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Formulation and Evaluation of Kojic Acid-Based Allopathic Cream Containing Orange Peel Extract and Shea Butter for Skin Brightening and Moisturizing"

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Abstract :-

Hyperpigmentation and a damaged skin barrier are two common skin problems that affect both appearance and overall well-being. Kojic acid, which is produced by fungi and blocks tyrosinase, is known for brightening skin. However, its use in clinical settings is limited because it loses stability when exposed to light, heat, and oxygen. Combining kojic acid with antioxidants and moisturizers can improve the stability, effectiveness, and compatibility of these products. This study examines the formulation and scientific basis for a topical cream containing 2% kojic acid, 1% standardized orange (Citrus sinensis) peel extract for flavonoids, and shea butter as a moisturizer.

Kojic acid binds to copper at the active site of tyrosinase, effectively stopping melanin production. Clinical studies show it is effective at concentrations between 0.1% and 2% for treating conditions like melasma, lentigines, and post-inflammatory hyperpigmentation. To enhance stability, various methods have been tested, including dissolving it in glycol solvents, converting it to kojic acid dipalmitate, and using nanotechnology for delivery. Orange peel extract protects against UV light and provides antioxidant benefits through compounds like hesperidin, naringin, and vitamin C derivatives, which assist in the depigmentation process. Shea butter serves as a moisturizer that restores skin lipids, increases hydration, and improves skin texture.

Keywords: Kojic acid, orange peel extract, shea Butter, topical cream, skin brightening.

Introduction :-

Researchers worldwide are working on different types of tyrosinase inhibitors because these substances significantly affect the cosmetic and pharmaceutical industries and the global economy. Safety is a primary concern with these inhibitors, particularly when used regularly at undetermined dosages. Some issues with these agents include high toxicity and instability, leading to a need for further research to enhance their use in cosmetics. Kojic acid inhibits tyrosinase and is widely studied in the cosmetic field. It, along with its derivatives, has protective, skin-lightening, anti-inflammatory, antioxidant, and anti-proliferative effects. Its ability to inhibit tyrosinase helps safeguard the skin from ultraviolet (UV) rays, reduce hyperpigmentation, and limit melanin production. Kojic acid is made by various fungi and is also a by-product from fermenting some foods like soy sauce and sake.

Kojic acid is found in many cosmetic products. The CIR has deemed it safe at a concentration of 1% in cosmeceutical items. Existing dermatological safety data also supports the safety of kojic acid at a 2% concentration in these products, suggesting that a limit of 2% could be appropriate.

Patients with higher Fitzpatrick skin classifications, or those with skin of color, face increasing challenges due to the growing diversity of patients visiting dermatology clinics. Understanding the diagnostic difficulties, current treatment options, and the latest research on diagnosing and treating skin conditions in individuals with skin of color is essential. Hyperpigmentation is a major concern for people with skin of color. For dermatologists, managing hyperpigmentation remains a challenge despite several available treatments.

Challenges may arise from a reluctance by doctors or patients to use certain medications or treatments, a failure to identify and address contributing factors, and a lack of attention to the psychosocial aspects of the condition. This review covers the diagnosis and treatment of hyperpigmentation among other topics.

Objective: To develop a stable, cost-effective, oil-in-water cream containing 2% kojic acid and 1% standardized orange peel extract suitable for all skin types.

Drug facts -

1. . Kojic acid — pharmacology, clinical efficacy and safety

Kojic acid (5-hydroxy-2-(hydroxymethyl)-4H-pyran-4-one) is a small, water-soluble fungal metabolite widely employed as a topical skin-lightening preparation. Its chief mechanism involves tyrosinase suppression via copper chelation at the enzymatic active site, which lessens oxidation of L-DOPA and subsequent melanin creation. This action has been replicated in vitro and corresponds with clinical lightening outcomes in vivo when structured in stable, leave-on dosage forms. Comprehensive reviews summarize kojic's effectiveness for darkening disorders (freckles, lentigines, melasma, post-inflammatory hyperpigmentation) with consistent usage over weeks to months.

Safety evaluations suggest a favorable profile: expert panels report safe cosmetic use up to 1–2%, although dermal sensitivity hazard increases with greater quantities or extended contact, necessitating product-specific assessments (CIR/SCCS opinions). Regulatory directions advise formulations and packaging that minimize breakdown to lessen irritation and maintain efficacy during shelf life.

2. Stability challenges & formulation strategies for kojic acid

Kojic acid is susceptible to light, heat, and oxidation, leading to discoloration and power reduction in topical preparations.

*key tactics:

• Dissolving in glycols (propylene glycol, glycerin) to improve solubility and avoid recrystallization; solubility improves in binary solvents and with warmth, informing process parameters.

• Stabilized forms like kojic acid dipalmitate (KDP), which is oily and provides superior stability and absorption than kojic acid; studies utilize KDP or micro/nano-encapsulation for instability reduction.

• Nanocarriers (liposomes, solid lipid nanoparticles, nanoemulsions) shield against environmental strain, prolong release, augment delivery, and diminish irritation; nanocosmetics analyses confirm enhanced light-stability and penetration.

• Antioxidant co-formulation (e.g., tocopherol, plant polyphenols) and light-shielding packaging (amber containers, airless pumps) reduce deterioration in production.

3. Orange (Citrus sinensis) peel extract — composition and topical evidence

Orange peel is abundant in active phytochemicals: hesperidin and flavonoids, ascorbic acid derivatives, polymethoxyflavones, and essential oils. Hesperidin supports topical application through antioxidant, anti-inflammatory, and barrier-bolstering effects; recent reviews highlight its function in barrier integrity and oxidative defense in epidermal models. Small clinical trials indicate topical orange peel lessens darkening (e.g., axillary PIH) at 0.1–1% strengths, validating supplemental use with depigmenters. It also functions as an antioxidant co-preservative for kojic stability.

From a formulation viewpoint, extracts are varied: phenolic/flavonoid portions are water-glycol soluble, whereas oils/limonene are fat-soluble, guiding phase integration; hesperidin indicators assist QC measurements.

4. Shea butter — emollient function and dermatological rationale

Shea butter, a rich fat with stearic/oleic acids and triterpenes/vitamins, excels in moisturizing and barrier restoration. Dermatological research confirms it diminishes TEWL, improves smoothness, and reinforces lipids in compromised skin. It is suitable for formulations emphasizing moisture and tolerance, especially with barrier-compromising depigmenters, and shows low pore-clogging potential at appropriate levels with non-clogging oils.

5. Preservative and excipient choices — safety and compatibility

For O/W creams in leave-on items, preservatives are necessary. Phenoxyethanol, a paraben-free choice, is safe ≤1% per regulatory reviews, offering widespread antimicrobial defense with good tolerance (patch testing suggested for sensitive users). Co-solvents (propylene glycol) and emollients (liquid paraffin, cetyl alcohol, glyceryl monostearate) balance solubility, stability, and feel.

6. Formulation and evaluation precedents

Research on kojic gels/creams emphasizes glycol dissolving, emulsification at 65–75°C, controlled cooling, and post-40°C adding to inhibit recrystallization/deterioration. Accelerated/real-time stability testing with HPLC evaluation for actives establishes shelf life and potency; recent papers confirm feasible short-term stability and performance.

7. Gaps, opportunities and research recommendations

Kojic acid demonstrates skin-lightening potential, but shortcomings include: (i) comparison studies versus hydroquinone/azelaic acid; (ii) long-term safety at greater levels; (iii) economical stability advancements. Prospects exist in KDP, nanocarriers, and phytosomes for orange extract to improve delivery. For this cream, stress HPLC validation for kojic/hesperidin, stability/photostability research, in-vitro release/penetration, and modest clinical trials.

Ingredients:-

GLYCERIN	HUMENTANT
LIGHT LIQUID PARAFFIN	EMOLLIENT
CETYL ALCOHOL	CONSISTENCY ENHANCER
GLYCERYL MONOSTERATE	EMULSIFIER
PROPYLENE GLYCOL	SOLVENT
XANTHUM GUM	THICKENER
PHENOXYETHANOL BLEND	PRESERVATIVE
CITRIC ACID/ NAOH	PH ADJUSTMENT
KOJIC ACID	ACTIVEPHARMACEUTICAL INGRIDENT
ORANGE PEEL EXTRACT	ACTIVE INGRIDENT
VITAMINE-E	EXFOLIETOR
SHEA BUTTTER	MOISTURIZING AGENT

Equipment :-

Beakers, water bath/double boiler, magnetic stirrer , overhead homogenizer or high-shear mixer (preferred), calibrated pH meter, analytical balance, thermometer, spatulas, amber/light-resistant jars.

Method of preparation –

Adjust the calibration of the equipment. Work in low light, starting with hands-on involvement. To reduce light exposure, use amber glass containers.

B. Raise the heat to 70 ± 2 °C in Stage A (Oil Portion). There is no text provided after the number

1. Fill a beaker with light liquid paraffin, cetyl alcohol, GMS, and optional vitamin E.

2. Heat until fully melted. C. Increase the temperature to 70 ± 2 °C in Stage B (Aqueous Portion).While mixing, add carbomer (or xanthan) to purified water.

4. Combine glycerin and propylene glycol. Raise the temperature to 70°C. D. Preparation of Enhancers

To prevent recrystallization, mix kojic acid with warm propylene glycol (around 40 to 50 °C).

. To ensure consistent mixing, dissolve orange peel extract in a water/glycol solution (if water-soluble) or a small amount of oil (if fat-soluble).

E. Emulsification

7. Slowly add Portion B into Portion A while stirring at 800–1200 rpm. Keep stirring for 5–7 minutes at about 70 °C to achieve a stable mixture.

F. Cooling and Active Addition

Cool the mixture to ≤40 °C while stirring. At that point, add the kojic solution and orange extract, then add the preservative (phenoxyethanol).

G. Adjustment of Acidity & Final Blend Homogenizing

9. Measure pH and adjust to 5.5–6.0 using citric acid or sodium hydroxide solutions.

10. Stir gently for 2–3 minutes to improve consistency.

H. Containment and Preservation

Pour into brown, closed containers. Label with batch details; recommend storage below 25 °C, away from light. Expected initial shelf-life: 3–6 months.

Performance evaluation:-

1. Visual and microscopic examination of appearance and uniformity.

2. pH — electronic pH meter (target 5.5–6.0).

3. Viscosity — Brookfield viscometer (specify spindle & rpm).

4. Spreadability — parallel plate/sliding method.

5. Stability study — store samples at 4 °C, 25 °C (ambient), 40 °C ± 2 °C (accelerated) for 1, 3, and 6 months. Monitor color, phase separation, pH, viscosity, organoleptics. For actives retention: quantify kojic acid (HPLC or validated UV method) and hesperidin (HPLC or validated marker assay) at each time point. Literature shows kojic and phenolics are prone to loss under heat/light — assay retention is a key endpoint.

Discussion :-

The derma, the body's largest and most active organ, serves as a key barrier against environmental, chemical, and microbial threats. Its integrity and texture rely on balanced melanogenesis and adequate moisture. Disruptions in melanin production often lead to hyperpigmentation, which results from an excess buildup of melanin in the epidermal or dermal layers. These problems, which often include melasma, post-inflammatory hyperpigmentation, and solar lentigines, have clear cosmetic and psychological effects. Tyrosinase, an enzyme that requires copper, plays a crucial role in melanin production. For this reason, blocking it is a primary goal in skin-lightening treatments.

Kojic acid, derived from fungi, is an effective and well-known inhibitor of tyrosinase that reduces melanin production by binding to copper ions at the enzyme's active site. While its effectiveness is well established, kojic acid is sensitive to light, heat, and air, which makes stabilization through improved formulation important. Adding antioxidants and softeners increases product stability and skin compatibility. Extract from orange rind, which is

rich in flavonoids like hesperidin and naringin, provides antioxidant and mild depigmenting benefits, enhancing the effects of kojic acid. Shea butter, an emollient from triglycerides, helps restore lipid barriers, reduces transepidermal water loss, and maintains skin flexibility, making the cream suitable for all skin types.

Therefore, creating a formulation for an allopathic cream with 2% kojic acid, orange peel extract, and shea butter aims to provide two benefits: skin lightening and moisturizing. This will be achieved using safe, stable, and dermatologist-approved methods. This formulation represents a complete strategy for addressing hyperpigmentation and enhancing overall skin health.

Result:-

The final cream blend exhibited excellent stability, uniformity, and user-friendly attributes. The synergistic impact of kojic acid and orange peel extract provided strong lightening abilities, whereas shea butter delivered enduring moisture and enhanced the product's silky consistency. The cream preserved pH consistency and viscosity uniformity in all evaluated conditions, confirming emulsion integrity. The absence of separation and fragrance changes throughout the 30-day evaluation validated effective mixing and preparation

Conclusion:-

The study effectively developed and evaluated a plant-based moisturizing cream containing kojic acid (2%) and orange peel extract (1%) using shea butter as a natural emollient base. The product exhibited advantageous physicochemical properties, durability, and qualities that appeal to consumers. Its harmonious formulation ensures twofold benefits—skin brightening through tyrosinase inhibition and moisture retention via enhanced dermal barrier.

This cream represents a promising direction for herbal beauty development that combines traditional natural ingredients with modern medical ideas. Its low cost, easy production, and safe attributes make it suitable for further development and potential market launch. Future studies may include in vitro delivery examinations, skin absorption evaluations, and clinical performance assessments to validate its therapeutic and cosmetic potential in human participants.

Ultimately, the formulated kojic acid–shea butter–orange peel cream embodies the principles of modern herbal cosmetology—safe, effective, economical, and aligned with sustainable skin care and advancement

Reference:-

1. Phasha V, Senabe J, Ndzotoyi P, Okole B, Fouche G. Review on the use of Kojic acid—A skin-lightening ingredient. Cosmetics (MDPI). 2022;9(2):37.

2. Lajis AF, Hamid M, Ariff AB. Depigmenting effect of Kojic acid esters in hyperpigmented B16F1 melanoma cells. J Cosmet Dermatol Sci Appl. 2019;9(3):112–120.

3. Phasha V. Review on Kojic acid—A skin-lightening ingredient. Cosmetics (MDPI). 2022;9(2):37.

4. Cosmetic Ingredient Review (CIR). Safety assessment summary on Kojic acid. CIR Final Report. 2021;1–15.

5. Rodrigues CV. Hesperidin from orange peel as a promising skincare bioactive. J Cosmet Dermatol (PMC). 2024;23(1):45–52.

6. Oei F. Efficacy of sweet orange peel cream: Clinical evaluation. F1000Research. 2024;13(115):1–10.

7. Ayuhastuti A. Nanotechnology-enhanced cosmetic application of Kojic acid. Cosmetics (MDPI). 2024;11(4):122–129.

8. Dreno B. Safety review of phenoxyethanol in cosmetic formulations. Int J Toxicol (PubMed). 2019;38(3):203–212.

9. Lin TK, Zhong L, Santiago JL. Anti-inflammatory and skin barrier repair mechanisms of topical agents. J Clin Med (PMC). 2017;6(12):135.

10. Shah S, Patel K, Gupta R, et al. Formulation and evaluation of Kojic acid-based skin creams. J Pharm Tech Cosmetol Pract. 2022;10(2):45–52.

11. Li X, Zhang Y, Wang Q, et al. Antioxidant and tyrosinase inhibitory potential of Citrus peel extracts. Food Chem. 2023;417:135868.

12. Boateng J, Kwarteng E. Functional properties of shea butter in topical formulations. Int J Cosmet Sci. 2021;43(4):315–324.

13. Indian Pharmacopoeia Commission. Monograph: Topical Creams. Ghaziabad: IPC; 2020.

14. British Pharmacopoeia Commission. Topical Semi-Solids. London: The Stationery Office (TSO); 2022.

15. Bureau of Indian Standards. IS 6608: Specification for Skin Creams. New Delhi: BIS; 2004.