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Development of Herbal Formulation Using Methanolic and Aqueous Extract of Elaeocarpus Ganitrus Leaves for Treating Pain

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ABSTRACT: Two words combine **"**Rudra**"** and **"**Aksha**"** which combinedly means eyes of Lord Shiva aka Rudraksha**.**
Elaeocarpus ganitrusis an evergreen tree with a hard and extremely attractive stone endocarp known as bead or nut and is well known in India as rudrakasha**.** Apart from its gorgeous stones, it has a popular notion supported by experiments that it has confirmed medical uses**.** Traditionally, the herb has been used to cure mental illnesses, hypertension, and epilepsy among other ointments**.** In this we formulated an ointment using rudraksha leaf extract which can be helpful for the cure of headache**.** We extracted out the API using the process of Maceration and evaporation of the filtrate the API was added in the ointment**.** Base was prepared by 2 methods **(**Table 2**)** F1 and F2 were prepared using Table 2 and F3 and F4 was prepared using Table 2**.** In F1, F2, and F3 methanolic extract was added as an API and in F4 aqueous extract was added as an API**.** when F1 was kept for some time it showed phase separation and when F2 was kept for some time its texture was seen as creamy**.** Evaluation parameters were carried out of all 4 formulations were of good strength, viscosity, spreadability with no sign of skin irritation and the pH measured was found to be skin friendly **(**6**.**80-7**.**02**)** and the viscosity calculated was between 545-670 CPC when kept for 10 days, no organoleptic changes were seen in the formulation**.**

KEYWORDS:Elaeocarpus ganitrus, Maceration, headache, methanolic extract, aqueous extract**.**

I. INTRODUCTION

Pain is an unpleasant feeling that arises from an injury's physical and psychological reactions.

Pain is defined by the International Association for the Study of pain (IASP) in 1996 as "an unpleasant, sensory, and emotional experience that is the result of actual or potential tissue damage" **[1]**.

Since pain is a subjective feeling, it is difficult to quantify.It necessitates awareness. By characterizing pain as an "experience," one may distinguish it from "nociception".

Nociception is the normal acute pain that occurs from the activation of nociceptors which are the receptors present in the skin, muscles, joints, viscera, and many internal organs.

Analgesics are commonly known as Painkillers; they are the medications that are used to treat acute or chronic pain**[2]**

There are 4 stages of Nociceptive pain**[3]**.

- Transduction (whose activity arises from peripheral receptors where activation of Nociceptor takes place)
- Transmission (after the activation of the receptor an electrical signal is generated which is transmitted from the periphery to the spinal cord and then to the brain using sensory neurons)
- Modulation (when the signals are transmitted to the spinal cord and brain, at this stage the signals can be modulated by different mechanisms and there is the release of neurotransmitters and neuromodulators)
- Perception (this is the last stage which involves the brain's conscious experience of pain when the signal reaches the specific part of the brain).

A viscous semi-solid preparation applied topically on several body parts is called an ointment. They are used in the skin and mucus membranes of the eyes, vagina, anus, and nose.

An ointment can be medicated or non-medicated. A medicament is dissolved, suspended, or emulsified based on medicated ointments. Protectants, antiseptics, emollients, antipruritic,

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keratocytes, astringents, and anhydrous bases are virtually always used in ointments.

They usually comprise one or more medicaments. In suspension, solutions or powder form or dispersal hydrocarbon (oleaginous), absorption, and water can all be used as an ointment base. They both are removable and water soluble **[3]**.

They are classified as epidermatic, endodermic, or diadermatic according to their level of effect or action**[4]**.

Most ointments have a foundation that serves primarily as a carrier or vehicle for the medicaments. the type of the base also influences its performance; thus, choosing an ointment base is a critical part of the formulation process**[5]**.

Traditional ointment bases are oleaginous in nature, consisting of hydrocarbons such as petroleum, beeswax, and vegetable oils which do not enable any water to be added, in contrast to fatty alcohols. Protective, antibacterial, emollients, antipruritic, keratolytic, and astringent ointments are used topically for a variety of functions. If the product is supposed to work in any of the following areas, the ointment base is critical. the composition of the ointment base regulates both the extent of penetration and the transfer of the medicaments from the base to the human tissue **[3,5]**.

Sunflower wax was used to manufacture ointment compositions using the fusing technique. The sunflower wax base's pH, appearance, strength, spreadability, water number, and washability were contrasted with those of the standard base.

Ointment Penetration to the Skin

The skin acts as a barrier, allowing bodily water to pass through while keeping bacteria and toxic chemicals out. Topical medicines, which are the cornerstone of dermatology treatment, are applied in the hopes of minimizing percutaneous absorption and avoiding systemic side effects.

However, it is becoming clear that skin is not as impervious as previously thought. Drugs can, without a doubt, be absorbed via the skin and cause unintended or intended systemic effects**[6]**.

Almost most the skin's barrier characteristics are provided by the stratum corneum, the epidermis' superficial layers. (The underlying dermis and the basal epidermal layers are porous; the term "transdermal absorption" is misleading). The stratum corneum is made up of overlapping cell plates that contain keratin, a fibrous protein. Most of the medication absorption happens transcellularly: significant absorption between cells or through sweat pores and hair follicles is improbable. It is a passive diffusion mechanism with a larger scale which shall be determined by the integrity and effectiveness. The epidermal barrier will be altered by the mechanism itself Low-molecular weight drugs are those that have a small molecular weight (less than 800 Daltons) with significant water and fat content. The most penetration is shown by solubility.

The vehicle in which the medication is applied is crucial. The degree of the moisture of the stratum corneum is also important. Which further increases the absorption of the drug**[7]**.

Elaeocarpus ganitrus (Rudraksha) is a member of the**Elaeocarpaceae** family that grows primarily in India's Himalayan are **[8]**. They are referred to as the king of herbal medicine, with numerous spiritual and medicinal properties both preventative and curative**[9]**.

There are about 360 species of the Elaeocarpus, which can be found in Australia, East Asia, Malaysia, and the Pacific islands. This genus has roughly 120 species from various areas of Asia, with 25 species found in India alone. Rudraksha beads have a great religious, spiritual, and materialistic significance in Hindu mythology: Rudraksha is also seen as a symbol of the link between earth and heaven **[10]**.

Wearing Rudraksha beads according to the Ayurvedic system of medicine, relieves stress, anxiety, and a lack of focus, sleeplessness, sadness, and hypertension are all symptoms of a lack of concentration, infertility, rheumatism, and asthma are all symptoms of palpitation and has anti-aging properties. The leaves and fruit extracts, in particular, have Analgesic, antiepileptic, anticonvulsive, antihypertensive, hypnotic, tranquilizing, and antihypertensive properties as well as hydrocholeretic activities found in the plant**[11]**.

II. MATERIAL AND METHOD

Ingredients

"Elaeocarpus ganitrus" (Rudraksha plant leaf extract), Stearic acid, White wax, Yellow Vaseline, Sodium stearate, Propylene glycol, Methyl paraben, Propyl paraben, Almond oil, Lemon oil, Rose water, Purified water or Distilled water.Elaeocarpus ganitrusleaf was collected from the university campus in large quantities.

- Stearic acid:is used as an emulsifying, emolliating, and lubricating agent it helps to make skin soft and does not let the product separation.

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- White wax: (beeswax) is used as a controlled-released vehicle, to stabilize an emulsion and to increase the viscosity of the preparation.
- Yellow Vaseline: is used as a base in an ointment, a protective dressing, and when applied on the skin provides a soothing effect.
- Sodium stearate: is used as a surfactant or as a pharmaceutical adjuvant and as buffering agent.
- Propylene glycol: is used as an emolliating agent as it does not let the skin lose water and form a layer of oil on the skin.
- Methylparaben: is used to inhibit harmful bacterial or mold growth in the preparation.
- Propyl paraben: is used to inhibit the growth of fungal or microbial agents and also acts as a preservative in the preparation.
- Almond oil, Lemon oil, and Rosewater: are used in the preparation to provide a pleasant odor and flavor. They are also used to combine and dilute other drugs or preparations.
- Hard Paraffin: is a mixture of solid hydrocarbon obtained from petroleum.
- Cetostearyl alcohol: is hydrophobic and an oil-soluble component.
- Wool Fat: is used as emollients and in an ointment base.

Preparation of Extract (Active Pharmaceutical Ingredient)

Rudraksha leaves were collected from the university campus in large amounts. They were washed and dried (sun-dried) after that they were converted into powder form using a simple grinder, then the powder was allowed to pass from the sieve having mesh size 41, then the fine powder was obtained, then the powder was weighed and the weight was noted down. The powder was placed inside the two containers containing 50gm each and named A and B. Aqueous (distilled water) 200ml was added in container A, and methanol 200ml was added in container B, then the two containers were covered with silver foil and allowed to macerate for 24 hours. After 24 hours the two containers were taken and filtered out, the remaining filtrate was transferred into the China dish and was allowed to evaporate in a water bath at 60 – 70^{0}C**[11,12]**. When all the content was evaporated the remaining content (active pharmaceutical ingredient) was taken from the China dish and transferred into a suitable for further use. White wax, stearic acid, and yellow vaseline were weighed accurately in a beaker and allowed to melt; the temperature was maintained between 65-70^{o}c **[12]**.

Preparation of Ointment Formulation

- **Preparation of oil phase**

White wax, stearic acid, and yellow vaseline were weighed accurately in a beaker and allowed to melt; the temperature wasmaintained between 65-70^{o}c **[12]**.

- **Preparation of Aqueous Phase**

Heat water at 65-70^{o}C. Weigh accurately propylene glycol, sodium stearate, methylparaben, and propylparaben were added to it at a maintained temperature of 65-70^{o}C. 1g of the ointment was taken in a beaker and water (25 ml) it was heated in a water bath at a uniform temperature and then the pH of the ointment was detected using a pH meter and three readings were taken down**[13]**.

- **Development of ointment**

The aqueous phase was slowly mixed with the oil phase for approximately 10-15min and when the temperature was maintained, the oil phase was gently agitated and stirred in the aqueous phase and was allowed to triturate till a creamy texture was obtained, now almond oil, lemon oil, and rose water are slowly added and continuously triturated, till the ointment is prepared. The ointment was transferred into a suitable container.

Evaluation Parameters

- **pH:** 1g of the ointment was taken in a beaker and water (25 ml) it was heated in a water bath at a uniform temperature and then the pH of the ointment was detected using a pH meter and three readings were taken down**[12]**.
- **Organoleptic Characteristics:**The ointment was formulated and then the following tests were conducted: Physical test based on appearance, color, texture, separation of phase, and detecting the homogeneity. The ointment was rubbed between the thumb and index finger by this the homogeneity and texture were tested. The presence of course particles was also detected.
- **Viscosity:**The sample (50 g) was placed in a beaker and allowed to equilibrate for 5 minutes before utilizing a T-D spindle to measure the dial reading at 10, 20, 30, 50, 60, and 100 rpm. The appropriate dial reading on the viscometer was noted at each speed. The spindle speed was gradually reduced, and the resulting dial reading was recorded. At room temperature, three measurements were taken in duplicate. The viscosity in centipoises was calculated by multiplying the dial readings by the variables

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listed in the Brookfield Viscometer catalog (CPS).

- **Skin irritation Test:** The sample was applied to the skin and checked if it feels irritated or not.

Table 1. Formulation 1

SR NO.	INGREDIENT	QUANTITY REQUIRED	F1 (10gm)	F2 (20gm)
1.	Stearic acid	15gm	1.5gm	3.8gm
2.	White Wax	2gm	0.2gm	0.4gm
3.	Yellow Vaseline	8gm	0.8gm	1.6gm
4.	Sodium stearate	1gm	0.1gm	0.2gm
5.	Propylene glycol	8gm	0.8gm	1.6gm
6.	Methyl paraben	0.2gm	0.02gm	0.2gm
7.	Propyl paraben	0.1gm	0.01gm	0.1gm
8.	Aqueous extract (API)	1gm	0.1gm	0.2gm
9.	Methanol extract	1gm	0.1gm	0.2gm
10.	Almond oil	2gm	0.2gm	0.3gm
11.	Lemon oil	1gm	0.1gm	0.2gm
12.	Rose water	1gm	0.1gm	0.2gm
13.	Purified water q.s.	100gm	10gm	20gm

Table 2. formulation Table 2

SR NO.	INGREDIENT	F3(gm)	F4(gm)
1.	Wool fat	0.50gm	0.5gm
2.	Hard paraffin	0.50gm	0.50gm
3.	Cetostearyl alcohol	0.50gm	0.50gm
4.	White soft paraffin	8.5gm	8.5gm
5.	Lemon oil	2 to 3 drops	2 to 3 drops
6.	Methanolic extract	0.5gm	-------
7.	Aqueous extract	--------	0.5gm

III. RESULT AND DISCUSSION

Result

- **Organoleptic characteristics**: It contains the physical appearance of the ointment, it's color, texture, separation of phase, homogeneity and immediate skin feel**.** The result showed that the ointment was appealing good in appearance and they had smooth texture and there was no homogeneity and there was no phase separation**.** All the formulation were light green in color **(**with methanolic extract**)** and brown incolor **(**with aqueous extract**).** All the formulation has lemon like odor.
- **pH:** all the ointment that were prepared went through pH testing and the pH of all the ointment was found to be between 6.80-7.02 which is normal to apply on the skin.
- **Viscosity:** Viscosity was determined using viscometer, the viscosity was found in the range between 520-670 CP at 20,40,60,80,100 rpm. It shows pseudoplastic flow.
- **Skin irritation Test:** when applied on the skin no irritation was observed. The 4ointments did not cause any skin irritation when applied in the skin.

Discussion

The ointment was prepared successfully and ere submitted in a suitable container**.** All the formulation that we prepared were formulated successfully**.** All of them have pseudoplastic flow on the basis of viscosity the pH of all the formulation were skin friendly they all were homogenous except for F1 which changed its phase after some time and has rough texture**.** we considered F3 as an ideal preparation as it was homogenous had skin friendly pH and was pleasant in appearance with the great aroma**.** when applied on the skin it did not cause any irritation**.** And were non greasy**.**

F1 formulation was prepared using **(**table 1**)** with continuous trituration and methanolic extract

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was added as an API in the formulation**.**it was appearing as an ointment at first but after some time the phase separation was seen**.**

F2 formulation was also prepared using **(**table 1**)** with continuous trituration and methanolic extract was added as an API in the formulation**.**it was appearing as an ointment at first but after some time it took the texture of the cream.

F3 formulation was also prepared using **(**table 2**)** with continuous trituration and methanolic extract was added as an API in the formulation**.**it was appearing as an ointment it has the correct texture and there was no phase separation even when kept for 4**-** 5 days and the color and odor were pleasant to eyes**.**

F4 formulation was also prepared using **(**table 2**)** with continuous trituration and aqueous extract was added as an API in the formulation**.**it was appearing as an ointment it has the correct texture and there was no phase separation even when kept for 4**-** 5 days and the color and odor were pleasant to eyes**.**

Figure 1. Formulation of ointment (F3, F4, F1)

Table 3. Organoleptic Characteristics

PROPERTIES	OBSERVATION			
	F1	F2	F3	F4
Texture	Rough and hard	Smooth nut After some time took creamy texture	Smooth	Smooth
Physical Appearance	Light Green in color	Green in color	Green in color	Brown in color
Homogeneity	homogenous	homogenous	homogenous	homogenous
Immediate skin feels	No grittiness and non-greasy	No grittiness and non-greasy	No grittiness and non-greasy	No grittiness and non-greasy

Table 4. pH Table

FORMULATION	OBSERVATION
F1	6.59
F2	6.90
F3	6.43
F4	6.80

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Table 5. Skin irritation Table

FORMULATION	SKIN IRRITATION **(**applied for 10 min**)**
F1	No skin irritation but had greasiness**.**
F2	No skin irritation but took creamy texture
F3	No skin irritation
F4	No skin irritation

Table 6. Viscosity table

VISCOSITY(rpm)	F1	F2	F3	F4
20	525	530	560	545
40	519	545	575	560
60	565	550	580	575
80	530	575	595	580
100	540	580	610	605

IV. CONCLUSION

The ointment using Elaeocarpus ganitrus (Rudraksha) leaves extract was prepared and the evaluation tests were done successfully. In general, we can say that Elaeocarpus ganitrus (Rudraksha) leaf contains analgesic properties in methanolic and aqueous extract. The ointment formed with active ingredient shows good strength, viscosity, spreadability with no sign of skin irritation thus it could be effective for relief of pain in headache.

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