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FORMULATION AND EVALUATION OF HERBAL ANTIINFLAMMATORY OINTMENT CONTAINING AEGLE MARMELOS LEAF EXTRACT

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ABSTRACT

Aegle marmelos L. (bael) is a tree belongs to Rutaceae family, widely grown all over the world. This plant is gaining popularity because of its nutrient-rich fruits and immense traditional medicinal usage and pharmacological properties. Bael is a common plant that originated in India, Bangladesh, Indonesia, China, and other Asian countries, for example, it is a spiritual, religious, and medicinal plant that can be found all over the world. This study evaluate efficacy of an herbal ointment formulated from extracts of Aegle marmelos leaves in case of inflammation. In this research study of formulation and evaluation Herbal ointment of beal leaves due to their anti inflammation property has been Traditionally used for its medicinal properties.The plant material, leaves of Aegle marmelos, was collected, and the leaves were dried in an oven at 50-55ºC for 72 h. The dried leaves were grounded and extracted in each acetone, ethanol and methanol solvents. Extracts were collected and evaporation of solvent was done on rotavapour. Phytochemical analysis showed the presence of carbohydrates, alkaloids, glycoside, flavonoids, saponins, tannins phenols in ethanolic leaf extracts. The plant possesses various significant activities such as antifungal, antioxidant, antibacterial, antiprotozoal,

antispermatogenic, anti-inflammatory, anthelmintic, antidiabetic, laxative, febrifuge, and expectorant, chemopreventive, antipyretic, ulcer healing, antigenotoxic, and diuretic. The formulated ointment was evaluated for various physicochemical parameters, including physical appearance (colour, odour, texture), wash ability, pH, spread ability, homogeneity, greasiness, and phase separation. An initial irritancy test was also performed to assess skin compatibility. The results of the evaluation indicated that the formulated herbal ointment exhibited desirable physical properties, was easily washable, had a skin-friendly pH, and demonstrated good spread ability and homogeneity. The irritancy test revealed no immediate adverse reactions on the skin. The fruits are also used to prepare a large number of by products such as candy, panjiri, toffee, jam etc with help of various post harvest technologies which also helps to reduce the post harvest losses and hence increases the shelf life which further helps in value addition and in generation a good income for a needy farmer.

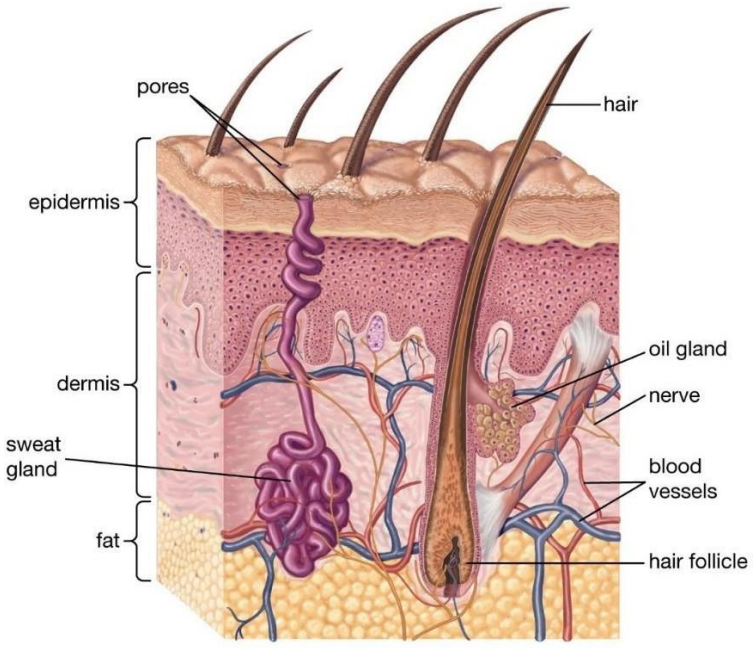
KEYWORDS: Aegle marmelos, Rutaceae, Herbal ointment, Anti inflammation, Phytochemical analysis, Physicochemical parameter.

INTRODUCTION

Many plants have been utilised for medical purposes for thousands of years. Themedicinal plants perform very important role in the lives of populations worldwide. Around 85 percent of the world's populationdepends on traditional medicine for basic health care. These plants are used in Ayurveda, Siddha and other healing systems. In India, rural communities know around 25,000 potent plant based remedies that are employed in traditional medicine. Many plants and trees exist in ayurveda, but few people know their benefits. Aegle marmelos (L) has been known to be one of the most important medicinal plants of India since Charak (1500 B.C.). It is commonly known as vilvam in tamil, bael in hindi, golden apple, wood apple, stone apple, Bengal quince, or Japanese bitter orange and is a species of tree native to the Indian subcontinent and Southeast Asia. which includes Bangladesh, Thailand, Sri Lanka, India, and Nepal. In India, it is present in nearly all states, including West Bengal, Kerala, Madhya Pradesh, Himachal Pradesh, and Jammu & Kashmir. It is also found in Egypt, Malaysia, Myanmar, and various other Asian nations. It belongs to the family Rutaceae. This tree is commonly found in temples dedicated to Shiva and Vishnu. This is considered a sacred tree by the Hindus, as its leaves are offered to Lord Shiva during worship. The plant has a wide range of adaptation to different soils and environments, and it can grow up to 1200 meters above sea level in ideal conditions. Aegle marmelos is a slow-growing, medium sized tree, up to 12-15

m tall with short trunk, thick, soft, flaking bark, and spreading, sometimes spiny branches, the lower ones drooping. The deciduous, alternate leaves, borne singly or in 2's or 3's, are composed of 3 to 5 oval, pointed, shallowly toothed leaflets, 4-10 cm long, 2-5 cm wide, the terminal one with a long petiole. Flowers occurs in clusters of 4 to 7 along the young branchlets, have 4 recurved, fleshy petals. The flowers are greenish white in color with a peculiar fragrant. Flowering occurs during the month of May and June. Fruit is spherical or oval in shape with a diameter of 2 to 4 inch. Shell is thin, hard and woody in nature. It is sweet at first taste and then irritating to the throat. Every part of Aegle marmelos plant such as its fruits, stem, bark, and leaves possesses medicinal property and is used for treating various eye and skin infections. Leaf is considered to be one of the highest accumulatory parts of the plant containing bioactive compounds which are synthesized as secondary metabolites. The chemical constituents present in Aegle marmelos are Skimmianine, Aegeline, Lupeol, Cineol, Citral, Citronella, Cuminaldehyde, Eugenol, Marmesinine, Marmelosin, Luvangetin, Aurapten, Psoralen and Marmelide. The various proved therapeutic values of Aegle marmelos are such as anti-diabetic activity, hepatoprotective activities, antimicrobial activity, analgesic, anti-inflammatory, antifungal activity, anticancer activity, antiulcer activity, antithyroid activity etc.

SKIN



The skin is the largest organ of the human body, covering an area of about 1.5–2.0 m² and accounting for nearly 15–16% of total body weight. It forms the first line of defense between the internal body environment and the external surroundings. The skin plays vital roles in

protection, sensation, thermoregulation, metabolism, immunity, and excretion.

Structure of Skin

The skin is composed of three main layers.

1. Epidermis

The epidermis is the outermost layer of the skin. It is avascular (no blood vessels) and consists of stratified squamous epithelium. Nutrition is supplied by diffusion from the dermis.

2. Dermis

The dermis lies beneath the epidermis and is composed of connective tissue rich in collagen and elastin fibers. It provides strength, elasticity, and nourishment to the epidermis.

Hypodermis

The hypodermis, also known as the subcutaneous layer, is the deepest layer of the skin, lying beneath the dermis. Although it is not considered a true part of the skin, the hypodermis plays a vital role in supporting, protecting, and regulating skin functions. It acts as a connecting interface between the skin and underlying tissues such as muscles and bones.

OINTMENTS

Ointments are semisolid pharmaceutical dosage forms intended for external application to the skin or mucous membranes. They are used for therapeutic, protective, and cosmetic purposes. Ointments provide prolonged contact of the drug with the skin surface, enhance drug penetration, and protect the affected area from environmental exposure.

According to pharmacopoeias, ointments are greasy, viscous preparations in which one or more drugs are dissolved or dispersed in a suitable base. They are widely used in the treatment of dermatological disorders, including infections, inflammation, burns, wounds, eczema, psoriasis, and fungal diseases.

ANTI-INFLAMMATORY AGENTS

Anti-inflammatory agents are drugs or substances that reduce or suppress inflammation without curing the underlying cause. Inflammation is a protective biological response to injury, infection, or irritation, characterized by redness, heat, swelling, pain, and loss of function. Excessive or chronic inflammation can lead to tissue damage, hence anti-inflammatory therapy is required.

AIM

To formulate a stable and effective herbal anti-inflammatory ointment using *Aegle marmelos* leaf extract and to scientifically evaluate its physicochemical characteristics, stability, safety, and anti-inflammatory activity in order to establish its potential as a natural topical therapeutic agent.

OBJECTIVES

1. **To collect, identify, and authenticate *Aegle marmelos* leaves** from a reliable source and ensure their quality for formulation purposes.
2. **To prepare a suitable extract of *Aegle marmelos* leaves** using an appropriate solvent system to obtain maximum yield of bioactive constituents.
3. **To carry out phytochemical screening** of the prepared leaf extract to identify the presence of active compounds such as flavonoids, alkaloids, tannins, phenolics, and coumarins associated with anti-inflammatory activity.
4. **To select and optimize an appropriate ointment base** that ensures good consistency, stability, spreadability, and skin compatibility.
5. **To formulate a herbal anti-inflammatory ointment** by incorporating the *Aegle marmelos* leaf extract into the optimized ointment base in suitable concentrations.

PLANT PROFILE

Botanical Name: *Aegle marmelos* (L.) Correa.

Family: Rutaceae.

Common name: Bel, Bael, Golden apple, Indian quince, Stone apple.

Habitat

Aegle marmelos is a subtropical and tropical plant, native to the Indian subcontinent. It grows widely in dry forests, plains, and hilly regions up to an altitude of about 1200 m.

Chemical Constituents: Alkaloid, Flavonoids, Coumarins, Tannins, Phenolic compunds Terpenoids, Saponins, Glycosides, Essential oils.

Botanical description

Aegle marmelos is a medium-sized, slow-growing tree with a short trunk, dense, fuzzy, flaking bark, up to 12-15 m tall, and spreading with spiny branches. A clear, gummy sap, similar to arabic gum, exudes from wounded branches and hangs in long threads, eventually becoming solid. At first taste, it is sweet and then unpleasant to the mouth.

Leaves

The leaves of aegle marmelos are about 2 to 3 inches in the length. Leaves are alternate Trifoliate petiolate. They are composed of 3 to 5 oval, pointed, shallowly toothed leaflets. The terminal one is with a longer petiole than the other.

Flowers

The flowering occur generally in the month of April and May. The flowers are generally in the clusters of 4-7. Each flower has 5 recurved fleshy petals; green outside and yellow is inside. Stamens are present inside the flower. The flower is 2 cm huge, sweet- scented, lax, erect.

Fruits

Fruits are about 5-20 cm in diameter, generally round oval or oblong in shape. The outer cover is hard and the inner pulp is soft gray- green in colour. After maturation fruits turn yellow. In the pulp 10 -15 flattened- oblong seeds are present.

Seeds

Seeds are about 1cm long, bearing adhesive, woolly hairs and each enclosed in a sack of transparent mucilage that solidifies on drying.10 – 15 flattened- oblong seeds are present in one pulp of the plant Aegle marmelos.

Bark

The bark is pale brown, smooth or finely fissured and flaking, armed with long straight spines, 1.2 to 2.5 cm singly or in pair. The slimy sap coming out from cut parts known as gum. The gum is also described as a clear, gummy sap, resembling gum Arabic.

MATERIAL AND METHODS

Extraction Procedure

I. Preparation of Aegle Marmelos Leaves

Collect fresh leaves of aegle marmelos or purchase dried leaves. If using fresh leaves, rinse them thoroughly to remove dust and other contaminants. Dry the leaves (if using fresh leaves) by spreading them in a shaded area or using a dryer, until they are completely dry to prevent

spoilage. Grind the dried leaves using a mortar and pestle or a blender to a coarse or fine powder, depending on the extraction method.

2. Extraction By Soxhlet Apparatus

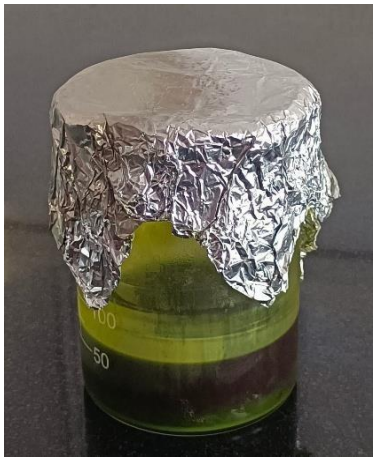
Place the powdered plant material in a thimble and position it in the Soxhlet extractor. Fill the round-bottom flask with an appropriate solvent (e.g., ethanol).Heat the solvent in the flask, allowing it to vaporize and condense over the plant material in the thimble. The solvent will repeatedly wash the material and extract the bioactive compounds. Continue the process for 6-8 hours. This ensures thorough extraction. After completion, remove the plant material, and filter the extract to remove any remaining solid particles.

3. Concentration And Removal Of Solvent (Optional)

To concentrate the crude extract, the solvent can be removed using a rotary evaporator under reduced pressure, or the extract can be evaporated in a water bath under a fume hood. If using a water bath, carefully heat the extract to evaporate the solvent, leaving behind the crude extract. For volatile solvents (like ethanol or methanol), make sure to perform the evaporation in a well-ventilated area, such as a fume hood, to avoid inhalation of fumes.

4. Storage

After solvent evaporation, a thick syrupy or sticky extract should remain. ahich is the crude extraet. Store the crude extract in tightly sealed glass containers. away from direct light and heat to preserve its potency. For long-term storage, keep the crude extract in a cool, dry place, or refrigerate it to prevent spoilage or degradation of active compounds.



FORMULATION OF OINTMENT

INGREDIENTS	Formulation
Aegle marmelos leaf extract	5g
Cetostearyl Alcohol	2.5g
Petroleum jelly	13g
Liquid paraffin	3.5g
Methyl paraffin	0.2g
Vitamin E capsule	0.2g
Lemon oil	0.2g

PREPARATION OF OINTMENT

PROCEDURE

1. All the active pharmaceutical ingredients and excipients were measured Accurately.
2. The oil phase was prepared by melting the Beeswax along with Petroleum jelly according to the desired ratio.
3. Melt the Petroleum jelly and beeswax mixture in a heat-resistant glass vessel using a water bath or a heating mantle and stir the mixture until it reaches a uniform temperature (around 70-80℃).

4 Weigh the Coconut oil and add it to the melted ointment base mixture. Stir well to ensure uniform distribution.

5. Open the Vitamin E capsule and add the contents to the mixture. Stir well to ensure uniform distribution.
6. Add the Fig leal extract to the mixture. Stir well to ensure uniform
7. Add the Lavender oil to the mixture. Stir well to ensure uniform distribution.

Allow the mixture to cool to around 30-40℃.

8. The ointment was stirred well, packed and stored in a well closed container.
9. Allow it to cool and solidify completely.

PHYTOCHEMICAL TEST

PHYTOCONSTITUENTS	TEST PERFORMED	OBSERVATION
Alkaloids	Wagner's test	Brown-reddish precipitate formed
Flavonoids	Alkaline reagent test	Yellow colouration that disappears on adding dilute acid confirms flavonoids.
Tannins	Ferric Chloride Test	Blue-black or green formed
Phenolic	lead acetate test	White precipitate formed
Terpenoids	Salkowski test	A reddish-brown formed

RESULT AND DISCUSSION

1) PHYTOCHEMICAL SCREENING

S.NO	PHYTOCONSTITUENTS	RESULT (PRESENCE/ABSENCE)
1.	Alkaloids	+
2.	Flavonoids	+
3.	Tannins	+
4.	Phenolic	+
5.	Terpenoids	+

2) PHYSICAL PARAMETER

S.NO	PARAMETERS	FORMULATION RESULT
1.	Colour	Light green
2.	Odour	Aromatic
3.	Texture	Smooth
4.	Homogeneity	Homogeneous
5.	Washability	Easy to wash
6.	Spreadability	Good & Evenly spread
7.	Stability	Stable
8.	Consistency	Good & Consistent

3) CHEMICAL PARAMETER

S.NO	PARAMETERS	FORMULATION RESULT
1.	pH	6.19
2.	Acid value	2.97

CONCLUSION

Aegle marmelos may impart health benefits when it is used in functional food products and should also be regarded as a potential nutraceutical resource in the future. In addition, it can be used as a food additive because of its typical color, flavor and texture. Aegle marmelos contains a number of phytoconstituents tannins, flavonoids, alkaloids, terpenoids, phenol, steroids and phytosteroids were found to present in methanol leaves extract. which reveals its uses for various therapeutic purposes such as antifungal, antioxidant, antibacterial, antiprotozoal, antispermatogenic, anti inflammatory, anthelmintic, antidiabetic, laxative, febrifuge and expectorant, chemopreventive, antipyretic, ulcer healing, antigenotoxic and diuretic. The extracts of this important medicinal plant can be the main form of health care for not only the poor tribal community of Jharkhand but can also form an integrated component of mainstream health care or an alternative or complement to the main form of health care. In an era when traditional know how is getting recognized, these indigenous drugs can serve as healthy, cheap and readily available substitutes of relatively more sophisticated, expensive and ill effect causing active principle based synthetic medicines.

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