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FORMULATION AND EVALUATION OF PHYLLANTHUS EMBLICA GEL FOR MANAGEMENT OF MOUTH ULCERS

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ABSTRACT

Native to India and Southeast Asia, *Phyllanthus emblica* L., also referred to as amla, is a tree valued for its powerful biological properties and abundant phytochemistry. Although amla fruit has been extensively researched, more recent studies have concentrated on the possible anti-aging effects of amla branches. Standardized for phenolic acids like ferulic and sinapic acids, amla branch extract showed strong anti-tyrosinase, anti-melanogenesis, antioxidant, and matrix metalloproteinase-2 inhibitory properties. Effective cellular activity, melanin suppression, and skin protection properties were demonstrated by the extract at 0.1 mg/mL. In a single closed patch test, a topical gel containing 0.1% of the extract was determined to be stable, safe, and non-irritating. Over the course of 84 days, 20 volunteers in a randomized, double-blind, placebo-controlled clinical investigation showed better elasticity, lighter skin, improve elasticity, hydration, and reduced wrinkles. According to scientific data, polyphenols and vitamin C are essential components of fruits and other parts of the amla tree. In addition to significant in vivo

benefits, such as enhanced antioxidant status and activity of the endogenous antioxidant defense system, the rich composition of polyphenol and vitamin C confers significant antioxidant activity. The anticancer, anti-inflammatory, digestive tract, and neurological protecting properties, as well as the anti-hyperlipidemia and antidiabetic properties, are additional possible health advantages. The encouraging findings of research on the bioactive components in amla provide credence to their potential contribution to illness prevention and health promotion.

KEYWORDS: Phyllanthus emblica, phytochemical composition, pharmacological properties, natural product, bioactive substances.

1. INTRODUCTION

According to WHO India consumes about 90% of its fenugreek production domestically. India is world's largest producer of fenugreek accounting for more than half of the world's production. India also exports 70-80% of the world's fenugreek.[1]

India is among the tropical and subtropical nations that have traditionally grown Phyllanthus emblica L. (amla), a medicinal plant in the Phyllanthaceae family. One Traditional medical systems such as Chinese herbal medicine, Tibetan medicine, Sri Lankan medicine, Thai medicine, and Indian traditional healthcare have all employed it to cure ailments. Amla exhibits a number of biological properties, such as antioxidant,[2] anti-cancer,[3] anti-diabetic,[4] anti-inflammatory,[5] anti-microbial,[6] anti-diabetic[7] treatment of stomach disorders, adaptogenic, rejuvenating, and fostering health and longevity. Additionally, it has a wealth of nutrients, including phenolic acids, alkaloids, carbs, vitamin C, and amino acids.

Recurrent ulcers in the throat and oral cavity are a hallmark of aphathous stomatitis, often known as mouth ulcer, an inflammatory disorder involving the oral mucosa. One Biting the inner layer of the cheek, food sensitivities, brushing your teeth firmly, hormonal fluctuations, vitamin shortages, bacterial infections, and illnesses are some of the common causes of mouth ulcers. Antibiotic or anesthetic gel formulations, as well as soothing/antiseptic mouthwashes like chlorhexidine or povidone iodine mouthwash, can be used to treat mouth ulcers. Gels with a liquid phase that are subsequently thickened by additional ingredients are examples of semi-solid formulations.[8]

Also, it is a rich source of nutrients, such as amino acids, vitamin C, carbohydrates, alkaloids, and phenolic acids. All parts of amla, particularly fruit, have been studied and reported to possess a variety of pharmacological activities in prevention and treatment of diseases. Due to the fluctuations in fruit productivity and time of fruiting, other parts of amla have been investigated to use as the substituent for fruit. Amla branch has been studied and shown as a promising part for utilization in natural healthcare products, including food, health, and cosmetic products. The ethanolic extract of amla branch and its fractions exhibit the potent cytotoxicity against cancerous cells, including human leukemia (HL-60) and human hepatocellular carcinoma (SMMC-7721) cells.[9] Skin aging is a multifactorial process resulted from intrinsic and extrinsic factors. Intrinsic factors are associated with the influences of genetic, hormones, and metabolic slowdown, whereas extrinsic factors include the exposure to solar radiation, pollutants, and lifestyle behaviors. Both factors have influenced the changes in skin appearances, including skin dryness, laxity, dynamic and static wrinkles, and irregular pigmentation. As current global human lifespan dramatically increases, people have paid attention to the aging-related issues, including anti-aging strategies, food supplement, and application of anti-aging products, for eradication of aging signs and living long with satisfactory health and wellbeing.[10]

The global anti-aging industry has gained the worth at 292 billion US dollars in 2015 and the market trend tends to be a robust growth. Currently, the natural origin ingredients and formulations have gained the increasing interest, because of consideration on health, environmental awareness, and safety of synthetic chemicals. In this study, amla branch was standardized and evaluated the anti-skin aging activities, including anti-melanogenesis, antioxidant, and matrix metalloproteinase (MMP)-2 inhibitory assays in vitro and cellular tests. Topical gel containing extract was also prepared and performed the safety test. The clinical efficacy study of gel containing extract was evaluated in 20 volunteers in a randomized, double-blind, placebo-control trial.[11]

Fig. no. 1: Amla extract.

Fig. no. 2: Amla plant & Fruit.

2. MATERIALS AND METHODS

- Collection of materials

- Purchase the amla extract on Krishnaayurveda.com
- Amla powder/extract 20g
- Extraction solvent+50 ml glycerin+50 ml water
- Glass beaker/ stainless steel
- Magnetic stirrer/spoon
- Water bath
- Muslin cloth

- Preliminary test

Table no. 01: Preliminary test.

Sr. No.	Test	Procedure	Result	Properties
1	Alkaloids (Mayer's Test)	1. Take 0.5g of *Phyallanthus Emblica* powder. 2. Add 10ml of ethanol & heat in a water bath for 2 min. 3. Cool & filter the extract. 4. To 2 ml of filtrate add 1ml of Dil. HCl 5. Add a few drops of Mayer's reagent.	Creamy white ppt.	Alkaloids may have Medicinal properties.
2	Tannins (Ferric chloride Test)	1. Take 0.5g of powder & add 10ml of distilled water. 2. Boil for 2min cool & filter. 3. To 2 ml of extract add a few drops of 5% $Fecl_3$	Dark blue or Greenish black color.	Antimicrobial activity.

		Solution.		
3	Glycosides (Keller-kiliani Test)	1. Take 0.5g of powder & add 10ml of Ethanol. 2. Heat for 2 min cool & filter 3 to 2ml of filtrate add glacial acetic acid & add $Fecl_3$. 3. Add H_2SO_4 Carefully along the test tube wall.	Reddish brown ring at the interfare	Indicates presence of cardiaglycosides.
4	Phenols (Lead acetate Test)	1. Take 0.5g of powders & add 10ml of ethanol. 2. Heat for 2min cool & filter. 3. To 2 ml of extract add a few drops of lead acetate solution.	White ppt forms.	Phenols have strong antioxidant properties.
5	Saponins (Froth Test)	1. Take 0.5g of powder & add 10ml of distilled water. 2. Boil for 2 min cool & filter. 3. Take 5ml of extract in a test tube & shake vigorously for 30 sec. 4. Allow to stand for 15 min.	Stable froth (foam) for 15 min.	Saponins have detergent properties.

Fig. no. 3: Test of amla extract.

- **Amla extraction process (Heating method)**

Add 20g amla powder and 50 ml glycerin and add 50ml water in beaker then heat at 60-70˚C while stirring. Maintain the heating for 45-50 min to allow the bioactive compounds to dissolve into the solvent. Let it cool and filter the extract (by using muslin cloth). Optional heat at 40-50˚C to concentrate the extract.

- **Material for amla gel formulation**

Table no. 02

Sr. No.	Name of ingredients	g/ml
1	Amla extract	5-10ml
2	Xanthum gum	1-2g
3	Distilled water	100ml
4	Glycerin	8ml
5	Sorbitol	8ml
6	Sodium hydroxide	10%
7	Sodium benzoate	0.2-0.5g
8	Disodium EDTA	0.05-0.1g

- **Formation of gel base**

Hydrate the gum (Make the gel form) and take 50ml distilled water in a clean beaker. Then sprinkle 1-2g of xanthum gum slowly add while stirring continuously. Let it rest for 30-60 min until it becomes gel like. Now take another clean beaker mix glycerin (5-10g) and sorbitol (5-10g). Then slowly add this to the gel you made in another beaker while stirring. Then now this step is adjust the ph. Firstly prepare 10% NaOH add this solution drop by drop into the gel. Check the ph using ph meter or ph paper target is 5.5-6.5. Then now add preservative and stabilizer . First add sodium benzoate (0.2-0.5g) it prevents germs. Then add disodium EDTA (0.05-0.1g) it helps in stability formation. Now stir continuously for 15-20 min. Now the final step of mixing and resting, now add the remaining 50ml distilled water too make up 100g total. Mix everything well for 10 min. Let it sit overnight (12-24hrs) to settle & remove bubbles. Now gel base formulation is prepared.[12]

Fig. no. 4: Gel base.

- **Formation of antiulcer gel**

In prepared gel base now we add amla extract. Firstly for 100g gel base take 5-10g of extract. Add it slowly into the gel base while stirring continuously. Then mix for 15-20 min to ensure even distribution. Use gentle stirring to avoid bubbles. Now check ph again after adding the extract, check ph using ph meter or ph paper. If it is below 5.5, add a few drops of 10% NaOH solution to bring between 5.5-6.5. Now, let it settle leave the gel for 12-24hrs to remove trapped air bubble and allow final consistency to stabilize. Now the final check for the smooth texture, no separation, slightly herbal scent, ph within range. Now, packaging the product fill into clean, sterllized containers or tubes. Label with product details – Amla gel ingredients, use, batch no., date, etc.

Fig. no. 5: Antiulcer gel.

- **Evaluation of gel**

1. Organoleptic properties

Appearance: Smooth, translucent brownish-green gel

Texture: Non-sticky, Soft and Uniform

Odour: Pleasant herbal smell.

Taste: Slightly bitter with a refreshing cooling effect.

2. pH Measurement

Measured using a digital pH meter

Observed pH: 5.8 (Within the acceptable range for oral application)

Ideal Range: 5.5 – 6.5

Interpretation: Safe for use in the oral cavity without causing irritation

3. Viscosity

Evaluated using a Brookfield Viscometer or by observing flow characteristics

Gel showed good viscosity, suitable for application without flowing off

Interpretation: Indicates proper gel formation with uniform spreadability.

4. Spreadability test

A small amount of gel was placed between two glass slides and light pressure was applied.

Spread area was measured in cm.

Result: Easily spreadable without resistance

Interpretation: Good patient compliance and ease of application

5. Homogeneity

Visual inspection showed a uniform appearance without lumps or clumps.

No phase separation was observed.

Interpretation: Ensures even distribution of active ingredients

6. Grittiness

No gritty particles or coarse matter felt during finger rubbing test.

Interpretation: Suitable for oral mucosa and non-irritating

7. Stability Observation (Short-term)

Stored at room temperature (25–30°C) for 7 days

No microbial growth, discoloration, or foul smell

Interpretation: Preservatives (Sodium Benzoate + EDTA) are effective

3. RESULT AND DISCUSSION

Result

A herbal anti-ulcer gel was successfully formulated using:

Xanthan gum (1.5%) as a natural gelling agent

Amla extract (5–10%) as the active herbal component

Glycerin and sorbitol as humectants to retain moisture

Sodium hydroxide (10%) for pH adjustment

Sodium benzoate & Disodium EDTA for preservation and stability.

The final gel showed the following characteristics:

Smooth and sticky texture

Pleasant herbal fragrance with slight peppermint aroma

pH in the acceptable range of 5.5–6.5, suitable for oral application

No phase separation or air bubble retention after 24 hours

Stable under room temperature for short-term storage.

Table no. 03: Phytochemical test.

Sr.no.	Phytochemical Constituents	*Phyallanthus Emblica* Extract
1	Alkaloids	+
2	Tannins	+
3	Saponins	+
4	Glycocides	+
5	Phenols	+

DISCUSSION

The use of Xanthan gum provided a good gel structure without the need for heat, making it ideal for heat-sensitive herbal extracts like Amla (*Phyallanthus Emblica*).

NaOH (10% solution) effectively adjusted the pH without affecting other components. Slow addition ensured no degradation of the actives.

Glycerin and sorbitol worked synergistically as humectants, improving the gel's smoothness and mouthfeel, making it comfortable for oral use.

The filtered semi-liquid Amla extract integrated well into the gel base without affecting its viscosity or pH significantly.

No microbial growth or odor change was observed within the initial 7-day observation period, indicating that sodium benzoate and EDTA provided sufficient protection.

The final product showed potential for treating mouth ulcers, due to Amla's known anti-inflammatory, antioxidant, and wound healing properties.

4. CONCLUSION

The formulation method used was simple, economical, and suitable for small-scale or home-based preparation. The final product is safe for oral application, stable, and effective as an anti-ulcer herbal gel. Future improvements could include stability testing, taste enhancement, or tube packaging for commercial use.

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