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PREPARATION AND ASSESSMENT OF A COMBINED KOJIC ACID AND VITAMIN C CREAM FOR DEPIGMENTATION THERAPY

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ABSTRACT

Hyperpigmentation is a common dermatological condition characterized by localized darkening of the skin due to excessive melanin production. Conditions such as post-inflammatory hyperpigmentation, melasma, solar lentigines, and ephelides significantly affect cosmetic appearance and may cause psychological distress. The present study focuses on the formulation and evaluation of a topical cream containing kojic acid and vitamin C for the management of hyperpigmentation. Kojic acid acts as a tyrosinase inhibitor by chelating copper ions at the active site of the enzyme, thereby reducing melanin synthesis. Vitamin C, a potent antioxidant, further suppresses melanogenesis by downregulating tyrosinase activity and neutralizing free radicals. The combined action of these agents provides enhanced depigmenting and skin-protective effects. The cream was formulated using the trituration method with suitable excipients to obtain an oil-in-water (O/W) base. The prepared formulation was evaluated for organoleptic characteristics, pH, homogeneity, spreadability, viscosity, and stability as per standard procedures. The cream exhibited a smooth texture, pleasant odor, neutral pH, good spreadability, and non-greasy smear. The viscosity was found to be 24476 cps, and the formulation remained stable under specified storage conditions for one month. The results suggest that the formulated kojic acid and vitamin C cream is stable, cosmetically acceptable, and potentially effective for the topical management of hyperpigmentation.

KEYWORDS: Hyperpigmentation, Kojic Acid, Vitamin C, Tyrosinase Inhibition, Melanogenesis, Topical Cream, Skin Depigmentation, Oil-in-Water Emulsion, Antioxidant.

INTRODUCTION

Hyperpigmentation Disorders

Hyperpigmentation is a common skin condition characterized by darkened patches due to excess melanin production.

1. Post-Inflammatory Hyperpigmentation (PIH)

PIH occurs after skin trauma or inflammation, especially in darker skin types (III–VI). It appears as irregular dark patches at sites of previous injury, acne, or dermatological procedures. Inflammation stimulates melanocyte activity, increasing melanin synthesis.

2. Melasma

Melasma is a chronic hypermelanosis commonly affecting women (9:1 ratio), particularly skin types IV–VI. It presents as symmetrical brown patches on sun-exposed areas, especially the face. It is often associated with pregnancy, oral contraceptives, or certain medications.

3. Solar Lentigines
Also known as liver spots, these are well-defined brown macules seen on sun-exposed areas like the face and hands, mainly in fair-skinned individuals.

4. Ephelides (Freckles)
Small, light-brown macules appearing after sun exposure, usually beginning in childhood. They are benign and require no treatment.

Structure of Skin
The skin consists of three main layers:

- Epidermis – Outer protective layer containing melanocytes responsible for melanin production.
- Dermis – Middle layer containing blood vessels, glands, and connective tissue.
- Hypodermis – Inner fatty layer providing insulation and support.

Melanin, produced by melanocytes in the basal layer, determines skin color. Overproduction leads to hyperpigmentation.

Drugs Used for Hyperpigmentation
Common depigmenting agents include:

- Tretinoin
- Azelaic acid
- Tranexamic acid
- Arbutin
- Hydroquinone
- Kojic acid
- Vitamin C

Kojic Acid
Kojic acid (5-hydroxy-2-hydroxymethyl-4-pyrone) is a fungal metabolite produced by *Aspergillus* and *Penicillium* species.

Mechanism
It inhibits tyrosinase by chelating copper ions, thereby reducing melanin production.

Properties

- Molecular formula: $C_6H_6O_4$
- Melting point: 151–154°C
- Water soluble

Adverse effects
Mild irritation, burning sensation, or allergic reaction.

Vitamin C (Ascorbic Acid)
Vitamin C is a water-soluble antioxidant essential for collagen synthesis and skin health.

Mechanism
It inhibits melanin formation by reducing tyrosinase activity and scavenging free radicals.

Properties

- Molecular weight: 176
- Freely soluble in water

Adverse effects
Mild irritation, redness, or tingling.

MATERIALS AND METHODS
Kojic acid: Skin whitening agent which acts by inhibition of tyrosinase.
Vitamin C: It helps fade hyperpigmentation. Vitamin C inhibits melanin synthesis by downregulating the activity of an enzyme known as tyrosinase.
Stearic acid: Emulsifying agent Cetostearyl alcohol: Softens the skin Glycerin: Softens and protect the skin
Triethanolamine: Stabilizer
Potassium hydroxide: Stabilize the pH of product
Methyl paraben and propyl paraben: Preservative

METHOD: The method used for formulation of cream was trituration.

Fig 1: Trituration.

EXPERIMENTAL METHODOLOGY

Formulation of kojic acid and vitamin c cream

Table 1

Serial No.	Composition	Weight in grams	Function
	Oil phase		
1	Stearic acid	21.5 gm	Emulsifying agent
2	Cetostearyl alcohol	1 gm	Soften the skin
3	Methyl parabens	0.1 gm	preservatives
4	Rose oil	0.1 gm	Fragrance
	Water phase		
5	Potassium hydroxide	1 gm	Stabilize the pH of a product
6	Glycerine	5.55 gm	Softens and protects the skin
7	Vitamin C	2.5gm	API
8	Kojic acid	2 gm	API
9	Triethanolamine	1.2 gm	Stabilizer
10	Propyl parabens	0.05 gm	Preservatives
11	Purified water	65 gm	Vehicle

Procedure

Step 1- The oil soluble ingredients such as steric acid, cetosteryl alcohol, propyl paraben are mixed and heated to 70 degree celcius in a suitable container generally in a borosilicate apparatus. This makes the oily phase of vanishing cream.

Step 2-The water soluble ingredients potassium hydroxide, glycerine, vitamin C, kojic acid, triethanolamine, methyl paraben, purified water are mixed and heated to 70 degree celcius. Simultaneosly in another suitable container these makes the aqueous phase of vanishing cream.

Step 3- When both phases were at 70 degree celcius oil phase is transferred to aqueous phase in a small portion with the continuous stirring until a clicking sound heard .Perfume was added just before the finished product is transferred to the suitable container.[8]

Fig. 2: Chemical Composition.

Fig. 3: Preparation of cream.

EVALUATION TESTS OF CREAM

1. ORGANOLEPTIC CHARACTERISTIC OF CREAM

-COLOR
-ODOUR
-APPEARANCE

2. DETERMINATION OF PH

Accurately weighed 5g of the cream was dispersed in 45 ml of water to determine the pH of the suspension at 27°C using digital pH meter.

3. DETERMINATION OF HOMOGENEITY

The formulations were tested for the homogeneity by visual appearance and by touch.

4. TYPES OF SMEAR

It was determined by applying the cream on the skin surface of human volunteer. After application of cream, the type of film or smear formed on the skin were checked.

5. SPREADABILITY

Spreadability: Spreadability is a term expressed to denote the extent of area to which the topical application spreads

on application to skin on the affected parts. The therapeutic efficiency of the formulation also depends upon its spreading value. Hence, determination of spreadability is very important in evaluating topical application characteristics. The spreadability of the cream was measured by spreading 0.5gm of cream on a circle of 2cm diameter premarked on a glass plate and then a second glass plate was employed half kilogram of weight was permitted to rest on upper glass plate for 5 min. The diameter of the circle after spreading of the cream was determined.

6. VISCOSITY: The viscosity determinations were carried out using a Brookfield Viscometer using spindle number S- 64 at a 20 rpm at a temperature of 25°C. The determinations were carried out in triplicate and the average of three readings was recorded.

Case	Study	Conditions	Min.Time[1]
General	Long term[2]	25 °C ± 2 °C/60% RH ± 5% RH; or 30 °C ± 2 °C/65% RH ± 5% RH	12 months
	Intermediate[2]	30 °C ± 2 °C/65% RH ± 5% RH	6 months
	Accelerated	40°C ± 2 °C/75% RH ± 5% RH	6 months
Stored in refrigerator	Long term	5 °C ± 3 °C	12 months
	Intermediate	25 °C ± 2 °C/60% RH ± 5% RH	6 months
Stored in freezer	Long term	–20 °C ± 5 °C	12 months

7. STABILITY STUDY: The formulation was kept at three different temperature(4, 25 and 40 degree celcius) for 1 month to evaluate its stability as per ICH guidelines.

RESULTS AND DISCUSSION

1. **ORGANOLEPTIC CHARACTERISTIC**

- **Colour:** White

Fig. 4: Formulation of kojic acid & Vitamin C.

-Odour: Pleasant

Appearance: Smooth

2. **PH:** PH was found to be neutral
3. **HOMOGENEITY:** It was found that the cream was homogeneous, smooth and consistent in nature.
4. **TYPES OF SMEAR:** It was found that the cream produced non greasy film on the skin.

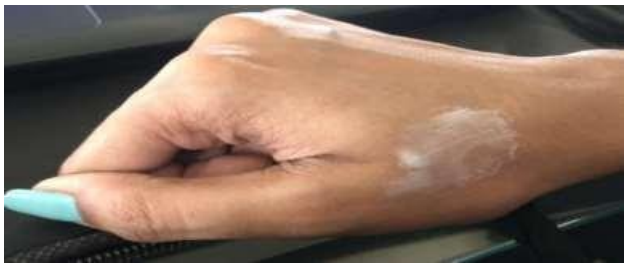

Fig. 5: Smear test.

5. **SPREADABILITY:** The spreadability of cream was found to be as follows.

Fig. 6: Spreadability test.

6. VISCOSITY: The viscosity of cream was found to be 24476 cps.

Fig. 7: Viscosity determination.

5. **STABILITY:** The product was found to be stable at the cool temperature(8 to 25 degree celcius) till one month as per IP.

STORAGE CONDITION: The formulation was stored in wide mouth container in cool and dry place away from the direct sunlight.

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