pharmaceutical Sciences
Madina College of Pharmacy
The university of Faisalabad
Email: misbahrasool.PHARM@tuf.edu.pk

4. Zain Ul Abidin
Department of Pharmaceutical Sciences
Madina College of Pharmacy
The university of Faisalabad
Zain.zaniii.786@gmail.com

5. Abdullah
Department of Pharmaceutical Sciences
Madina College of Pharmacy
The university of Faisalabad
abdullahmali325@gmail.com

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Abstract

In the past few years, there has been an increasing trend in using herbal cosmetics due to their higher safety and skin tolerance compared to cosmetic products derived from artificial sources. In this research, we formulated a polyherbal cream with natural ingredients that have antioxidant properties and help improve skin health. During the preparation of the product, we used extracts from blue pea flowers (Clitoria ternatea), tulsi (Ocimum sanctum), aloe vera, and turmeric oil. Moreover, beeswax, liquid paraffin, borax, methyl paraben, rose water, and distilled water were also used in the base composition. Niacinamide, vitamin E, and saffron extract were added for increased antioxidant activity and whitening action of the cream. The formulated product had a pH of 5.8 ± 0.2 and a viscosity of 3200 ± 100 cps, thus making the product fit for topical applications. The formulation was spreadable, had a homogeneous texture, and did not cause any form of skin irritation. From the analysis conducted on the stability of the formulated product, there was no indication of any phase separation in the preparation. The polyherbal formulation showed much better activity than the base formulation, a result that was statistically significant ($p < 0.05$). The formulated product had a pH of 5.8 ± 0.2 and a viscosity of 3200 ± 100 cps, thus making the product fit for topical applications. The formulation was spreadable, had a homogeneous texture, and did not cause any form of skin irritation. From the analysis conducted on the stability of the formulated product, there was no indication of any phase separation in the preparation. The polyherbal formulation showed much better activity than the base formulation, a result that was statistically significant ($p < 0.05$). From the study, the formulated polyherbal product showed promising physicochemical properties and stability, which makes it an excellent cosmetic product. From the study, the formulated polyherbal product showed promising physicochemical properties and stability, which makes it an excellent cosmetic product.

Keywords: Polyherbal cream, Herbal cosmetics, Antioxidant activity, Niacinamide, Physicochemical evaluation

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Introduction

In the last few decades, many developments have taken place in the cosmetic sciences because of the rising awareness of people about the safety and effectiveness of beauty care products. Although there is an extensive usage of artificial cosmetics because of their quick and immediate results on the skin; yet, it is evident that prolonged use of synthetic cosmetics can lead to negative consequences like skin irritation, hyper sensitivity, and other health issues. As a result of this, a significant trend of using natural and herbal cosmetics has emerged since they are comparatively safe for use and biocompatible.

Herbal cosmetics refer to those types of beauty care products which consist of plant extracts, plant-based oils, and phytochemicals. These natural ingredients possess secondary metabolites like flavonoids, phenolics, tannins, alkaloids, and terpenoids which have various biological functions. However, antioxidant activity of these ingredients is considered to be the most important since antioxidants neutralize free radicals present in the environment and cause oxidative stress. This can affect the quality of the skin in terms of causing premature skin aging, hyperpigmentation, and dullness. Anti-inflammatory and antimicrobial properties further add to the advantages of using herbal cosmetics as they help prevent redness and acne problems.

Polyherbal formulations have become very popular in recent times because of their synergistic nature. Unlike traditional single herbo-formulations, multi-herbo-products comprise extracts from various plants targeting various pathways and providing enhanced benefits. The most popular herbs that can be used in dermatology include Clitoria ternatea, butterfly pea flower extract, Tulsi (Ocimum sanctum), aloe vera gel, and turmeric oil. Clitoria ternatea is a potent antioxidant and anti-aging herb due to the presence of anthocyanins in this plant. The tulsi herb has antimicrobial and anti-inflammatory properties, which help protect the skin from various infections. At the same time, aloe vera gel is moisturizing and soothing. Finally, turmeric oil contains curcuminoids, which have antioxidant and skin-lightening properties.

However, there are some shortcomings of herbal cosmetic formulations which limit their applicability in the industry. One of the major limitations is physico-chemical instability resulting into phase separation, discoloration and shortened shelf life. In addition, variations in the phytochemical composition based on plant source, extraction process and storage conditions limit their consistency and efficacy. Further, some herbs fail to exhibit effective results in case of certain dermatological disorders like hyperpigmentation.

To mitigate these weaknesses, the inclusion of dermatologically proven actives within herbal formulas has shown promise. For instance, vitamin B3, or niacinamide, has been shown to support the formation of the skin barrier, decrease sebum production, lower transepidermal water loss (TEWL), and inhibit melanin transport. Vitamin E, which is a lipid soluble antioxidant, offers protection against oxidative stress and helps in maintaining skin moisture levels. Crocus sativus, otherwise known as saffron, is another example of an herb containing bioactives including crocin, crocetin, and safranal, which have antioxidative, anti-inflammatory, and skin-lightening effects.

Despite extensive studies supporting the effectiveness of each of these individual herbs or active ingredients, little information is available regarding their combined action within a single polyherbal

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formula. This might suggest synergism, increasing antioxidant levels, boosting skin moisture levels, and offering additional benefits targeting skin pigmentation or complexion. However, this needs further investigation.

In addition, the lack of standardized procedures in the formulation and evaluation of herbal cosmetic products is one of the limitations observed in the study. Some of the physical properties, such as pH, viscosity, spreadability, and homogeneity, are essential determinants in determining the quality, stability, and usability of the formulations. Stability testing under various conditions is a critical determinant in ensuring the stability of the product, while skin irritation testing ensures the safety of the product on the skin surface.

Hence, the current investigation was conducted with the following objectives in mind:

(i) To formulate a polyherbal topical cream incorporating certain herbal extracts with niacinamide, vitamin E, and saffron extract;

(ii) To analyze the physicochemical characteristics of the formulated preparation, namely, pH, viscosity, spreadability, and homogeneity;

(iii) To conduct the stability test of the formulated preparation under different storage conditions; and

(iv) To estimate the skin irritation potential of the prepared cream.

2. Ingredients and Apparatus Required

2.1 Ingredients

The following are the ingredients used in the preparation of the polyherbal topical formulation:

Extract of Butterfly pea flower, Extract of Tulsi leaves, Aloe vera gel, Oil of Turmeric, Beeswax, Liquid paraffin, Borax, Methyl paraben, Rose water, Distilled water, Vitamin E, Niacinamide, and Extract of Saffron.

All the above ingredients were of cosmetic/pharmaceutical grade and used without any purification.

Table1: Source of Ingredients

Sr no	Ingredients	Types	Sources	Grade/Specification
1	Butterfly pea flower extract	Herbal extract	Local herbal supplier/commercial vendor	Cosmetic grade
2	Tulsi leave extract	Herbal extract	Local herbal supplier	Cosmetic grade
3	Aloe vera gel	Herbal gel	Commercial cosmetic store	Natural/Cosmetic grade
4	Turmeric oil	Herbal oil	Pharmaceutical supplier	Cosmetic grade
5	Beeswax	Natural wax	Chemical supplier	Pharmaceutical grade
6	Liquid paraffin	Mineral oil	Chemical supplier	Pharmaceutical grade
7	Borax	Inorganic salt	Chemical supplier	Analytical grade
8	Methyl paraben	Preservative	Pharmaceutical supplier	Pharmaceutical grade
9	Rose water	Aqueous base	Commercial	Cosmetic grade

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			cosmetic supplier	
10	Distilled water	Solvent	Laboratory/ distilled unit	Analytical grade
11	Vitamin E	Active ingredient	Pharmaceutical supplier	USP Grade
12	Niacinamide	Active ingredient	Pharmaceutical supplier	Cosmetic grade
13	Saffron extract	Herbal active	Herbal/spice supplier	Cosmetic grade

Table2: Composition of Polyherbal Cream Formulation

Sr no	Ingredients	Quantity	Functions
1	Beeswax	10g	Thickening agent, emulsifier
2	Liquid parrafin	15g	Emollient
3	Tumeric oil	2g	Anti-inflmmatory, Antioxidant
4	Distilled water	40ml	Solvent (aqueous phase)
5	Rose water	10ml	Fragrance,soothing effect
6	Borax	1g	Emulsfying agent
7	Methyl paraben	0.2g	Perservative
8	Aloe vera	10g	Mositure,soothing agent
9	Tulsi extract	3g	Antimicrobial
10	Butterfly pea flower extract	3g	Antioxidant
11	Niacinamide	2g	Barrier repair
12	Saffron extract	0.5g	Skin brightening
13	Vitamin E	1capsule	Moisturizing agent

2.2. Apparatus Required

The above mentioned equipment were required for the preparation and testing of the Polyherbal Cream:

•Beakers (100 ml, 250 ml) - for preparation of oil phase and aqueous phase
•Glass Rod - for stirring purpose
•Hot Plate/ water bath - for heating process
•Digital weighing Balance - for exact calculation of amount of ingredients
•Temperature Gauge – for temperature control during heating
•pH Meter/pH paper - for pH analysis of the cream formulation
•Spatula – for cream handling
•Measuring cylinder - for liquid measurements (water/rose water)
•Glass Slides - for Spreadability study
•Brookfield Viscometer - (optional) for viscosity study
•Stability Chamber – for conducting Stability test
•Storage Container – for Storage of product

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Extraction process

Different stages of this process

(a). Butterfly pea flower

The flower extract of Clitoria ternatea was chosen for ethanolic extraction.

⇓

The required amount of 5 g of dried flower (crude sample) was used for extraction.

⇓

About 2 g of extract was achieved from the first 5 g sample after the procedure

⇓

The extracted crude sample was poured into a new clean beaker.

⇓

The solvent ethanol (40-45 mL) was added into the beaker.

⇓

The container were covered with aluminum foil.

⇓

The beaker was kept on a hot plate for heating.

⇓

Continuous stirring was done, and the mixture was stirred every 15 min.

⇓

This was done to make sure that the mixture had been dissolve.

⇓

The extraction procedure was conducted for about 45-50 minutes.

⇓

The heated mixture was cooled down to room temperature.

⇓

The mixture was filtered using filter paper and the filtrate was collected in another beaker

⇓

The filtrate ethanolic extract was collected for later use.

(b).Tulsi leave

Ethanolic extraction was conducted with the leaf extract of Ocimum sanctum (Tulsi).

⇓

A specific amount of 6 g dried Tulsi leaves (crude material) was used for extraction purposes.

⇓

The crude extract was poured into a beaker.

⇓

An appropriate volume of ethanol (40-45 mL) was poured into the beaker as an extracting agent.

⇓

Aluminum foil was used to cover the beaker.

⇓

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This beaker with contents was kept on a hot plate under controlled heating conditions.

⬇

Stirring was done continuously, and the mixture was also stirred after every 15 minutes. The process of extraction was conducted for around 45-50 minutes.

⬇

On completion of heating, the solution was cooled to room temperature.

⬇

Filter paper was used to filter the cooled mixture.

⬇

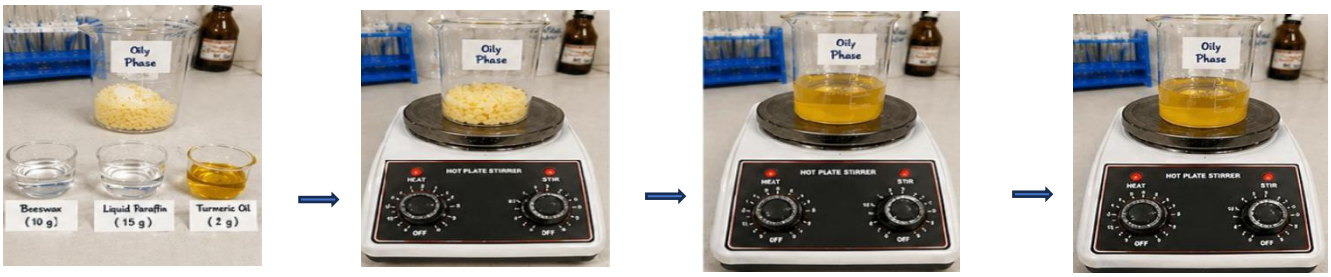
The extracted ethanolic material was collected separately in a beaker.

3.2 Method of Preparation (Cream Formulation Procedure)

The polyherbal cream was made through a process that involved the simple process of emulsification of the ingredients weighed precisely. The formula of the polyherbal cream consisted of three stages, which include oil stage, aqueous stage, and active stage.

Oil Phase Preparation (Phase A)

A blend of beeswax (10 g) and liquid paraffin (15 g) was mixed in a clean beaker and then heated up to temperatures between 70–75°C for proper melting. Then turmeric oil (2 g) was mixed into the melted substance to produce an oil phase.



Aqueous Phase Preparation (Phase B)

In another beaker, distilled water (40 ml) and rose water (10 ml) were taken and mixed. Both the solutions were heated to the same temperature, that is, 70 – 75°C. Then borax (1g) was dissolved completely in the aqueous phase, followed by methyl paraben (0.2 g) as a preservative.

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Emulsification Process (Phase B)

The hot aqueous Phase B was gradually introduced into the oil Phase A under constant stirring. The mixture was constantly stirred in one direction only until it formed an emulsified oil-in-water emulsion. This stirring process was repeated until a cream base was produced.

Incorporation of Active and Herbal Ingredients (Phase C)

Once the temperature of the mixture had been lowered to less than 40°C, the heat-sensitive components were then introduced one after another. The components added included 10 g of aloe vera gel, 3 g of tulsi extract, 3 g of butterfly pea flower extract, 2 g of niacinamide, 0.5 g of saffron extract, and 1 capsule of vitamin E.

Final Mixing and Packaging (Phase D)

The last mixture was blended very well in order to get a smooth and homogenous cream. The produced cream was then poured in a clean, tightly-closed bottle for storage at ambient temperature for further testing.

Table2: Functional Role of Ingredients in the Formulation

Sr no	**Ingredients**	**Uses**	**Advantages**	Disadvantages
1	Butterfly pea flower extract	Antioxidant, natural colorant, anti-aging	Rich anthocyanins, protects against oxidative stress	Light& temperature sensitive, stability issues
2	Tulsi leave extract	Antimicrobial, anti-inflammatory, acne treatment	Strong antibacterial activity, natural healing	Strong odor, possible skin irritation
3	Aloe vera gel	Moisturizer, soothing agent, wound healing	Deep hydration, skin regeneration	Microbial contamination risk without preservatives
4	Turmeric oil	Anti-inflammatory, skin brightening	Antioxidant, improves skin glow	Skin staining, irritation in high dose
5	Beeswax	Thickener, emulsifier, protective barrier	Natural, improves texture & moisture retention	Heavy feel for oily skin
6	Liquid paraffin	Emollient, skin softening	Smooth application, moisture retention	May clog pores
7	Borax	Emulsifying &	Improves stability of	Irritation at high

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		stabilizing agent	formulation	concentration
8	Methyl paraben	Preservative	Increases shelf life, prevents microbes	Safety concerns in long-term use
9	Rose water	Fragrance, mild toner	Soothing, refreshing effect	Mild therapeutic effect only
10	Distilled water	Solvent, base medium	Pure, contamination-free	No therapeutic activity
11	Vitamin E	Antioxidant, anti-aging	Protects from free radicals, improves hydration	Oily feel, possible irritation
12	Niacinamide	Skin brightening, anti-acne	Improves texture, reduces pigmentation	Redness at high concentration
13	Saffron extract	Skin brightening, rejuvenation	Enhances glow, antioxidant activity	Expensive, sensitivity risk

3.3 Evaluation of Formulation

Parameters on which the cream was tested were as follows:

Testing pH: To check whether it is compatible with skin (range: 5.5 – 6.4)

Viscosity: For consistency and spread ability

Spread ability test: To test spread ability of the cream

Stability tests: At different temperatures

Test for skin irritation: To test safety for topical application

Homogeneity: Observed for uniform distribution of ingredients.

Table 3: Evaluation Summary of Formulation

Parameter	Observation	Result
Appearance	Smooth, light yellow cream	Acceptable
pH	5.5 – 6.4	Skin compatible
Viscosity	Moderate	Suitable
Spreadability	*Good*	*Easy application*
Stability	No phase separation	Stable
Irritation test	No irritation	Safe

4. Results and Discussion

The polyherbal preparation that was developed was evaluated on the basis of its physicochemical properties, stability, and applicability to the skin. The preparation methodology was employed by combining the traditional herbal ingredients with the scientifically validated bioactive compounds such as niacinamide, vitamin E, and saffron extract.

4.1 Physical Appearance and Homogeneity

The creams that are made properly should have properties such as smoothness, homogeneity, and no separation. The emulsification of the components and dispersion are some of the factors that are considered to be crucial in ensuring that the creams remain stable and maintain good quality.

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Table 4.1: Characteristics of the three creams

Formulation	Physical Appearance	Homogeneity	Overall Assessment
Cream 1	Smooth,uniform texture with consistent color and appearance	Homogeneous	Exhibited excellent stability and desirable properties
Cream 2	Slighly irregular texture with minor visual incosistencies	Partially homogeneous	Acceptable
Cream 3	Transformed into liquid form with liquid phase sepration	Non-Homogeneous	Demonstrated poor stability and formulation failure

4.2 pH Analysis

The pH value is one of the key factors that play a critical role in the formulation of topical drugs. This is because the pH level determines the safety of the drugs to use on the skin. The recommended pH level for the drug must match the skin pH value, which ranges between 5.5 and 6.5.

Table 4.2: Formulation

Formulation	pH Value (Mean ± SD)	pH Range Suitability	Overall Assessment
Cream 1	6.4 ± 0.1	Within acceptable range	Suitable for topical application close to skin pH
Cream 2	9.4 ± 0.2	Alkaline (Not suitable)	May cause skin irritation requires pH adjustment
Cream 3	5.8 ± 0.1	Ideal skin compatible	Considered optimal for skin good formulation stability

4.3 Viscosity and Spread ability

The factors that govern the applicability of topical formulations are viscosity and spreadability. If a formulation is of proper viscosity, it will be stable while being stored, and application to the skin surface will not pose any problems. Spreadability is important, as the formulation should be evenly applied to come in contact with the skin surface. Both viscosity and spreadability are greatly dependent on the nature and quantity of the emulsifier and thickener present in the formulation.

Table 4.3: Characteristics of cream

Formulation	Viscosity (cP) (Mean ± SD)	Spreadability (g·cm/sec) (Mean ± SD	Overall Assessment
Cream 1	15,200 ± 120	7.8 ± 0.2	Optimal viscosity with good spreadability

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			suitable for application
Cream 2	9,500 ± 150	10.5 ± 0.3	Lower viscosity with higher spreadability moderately acceptable
Cream 3	3,200 ± 100	15.2 ± 0.4	Very low viscosity; excessively high spreadability indicating instability

4.4 Stability Studies

The formula must be stabilized to ensure its effectiveness. Stabilization includes the prevention of phase separation, deterioration, and color changes in the formula. The surroundings are essential when it comes to determining the stability of a formula. Antioxidants, such as Vitamin E, should be included in formulations to ensure their stability.

Table 4.4: Characteristics of cream

Formulation	Storage condition	Duration	Physical Appearance	pH (Initial →Final)	Homogeneity	Overall Evaluation
Cream 1	2°C+(room temperature)+25	30 days	No visible change	6.4→ 6.3	Maintained	Stable Formulation
Cream 1	2°C+40 (Accelrated)	30 days	Slightly increases thickness	6.4→ 6.2	Maintained	Stable with minor variation
Cream 2	2°C+(room temperature)+25	30 days	Slightly inconsistency observed	9.4→ 9.1	Partially retained	Moderately stable
Cream 2	2°C+40 (Accelrated)	30 days	Phase sepration observed	9.4→ 8.8	Reduced	Unstable
Cream3	2°C+(room temperature)+25	30 days	Liquefaction observed	5.8→ 5.5	Lost	Unstable
Cream 3	2°C+40 (Accelrated)	30 days	Complete phase sepration	5.8→ 5.2	Lost	Highly unstable

4.5 Skin Irritation Test

Another key element that needs to be considered in the creation of this product is the skin compatibility. It should be such that it does not irritate the human skin at all. The inclusion of some herbs like aloe vera will make the product soothing and hence reduce the chances of skin irritation.

Table 4.5: Characteristics of cream

Formulation	Test site condition	Observation time	Erythema (Redness)	Edema (Swelling)	Irritation Leve	Overall Assessment
Cream 1	Applied on skin	24 hours	None	None	No irritation	Safe for topical use
Cream 2	Applied on skin	24 hours	Mild redness	Slight swelling	Mild irritation	Acceptable with caution

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Cream 3	Applied on skin	24 hours	Moderate redness	Visible swelling	Irritating	Not suitable for skin

4.6 Role of Bioactive Components

The presence of bioactive substances is essential in influencing the properties of the drug. For example, niacinamide aids in improving the skin barrier strength, treating hyperpigmentation and maintaining healthy skin. In contrast, Vitamin E acts as an antioxidant and helps the body cells avoid getting oxidized or damaged due to environmental factors. Saffron, in contrast, contains phytochemicals that contribute to skin revitalization and brightening.

Table 4.6 : Components of a cream , properties, action and features

Bioactive Component	Functional Properties	Mechanism/Action	Contribution to Product Performance
Niacinamide	Enhances skin barrier, reduces hyperpigmentation	Improves ceramide synthesis and regulates melanin	Promotes healthy skin condition and even skin tone
Vitamin E	Potent antioxidant	Neutralizes free radicals and prevents oxidative damage	Protects skin cells from environmental stress
Saffron	Skin regeneration and brightening	Contains natural phytochemicals with revitalizing effects	Improves skin radiance and supports regeneration
Herbal Components (Combined)	Synergistic therapeutic effects	Combined action of multiple phytoconstituents	Enhances overall efficacy and performance of the formulation

Conclusion

The developed formulation comprises traditional herbal extracts in conjunction with bioactive agents like niacinamide, Vitamin E, and saffron extracts. The developed formulation is intended for topical application with primary benefits associated with improved skin tone, reduction of skin hyperpigmentation, enhanced skin brightness, and improved skin barrier. Evaluation of the formulation included testing the physicochemical properties, stability, and skin compatibility.

In accordance with theoretical considerations and formulation design criteria, the formulation in question should possess the following beneficial characteristics: desirable physicochemical properties, such as pH level, viscosity, and spreadability; stability; and skin compatibility. Thus, the use of bioactives should result in improved antioxidant capacity, increased effectiveness in terms of maintaining the integrity of skin barrier, and skin lightening effect. Considering the combination of herbal extracts with bioactive substances, which are used in modern dermatology for treating various problems, the developed formulation can be recommended for everyday skincare. Individuals with dull skin and mild hyperpigmentation will greatly benefit from the use of cosmeceutical cream that promotes rejuvenation of skin, improves skin tone, and enhances skin brightness.

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As such, the research makes for an excellent platform for further experimental verification and will go a long way towards aiding in the formulation of safe and commercialized herbal products for skin care purposes.

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