

## FORMULATION AND EVALUATION OF CREAM FOR HYPOPIGMENTATION

<sup>1\*</sup>Khushali D. Jepulkar, <sup>2</sup>Humaira Firdoas Abdul Saleem, <sup>3</sup>Janhvi S. Waster, <sup>4</sup>Kewal G. Mekalwar, <sup>5</sup>Bhagyashri S. Patil

<sup>1,2,3,4,5</sup>Undergraduate Student (Pharmacy), P. R. Patil Institute of Pharmacy, Talegaon (S.P.), Wardha, India.



\*Corresponding Author: Khushali D. Jepulkar

Undergraduate Student (Pharmacy), P. R. Patil Institute of Pharmacy, Talegaon (S.P.), Wardha, India.

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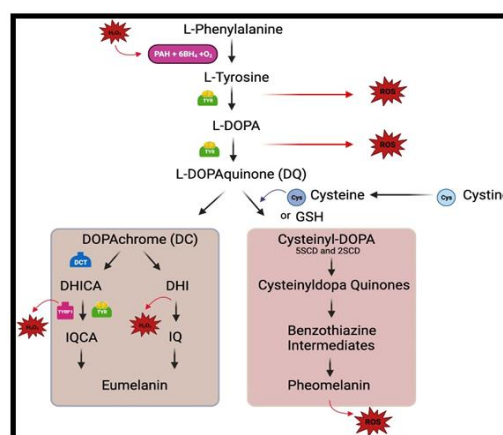
### ABSTRACT

Skin pigmentation is a natural phenomenon that plays an important part in the appearance and biology of all animals including humans. The process of melanogenesis, which results in the formation of the pigment melanin within melanocytes, determines skin color. Disturbance in these pathway lead to different skin disorders like hypopigmentation, leukoderma, vitiligo etc. Hypopigmentation is a skin condition characterized by reduced or absent melanin production, leading to light or white patches on the skin. It may arise due to genetic factors, autoimmune disorders, infections, skin injury or exposure to chemicals. Common examples include vitiligo and post-inflammatory hypopigmentation. Conventional synthetic treatments such as corticosteroids, calcineurin inhibitors, and psoralen-based therapies are used, but prolonged use may cause irritation, erythema, skin thinning, and photosensitivity. The present study focuses on the formulation and evaluation of an herbal cream for management of hypopigmentation. The formulation includes Bakuchi oil, Turmeric extract, Neem extract, Aloe vera incorporated into a suitable cream base. The prepared cream was evaluated for pH, viscosity, spreadability, homogeneity, stability and appearance. The herbal ingredients used are known to promote melanocyte activity and provide antioxidant and anti-inflammatory benefits. Based on the findings, the herbal formulation can be considered as a safe, effective, and economical alternatives to synthetic treatments with improved patient acceptability and minimal side effects, offering potential benefits in long-term management of hypopigmentation.

**KEYWORDS:** Hypopigmentation, Herbal cream, Bakuchi oil, Melanin, Antioxidant, Topical formulation.

### INTRODUCTION

Skin is the largest organ of human body and plays crucial role in protection, thermoregulation, and sensory perception. One of its defending features is pigmentation, which determines skin colour and is primarily governed by the pigment melanin.<sup>[1]</sup> Melanin is synthesized by specialized cells known as melanocytes, located in the basal layer of the epidermis. The process of melanin production, called melanogenesis, involves the enzyme tyrosinase, which catalyzes the conversion of tyrosine into melanin.<sup>[2]</sup> This pigment not only provides color to the skin, hair, and eyes but also protects against harmful ultraviolet (UV) radiation by absorbing and dissipating it. Any disruption in melanocyte function or melanin synthesis can lead to pigmentation disorders.<sup>[3]</sup>



**Fig. 1: Melanin Synthesis Pathway.**

Hypopigmentation results from interruptions in melanogenesis, the process by which melanin is produced and delivered to keratinocytes.<sup>[4]</sup> These

disruptions lead to lower melanin levels and can occur through several mechanisms, such as suppression of tyrosinase (the key enzyme in melanin formation), defects in melanosome development or movement (as seen in albinism), or immune-driven melanocyte loss (as in vitiligo). The final outcome is reduced production of both eumelanin and pheomelanin.<sup>[5]</sup>

### Main Points of Disruption in the Pathway

**Decreased Tyrosinase Function:** Tyrosinase catalyzes the conversion of tyrosine to DOPA and then to dopaquinone, which is essential for melanin formation. When tyrosinase activity is lowered, this initial step is blocked, stopping the production of both dark (eumelanin) and light (pheomelanin) pigments. **Melanosome Abnormalities:** Problems in the formation, movement, or transfer of melanosomes—the organelles that carry pigment—from melanocytes to keratinocytes cause hypopigmentation. These issues are often linked to rare genetic disorders such as Hermansky-Pudlak syndrome and Chediak-Higashi syndrome. **Oxidative Stress and Immune Involvement:** High levels of oxidative stress, including the buildup of hydrogen peroxide, can break down melanin and damage melanocytes. This stress may also trigger immune

responses, such as attacks by CD8+ T cells, leading to melanocyte destruction in vitiligo. **Disrupted Signaling Pathways:** Interference with signaling routes like the  $\alpha$ -MSH/MC1R pathway, which regulates tyrosinase production and melanosome formation, can reduce melanin synthesis<sup>[5]</sup>. Among these, hypopigmentation is a commonly observed condition characterized by partial or complete loss of skin colour. It appears as lighter patches or areas on the skin compared to the surrounding normal skin tone. Hypopigmentation may result from a decrease in melanin production, destruction of melanocytes, or impaired transfer of melanin to keratinocytes.<sup>[6]</sup> Common types of hypopigmentation include vitiligo, post-inflammatory hypopigmentation, tinea versicolor, and genetic conditions such as albinism. These conditions may arise due to various factors such as autoimmune responses, infections, exposure to chemicals, nutritional deficiencies, and environmental stressors.<sup>[7]</sup> Hypopigmentation not only affects physical appearance but also has significant psychological and emotional consequences. Individual suffering from visible skin disorders often experience psychological distress, and safe treatment of hypopigmentation is of great importance in both dermatological and cosmetic fields.<sup>[8]</sup>



Fig. 2: Hypopigmentation.

### Types of Hypopigmentation

**Vitiligo:** An autoimmune condition causing progressive, distinct white patches on the skin, often around body openings. **Post-Inflammatory Hypopigmentation (PIH):** Temporary light spots that develop after skin inflammation, such as acne, eczema, or psoriasis. **Pityriasis Alba:** Common in children, this condition presents as mild, scaly, light-colored patches, usually on the cheeks. **Tinea Versicolor:** A fungal infection that causes scaly, light, or dark spots on the trunk, neck, and arms, often appearing in warm, humid conditions. **Idiopathic Guttate Hypomelanosis (IGH):** Small, white, sun-damaged spots that appear on the arms and legs, often related to aging. **Albinism:** A genetic condition causing a significant reduction or absence of melanin, affecting the skin, hair, and eyes. **Progressive Macular Hypomelanosis:** A condition characterized by increasing numbers of asymptomatic, non-scaly white spots, often on the trunk, caused by *Cutibacterium acnes* bacteria.<sup>[9]</sup> Currently, several conventional treatments are available for managing hypopigmentation. These include topical corticosteroids, calcineurin inhibitors such as tacrolimus, psoralen combined with

ultraviolet A (PUVA) therapy, narrowband UVB phototherapy, and skin grafting techniques in severe cases. Additionally, synthetic topical formulations containing chemicals that stimulate melanogenesis are widely used. While these treatments can provide improvement in certain cases, they are often associated with limitations such as high cost, time-consuming procedures, inconsistent results, and potential side effects. Long-term use of corticosteroids may cause skin thinning, irritation, and increased susceptibility to infections. Phototherapy, although effective, requires repeated clinical visits and may increase the risk of skin damage with prolonged exposure.<sup>[10]</sup> Due to these drawbacks, there has been a growing interest in alternative approaches, particularly herbal and natural formulations, for the treatment of hypopigmentation. Herbal medicine has been used for centuries in traditional systems such as Ayurveda for managing various skin disorders.<sup>[11]</sup> Herbal formulations are gaining popularity because of their safety, affordability, and minimal side effects compared to synthetic drugs. They contain a wide variety of bioactive compounds such as flavonoids, alkaloids, glycosides, terpenoids, and

phenolic compounds, which exhibit diverse pharmacological activities including antioxidant, anti-inflammatory, antimicrobial, and melanocyte-stimulating effects. One of the key mechanisms by which herbal ingredients help in treating hypopigmentation is by enhancing melanogenesis.<sup>[12]</sup> Certain plant-derived compounds can activate tyrosinase enzyme activity, stimulate melanocyte proliferation, and promote the

transfer of melanin to skin cells. Additionally, antioxidants present in herbal extract protect melanocytes from oxidative stress, which is one of the major causes of pigment loss. Anti-inflammatory properties further aid in reducing skin damage and promoting regeneration. Several medicinal plants have been traditionally used for restoring skin pigmentation.<sup>[13]</sup>



**Fig. 3: Bakuchi Plant.**



**Fig. 4: Neem.**



**Fig 5: Mango ginger.**



**Fig 6:- Aloe vera.**

**Bakuchi** (*Psoralea corylifolia*) is one of the most important herbs known for its effectiveness in treating vitiligo and hypopigmented conditions. It contains active constituents such as psoralen and bakuchinol, which increase melanin production when exposed to sunlight or UV radiation.<sup>[14]</sup> **Mango ginger** (*Curcuma amada*) is widely known for its anti-inflammatory and antioxidant properties due to the presence of curcumin, which helps in protecting skin cells and promoting healing.<sup>[15]</sup> **Neem** (*Azadirachta indica*) exhibits strong antimicrobial and immunomodulatory activities, making it useful in preventing infections and supporting skin health. **Aloe vera** (*Aloe barbadensis*) is rich in vitamins, enzymes, and polysaccharides that provide soothing, moisturizing, and regenerative effects on the skin.<sup>[16]</sup> The combination of these herbal ingredients in a suitable formulation can provide a synergistic effect, enhancing their overall therapeutic efficacy. Herbal creams, gels, and ointments are commonly preferred dosage forms due to their ease of application, better patient compliance, and targeted delivery to the affected area. Such formulation not only help in restoring pigmentation but also improve overall

skin texture and health.<sup>[17]</sup> The present study is focused on the development and evaluation of an herbal formulation for the treatment of hypopigmentation.<sup>[18]</sup> The aim is to prepare a stable and effective topical formulation using selected medicinal plant extract known for their melanogenic and skin-protective properties. The study also aims to evaluate the physicochemical characteristics of the formulation, such as pH, viscosity, spreadability, and stability, along with its therapeutic potential. By utilizing natural ingredients, the objective is to develop a formulation that is safe, economical, and effective, offering a promising alternative to conventional synthetic treatments for hypopigmentation.<sup>[19]</sup>

**AIM:** To formulate and evaluate a herbal cream for the treatment of Hypopigmentation using natural ingredients such as Bakuchi Oil, Mango Ginger, Aloe Vera And Neem.

**OBJECTIVES:** To formulate a polyherbal cream for hypopigmentation, To evaluate its physicochemical

properties, To study the stability of the formulation, To assess its skin compatibility and safety.

## MATERIALS AND METHODS

**Table 1: Hypopigmentation Cream Ingredients.**<sup>[20]</sup>

Sr.no	Ingredients	Role
1	Bakuchi oil	Stimulates melanocytes and increases melanin production
2	Mango ginger	Reduces inflammation and promote skin healing
3	Neem	Provides antioxidant and antimicrobial protection to melanocytes
4	Aloe vera	Moisturizes skin and enhances penetration of active ingredients
5	Bees wax	Emulsifying and thickening agent
6	Cetyl alcohol	Emollient , prevent phase separation
7	Liquid paraffin	Lubricating agent
8	Methyl paraben	Preservative
9	Rose oil	Fragrance
10	Distilled water	Vehicle

## METHODS

For mango ginger and neem we used Hydroalcoholic Maceration Method

**A. Extraction of Curcumin:-** Fresh rhizomes of mango ginger are washed thoroughly to remove dirt and impurities. The cleaned rhizomes are cut into small pieces and dried under shade for several days until moisture is removed. The dried material is then powdered using a grinder to obtain a coarse powder. About 10 g of powdered drug is transferred into a clean conical flask. Add 100 mL of hydroalcoholic solvent to the flask. The mixture is kept for 48–72 hours at room temperature with occasional shaking to ensure proper extraction. After maceration, the mixture is filtered using filter paper. The filtrate obtained is concentrated by evaporating the solvent on a water bath at low temperature. The concentrated extract is collected and stored in an airtight container for further use.<sup>[21]</sup>

**B. Extraction of Neem:** Fresh neem leaves were collected and washed thoroughly with water to remove impurities. The leaves were shade dried for 5–7 days until complete removal of moisture. The dried leaves were coarsely powdered using a grinder. About 10 g of powdered neem leaves was weighed and transferred into a conical flask. 100 mL of hydroalcoholic solvent was added. The flask was tightly closed and kept for 48–72 hours for maceration at room temperature. The mixture was shaken occasionally to enhance extraction. After maceration, the mixture was filtered using Whatman filter paper. The filtrate obtained was concentrated by evaporating the solvent on a water bath. A semi-liquid extract was obtained and collected. The extract was stored in an airtight container for further use.<sup>[22]</sup>



**Fig. 7: Maceration.**



**Fig. 8: Filtration of extract.**



**Fig. 9: Final Extract.**

**C) Cream Base Preparation**

By Fusion Method

**Preparation of Oil Phase:-** Beeswax, cetyl alcohol, and liquid paraffin were accurately weighed and taken in a clean beaker. The mixture was heated on a water bath at 70–75°C until all ingredients melted completely.

**Preparation of Aqueous Phase:-** In another beaker, distilled water was taken and heated to the same temperature. Preservatives (methyl paraben and propyl paraben) were dissolved in the warm aqueous phase.

**Emulsification:** The hot aqueous phase was slowly added to the oil phase with continuous stirring. Stirring was continued until a uniform emulsion was formed.

**Cooling:-** The prepared emulsion was allowed to cool gradually with constant stirring to obtain a smooth and stable cream base.

**Storage:** The cream base was transferred into a clean, dry container and stored in a cool and dry place for further use.

**D) Incorporation of Active Ingredients**

The prepared cream base was allowed to cool to about 40°C.

Required quantities of active ingredients such as Bakuchi oil, Aloe vera gel, Neem extract, Mango Ginger extract were accurately measured.

The active ingredients were added slowly to the cream base with continuous stirring.

Mixing was continued until a uniform and homogenous cream was obtained.

Care was taken to avoid formation of lumps and ensure even distribution of all ingredients.

A small quantity of fragrance was added and mixed thoroughly.

The final formulation was transferred into suitable containers and stored in a cool and dry place.<sup>[23]</sup>

**Evaluation parameters**

**1. Organoleptic Assessment:-** The prepared cream was visually examined for color, odor, texture, and homogeneity. The presence of any lumps or phase separation was observed.

**2. Physical assessment**

**a) pH Determination:** About 1 g of cream was dissolved in 10 mL distilled water. The pH was measured using a digital pH meter. Ideal Range: pH should be between 5–7 (skin compatible)

**b) Determination of Spreadability:** A small amount of cream was placed between two glass slides. A known weight was placed on the upper slide. The time taken for the slides to slip apart was noted.

**c) Washability Determination:** A small amount of cream was applied on the skin. It was washed with water to check ease of removal.

**d) Irritancy Test:** The cream was applied on a small area of skin (hand). The area was observed for 24 hours for redness, itching, or irritation.

**e) Homogeneity:** A small quantity of the prepared cream was taken in a clean beaker. The sample was subjected to mixing using a homogenizer at a suitable speed for a few minutes. After homogenization, the cream was observed visually for uniformity and smoothness. The presence of any lumps, coarse particles, or phase separation was checked.

**f) Stability Study:** The cream was stored at different conditions: Room temperature, Refrigerated condition. Observed for color change, phase separation, or odor change over time.<sup>[24,25]</sup>

**Table 2: Formulation of cream batches by Trial and Error Method.**

Sr.no	Ingredient used	F1	F2	F3
1	Bakuchi oil [ml]	0.5ml	1ml	1.5ml
2	Neem extract [g]	1g	1.5g	2g
3	Mango ginger extract [g]	1g	1.5g	2g
4	Aloe vera [g]	2g	3g	5g
5	Bees wax [g]	5g	6g	7g
6	Cetyl alcohol [g]	1.5g	1.5g	1.5g
7	Liquid paraffin [ml]	25ml	27ml	30ml
8	Methyl paraben [g]	0.05g	0.05g	0.05g
9	Rose oil [q.s]	q.s.	q.s.	q.s.
10	Distilled water [q.s]	q.s to 50g	q.s to 50g	q.s to 50g

**Table 3: Optimize formulation of cream.**

Sr.no	Ingredient	Quantity
1	Bakuchi oil [ml]	1ml
2	Neem extract [g]	1.5g
3	Mango ginger extract [g]	1.5g
4	Aloe vera [g]	3g
5	Bees wax [g]	6g
6	Cetyl alcohol [g]	1.5g
7	Liquid paraffin [ml]	27ml
8	Methyl paraben [g]	0.05g
9	Rose oil [q.s]	q.s.
10	Distilled water [q.s]	q.s.to 50g

**Experimental Work done**

Fig. 10: Weighing Of Materials.



Fig. 11: Melting of Oil and Water phase individually

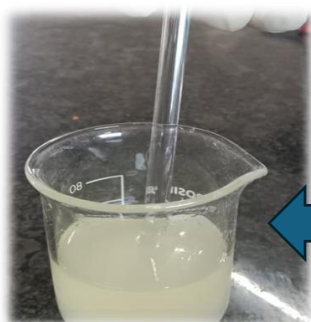


Fig. 13: Continuous stirring.

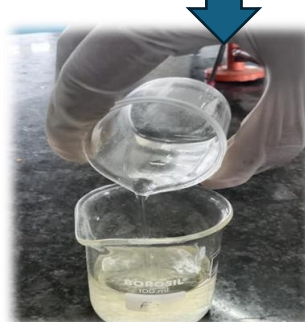


Fig. 12: Incorporation of water phase into oil phase.



Fig. 14: Incorporation of active ingredients.



Fig. 15: let it cool.

[Process of Formulation of Cream]



Fig. 16:-Batches prepared by trial-and-error method.

**RESULT AND DISCUSSION**

Organoleptic evaluation of the prepared cream formulations (F1, F2, and F3) was carried out by visual inspection and sensory perception. The parameters evaluated included color, odour, appearance, texture,

consistency, homogeneity, greasiness, and washability. All three batches exhibited acceptable organoleptic properties. The color of the formulations ranged from pale yellow(creamy white) to yellowish cream, which is characteristic of the presence of herbal ingredients such

as bakuchi oil. The odour of all batches was found to be pleasant, indicating suitability for topical application. The appearance of the creams was smooth, with batch F3 showing a slightly glossy nature. The texture of F1 and F2 was soft and smooth, whereas F3 was slightly thicker, possibly due to variation in ingredient concentration. All batches showed semi-solid consistency, with F3 being comparatively more viscous. Homogeneity was good in F1 and F2 formulations, indicating uniform distribution of ingredients without any lumps or aggregates. No phase separation was observed in any batch, which confirms the stability of the formulations. All formulations were easily washable, although F3 required slightly more effort due to its thicker consistency. The stability study of cream formulations F1, F2, F3 was carried out at 40<sup>0</sup> C and 4<sup>0</sup> C for 7 days to observe any changes in their properties during storage. At 40<sup>0</sup>C, slight changes were noticed in batches F1 and F2. There was

minor variation in color, odor and pH. These changes may be due to the effect of higher temperature on the formulation, which can affect the consistency and overall stability of the cream. However, batch F2 did not show any noticeable change and remained stable under the same conditions. At refrigerated temperature 4<sup>0</sup>C, all batches remained stable. No change in color, odor, or appearance was observed. The pH of the formulation was also maintained, and no phase separation occurred. This indicates that lower temperature helps in maintaining the stability of the cream. The pH values of all batches remained within a suitable range for skin application. From the observation, it is clear that batch F2 showed better stability compared to F1 and F3 under both storage conditions. Therefore, F2 can be considered as the optimized and most stable formulation.

### 1. Organoleptic properties

**Table 4: Organoleptic Evaluation Table.**

Sr.No	Parameters	F1	F2	F3
1	Color	Pale Yellow	Pale Yellow	Yellowish
2	Texture Grade	Fine	Smooth and fine	Thick and stiff
3	Odour	Pleasant	Pleasant	Slightly strong
4	Visual Aspect	Homogenous	Homogenous	Not completely homogenous
5	Softness	Present	Present	Slightly present

### 2. Physical evaluation

**Table 5: Physical Evaluation Table.**

Sr.no.	Parameters	F1	F2	F3
1	Uniformity	uniform	Uniform	Slightly uniform
2	Ability to spread	Uniformly spread	Uniformly spread	Not Uniformly spread
3	Absorption	Easily absorbs on skin	Easily absorbs on skin	Not Easily absorbs on skin
4	Smear kind	Slightly greasy	Non-greasy and smooth	Thick and sticky
5	Solubility	Water-insoluble	Water-insoluble	Water-insoluble
6	Emolliency	No residue observed	No residue observed	Slight residue observed
7	Phase separation	No phase separation observed	No phase separation observed	phase separation observed
8	Ease of removal	Good	Excellent	Poor
9	pH	5.2	5.9	6.5

### 3. Stability study

**Table 6: Stability study table.**

Parameters	Batch	Initial	7days at room temperature	7 days at refrigerated condition
Color	F1	Pale yellow	No change	No change
	F2	Pale yellow	No change	No change
	F3	yellowish	No change	No change
Odor	F1	Pleasant	No change	No change
	F2	Pleasant	No change	No change
	F3	Pleasant	Slight change	No change
pH	F1	5.2	5.5	6.5
	F2	5.9	6.1	6.8
	F3	6.5	6.8	6.9
Phase separation	F1	Absent	Absent	Absent
	F2	Absent	Absent	Absent
	F3	Absent	Absent	Absent



Fig. 17: pH of cream.



Fig. 18: Application of cream on hand.

## SUMMARY AND CONCLUSION

### SUMMARY

The present study focused on the formulation and evaluation of a cream for hypopigmentation using suitable ingredients. Three different batches (F1, F2, and F3) were prepared by varying the concentration of components to obtain an optimized formulation. The prepared creams were evaluated for organoleptic properties such as color, odour, appearance, texture, consistency, homogeneity, greasiness, phase separation, and washability. All formulations showed satisfactory results with good physical appearance and stability. The creams were smooth, homogeneous, and free from any phase separation, indicating proper formulation and emulsification. Slight differences were observed among the batches in terms of texture and consistency, which may be due to variation in the concentration of waxes and oils. Overall, the formulations were found to be suitable for topical application.

### CONCLUSION

From the present study, it can be concluded that all three cream formulations were successfully prepared and evaluated. The results showed that the formulations possessed acceptable organoleptic properties and good stability. Among the three batches, F2 showed better overall characteristics such as smooth texture, non-greasiness, and ease of application. Therefore, F2 can be considered as the optimized formulation for further studies. The developed cream has good potential for use in the management of hypopigmentation.

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