Formulation and Evaluation of Herbal Pain Relief Balm

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Abstract-
Modern life is stressful, and tension headaches are one result of that stress. cosmetics have great demand since ancient time, now a days, a focus has been shifted more towards derived cosmetic products. Not only cosmetics products, but also to the skin products due to their ease of application among all dermal drug delivery product, pain balm formulation are preferably used so as to get the faster local effect.

Menthol is naturally occurring cyclic terpene alcohol of plant origin, which has been used since antiquity of medicinal purpose. Its use in dermatology is ubiquitous, where it is frequently part of topical anti-pruritic, antiseptic, analgesic and cooling formulation. Despite its widespread, it was only recently that the mechanism by which menthol elicits the same cool sensation as low temperature was elucidated upon, with the discovery of the TRPM 8 receptor. Although almost 5 years have passed since this receptor, many dermatologists are still unaware of methols underlying target.

Keywords: Herbal Balm, Anti-Inflammatory Activity, Eucalyptus Oil.

1. Introduction:
Inflammation is the painful redness and swelling of a portion of the body caused by an infection, injury, or illness. Inflammation is a normal, defensive response to tissue injury produced by physical trauma, toxic chemicals, or microbiological organisms. It is a component of the complicated biological reaction of a body tissue to damaging stimuli such as infections, damaged cells, or allergens, and is a defensive response involving immune cells, blood vessels, and nerves. Inflammation can be acute or persistent. Inflammation has two types: Acute inflammation, and Chronic inflammation.

Fig. No.1. Inflammation
Acute inflammation:
Acute inflammation is the body's initial response to damaging stimuli, and it is characterized by accelerated flow of plasma and leukocytes from the blood into the wounded cells. Acute inflammation is a short-term process that usually manifests itself within a few minutes or hours.

Chronic inflammation:
It is related with the infiltration of mononuclear immune cells, macrophages, monocytes, neutrophils, fibroblast activation, proliferation (angiogenesis), and fibrosis. Chronic inflammation is a gradual, longterm inflammation that lasts for months or years. Chronic inflammation is a sign of other health disorders, such as rheumatoid arthritis (RA), which affects roughly 1% of the population in affluent countries. Chronic inflammation is a response of prolonged duration in which inflammation tissue injury, and attempts at repair coexist, in varying combination.

PAIN:
In the early stages, the most prevalent disease is pain. Pain is a vital nervous system function that alerts the body to possible or existing injury. Pain is an unpleasant sensation induced by severe or destructive stimuli such as stubbing a toe, burning a finger, putting alcohol on a cut, or bumping the "funny bone." "Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, described in terms of such damage". Pain pushes people to avoid dangerous circumstances, safeguard a wounded bodily part while it heals, and avoid similar experiences in the future.

Types of pain:
1. Acute Pain
2. Chronic Pain
3. Neuropathic pain
4. Nociceptive pain

Mechanism of Inflammation:
NSAID

(Non steroidal Anti-inflammation drug)

Aspirin

Phospholipids

Arachidonic acid

COX-1  COX-2

Activates platelets Mediates inflammation

Pain and fever Protects gastric mucosa

Principle of Herbal Balm:
Herbal balm is an ayurvedic preparation of potent essential oils for reducing pain and providing fast relief from headache, backache, cold and other symptoms. Herbal balm composition offers medicinal topical
preparations for application to skin to relieve pain and stiffness. It consists of organic essential oils, organic bases, wax, and other desired herb components. Pain balms generally contain 3 components namely (1) Propylene glycol (2) Menthol (3) Camphor. All these are easily absorbed through the skin. Chemicals that reduce irritation are present in the balm, including propylene glycol. Propylene glycol is used to absorb extra water and maintain moisture in certain medicines. Analgesic when absorbed via the skin. Camphor is extremely flammable and quickly absorbed to the skin. Both a rube face and a mild local anesthetic, it provides a cooling sensation. Menthol: The main component of peppermint oil and a white crystalline material, menthol widens blood vessels. One experiences a cooling sensation where balm has been administered due to increased blood flow. Petroleum jelly is the common base for any kind of balms. Petrolatum, often known as petroleum jelly, is a semi-solid hydrocarbon combination that is used in household preparations for medical purposes. A combination of these active ingredients is useful in headache and rheumatic pains. The other ingredients in the pain relief balm are Eucalyptus oil, Thymol, nyctanthes arbor tristis, and clove oil Although the various pain relief balms have unique pharmacological effects in relieving pain, the primary function is to act as a local anaesthetic and, in the end, to create a comfortable stage. These products don’t create inflammation at the application site or have any side effects or allergic reactions like skin irritation or skin discoloration. Consequently, the customer grows to like the selected product.

Advantages:
1) Avoidance of first pass metabolism.
2) Convenient and easy to apply.
3) Improving physiological and pharmacological response.
4) Improving patient compliance.
5) Provide suitability for self medication.

Disadvantages:
1) Skin irritation of contact dermatitis may occur due to the drug and excipients.
2) Poor permeability of some drug through the skin.
3) Possibility of allergic reaction.
4) Can be used only for drugs which require very small plasma concentration for action.

2. MATERIAL AND METHODS:

Material –

2.1 Nyctanthes Arbor-tristis Linn:

Scientific Name: Nyctanthes Arbor-tristis L.
Synonym: Parijat.
Family: Nyctantheaceae.
Chemical constituents:
Alkaloids, Glycosides, Anisaldehyde, Phenyl acetaldehyde, p-cymene, 1-deconol, 1- hexanol methyl heptanone, α-pinene, Ascorbic Acid, Benzoic Acid, Carotene, D-Mannitol, Flavanol Glycosides - Astragaline, Friedeline, Fructose, Glucose, Iridoid Glycosides, Lupeol, Mannitol, Methyl Salicylate,
Nicotiflorin, Nyctanthic Acid, Oleanolic Acid, Tannic Acid, β-Sitosterole.

**Uses:**
1. Anti-helminthic
2. Anti-pyretic
3. Laxative, rheumatism
4. Reduce inflammation
5. Expectorant
6. Carminative
7. Stomachic

**2.2 Eucalyptus oil:**
Osteoarthritis, the most prevalent musculoskeletal disorder throughout the world, is a common chronic disease that causes pain, restricts activity, and reduces quality of life. Osteoarthritis may occur in all joints, but the knee is the most frequent site. The most common clinical features of osteoarthritis include pain, stiffness, swelling, and inflammation. Surgery may be considered in patients who do not show symptom improvements on nonsurgical treatments, especially when severe pain interferes with daily life.

![Eucalyptus oil](image)

**Scientific name:** Eucalyptus globules labill
**Synonym:** Eucalyptus
**Family:** Myrtaceae
**Chemical constituents:**
The essential oil was extracted by steam distillation and was analyzed for various chemical compositions using GC–MS. The major identified compounds in the leaf essential oil of *E. maculata* were Eucalyptol (54.29%), *p*-cymene (10.10%), *α*-pinene (7.78%), *β*-myrcene (7.78%), γ-terpinene (1.73%) and citronellal (1.62%); while Eucalyptol (51.62%), *α*-pinene (23.62%), *p*-cymene (10%), *β*-myrcene (8.74%), Terpinen-4-ol (2.74%) and γ-terpinene (2.59%) were the major compounds for *E. globulus*.

**Uses:**
1) Relieves stuff nose.
2) Eases sore muscle and joint pain.
3) Clears respiratory complaints.
4) Reduce stress.
5) Disinfects wounds and cuts.

**2.3 Menthol:**
Menthol is an organic compound, more specifically a monoterpenoid, made synthetically or obtained from the oils of corn mint, peppermint, or other mints. It is a waxy, clear or white crystalline substance, and
melts slightly. Menthol provides a cooling sensation when applied to the skin, which helps relieve pain in the tissues underneath the skin. Menthol topical (for use on the skin) is used to provide temporary relief of minor arthritis pain, backache, muscles or joint pain, or painful bruises.

![Menthol](image1)

**Fig. No.4. Menthol**

1. **Scientific Name:** Hexahydrothymol
2. **Synonym:** Pappermint camphor
3. **Family:** Lamiaceae
4. **Chemical constituent:**
   - Volatile oil, Menthol, Menthone, Methyl acetate, Cineole, Limonene, Flavoniods, Tannin, Resins, Azulene, Limonene.
5. **Uses:**
   1. Reduces spasm and pain caused by endoscopy.
   2. In migraine headache.
   3. To treat nausea.
   4. To reduce inflammation.

2.4 Camphor:
Camphor is derived from the wood of camphor laurel and other related trees of laurel family. Camphor is bicyclic mono Terpenoids. It is a white crystalline substance with strong odor and pungent test. It is a waxy flammable substance obtained from steam distillation, purification and sublimation of wood, twings and bark of the tree. Camphor has decongestant properties, making it a helpful ingredient for clearing chest congestion.

![Camphor](image2)

**Fig. No. 5 Camphor**

1. **Scientific Name:** Cinnamomum camphora
2. **Synonym:** Alcanfor
3. **Family:** Lauraceae
4. **Chemical constituent:**
   Camphor (40.54%), linalool (22.92%), cineole (11.26%), and 3,7,11-trimethyl-3-hydroxy-6,10dodecadine-1-ylacetate (4.50%).

5. **Uses:**
   1. Provide relief from cold cough, chest congestion, bronchitis and asthma.
   2. Improves blood circulation and help to curb muscular and joint aches.
   3. Powerful analgesic oil that produces a cooling sensation to numb pain and a warming sensation to increase circulation.
   4. Versatile anti-inflammatory and antifungal compounds that reduce pain and irritation while preventing the spread of fungal infection.
   5. Promote better sleep.

2.5 **Bees wax:**
   One product made from the honeycomb of bees and other bees is beeswax. The white wax turns yellow or brown when pollen oils are mixed with honeycomb wax. High cholesterol, discomfort, fungus-related skin diseases, and other ailments are treated with beeswax. However, these uses are not supported by credible scientific evidence. Absolute (yellow beeswax processed with alcohol) and white beeswax are used as stiffening agents in food and drink. Beeswax, both yellow and white, is utilized in cosmetic manufacture as thickeners, emulsifiers, and stiffening agents.

![Fig. No. 6 Beeswax](image-url)

1. **Scientific Name:** Ceraalba
2. **Synonym:** Yellow wax
3. **Family:** Apidea
4. **Chemical constituent:**
   Myricylpalmitate (80%), free cerotic acid (15%), melissic acid, cerolein.
5. **Uses:**
   1. Used as antibacterial, antifungal.
   2. It has anti-inflammatory and anti-allergic properties.
   3. It mainly use as an emulsifying agents, stiffener and gentle skin adhesive.
   4. Relieves stress and promotes relaxation.
   5. Relieves pain.

2.6 **Petroleum jelly:**
   Petroleum jelly is a thick, waxy paste that many people use as a skin care product and treatment for minor cuts and burns. Other names for petroleum jelly include petrolatum and Vaseline, a common brand name

People use petroleum jelly for diaper rash, as a moisturizer, to treat skin conditions such as eczema, and as a lubricant.
Benefits of petroleum jelly:
1) Soothes skin
2) Soften skin
3) Relieve cracked heels
4) Help wound heal
5) Relief for eczema and psoriasis
6) Relieves diaper rash
7) Cuticle moisturizer
8) Has a long lasting fragrance

2.7. Propylene glycol:
Propylene glycol (PG) has been used in formulations as a co-solvent and/or to enhance drug permeation through the skin from topical preparations. Two skin in vitro permeation approaches are used to determine the effect of PG on drug penetration. The in vitro Skin-PAMPA was performed using 24 actives applied in aqueous buffer or PG. PG modulates permeability by increasing or diminishing it in the compounds with poor or high permeability, respectively. Percutaneous absorption using pigskin on Franz diffusion cells was performed on seven actives and their commercial formulations.

Chemical names: Propane-1, 2-diol, 1, 2-dihydroxypropane
C.A.S. number: 57-55-6  Chemical formula: C3H8O2  Structural formula:

Molecular weight: 76.10  
Assay: Not less than 99.5% on the anhydrous basis  
Description: Clear, colourless, hygroscopic, viscous liquid  
Functional uses: Solvent, glazing agent, humectants

3. Method of preparation:  

Preparation of Herbal balm:  
Weighing all the required herbal ingredients for herbal pain relieving balm preparation were accurately weighed by using digital balance.  
Weigh all the ingredient and blend menthol, beeswax, petroleum jelly and eucalyptus oil

\[ \text{This mixture was heated up to 80 }^\circ\text{C with stirring to melt the ingredients.}\]
\[ \text{Mix till homogeneous}\]
\[ \text{Cool the content to 65 }^\circ\text{C with mixing}\]
\[ \text{Add the camphor at 60 }^\circ\text{C and mix well}\]
\[ \text{Add the Nyctanthes Arbor-}\]
\[ \text{Tristis to the above mixture with continuous}\]
\[ \text{stirring, till the uniform mixing}\]
\[ \text{Fill the mixture into the container when it is hot}\]
\[ \text{Allow the mixture to cool in the container and close the container with tight lead.}\]

3.2. Container on Storage:  
Store it in well closed mouth bottle at room temperature.

3.3. Category:  
Used as an analgesic.

3.4. Direction for use:  
1) To be rubbed externally.
2) Rub gently on the skin with the help of finger.
3) Do not apply on skin on cuts.

3.5. Uses:  
1. Arthritis  
2. Backache  
3. Sore muscle  
4. Joint pain  
5. Leg cramps

4. FORMULA:

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Ingredients</th>
<th>Quantity Taken</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. Nyctanthes Arbor- Tristis Linn. 5.4 gm Anti-inflammatory
2. Beeswax 6.6 gm Base
3. Menthol 4 gm Counter irritant
4. Camphor 1.2 gm Antiseptic
5. Petroleum jelly 0.8 gm Moisturiser
6. Eucalyptus oil 1.0 ml It helps to decrease pain, promote relaxation, and relieve cold symptoms.
7. Propylene glycol 1.0 ml Penetration enhancer

Table No. 1. Formula for pain relieving balm.

5. EVALUATION PARAMETERS:
5.1. Organoleptic evaluation:
It refers to the evaluation of the herbal balm by its colour, odour, appearance, texture, etc. The external characters of the formulation were examined.

5.2. Consistency:
The consistency of formulation was checked by applying on the skin.

5.3. Determination of pH:
The pH of the prepared formulation was determined by using digital pH meter by preparing 10% solution and dipping the glass electrode completely in the solution system to cover the electrode.

5.4. Viscosity:
Viscosity of balm was determined using brook filled viscometer at 25°C with a spindle speed of the viscometer rotated that 12rpm.

5.5. Phase separation:
The prepared balm was transfer in a suitable wide mouth container. Set aside for storage, the oil phase and aqueous phase separation were visualizing after 24hrs.

5.6. Spreadability:
The spreadability was determined by placing sample between two glass slides which was compressed to uniform thickness by applying definite time period. The time required to separate the two slides was measured as spreadability less time taken for separation of two slides shown better spreadability calculated by formula, 
\[ S = \frac{M \times L}{T} \]

S= Spreadability
M= Weight applied to slides
L= Length of slide
T= Time taken to separate the slide

5.7. Solubility:
Soluble in boiling water, miscible with alcohol and ether.

5.8. Non-irritancy:
Prepared formulations was applied to the skin of human being and observed the effect.

5.9. Stability study:
Physical stability of the prepared ointment was carried out for 3 months at various temperature conditions like 20°C, 25°C and 370°C.

5.10. Washability:
Ointment was applied to the skin then washability with water was checked.
6. RESULT AND DISCUSSION:

The physicochemical parameters of the prepared balm were determined parameters such as color, odour, appearance, and PH were tested. The formulations exhibited good appearance quality as well as PH was found in the range 7.0 which is desired PH of the skin.

Table No. 2: Physical parameters of Herbal pain balm

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Organoleptic characters</th>
<th>Herbal balm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Category</td>
<td>Pain balm</td>
</tr>
<tr>
<td>2.</td>
<td>Color</td>
<td>Greenish</td>
</tr>
<tr>
<td>3.</td>
<td>Odour</td>
<td>Strong Aromatic</td>
</tr>
<tr>
<td>4.</td>
<td>Appearance</td>
<td>Smooth</td>
</tr>
<tr>
<td>5.</td>
<td>State</td>
<td>Semi solid</td>
</tr>
</tbody>
</table>

Table No. 3: Evaluation Result of Herbal Pain Balm

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Parameters</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>PH</td>
<td>5.72</td>
</tr>
<tr>
<td>2.</td>
<td>Spreadability</td>
<td>7.2 g.cm/sec</td>
</tr>
<tr>
<td>3.</td>
<td>Phase separation</td>
<td>No phase separation</td>
</tr>
<tr>
<td>4.</td>
<td>Viscosity</td>
<td>32561cps</td>
</tr>
<tr>
<td>5.</td>
<td>Irritation</td>
<td>No irritation</td>
</tr>
</tbody>
</table>

6. FORMULATION OF ANTI-INFLAMMATORY HERBAL BALM:

![Formulation of Herbal Balm](image)

Fig no. 9 Formulation of Herbal Balm
7. **CONCLUSION:**

Frequency of intake the allopathic drugs for the treatment of acne vulgaris results to produce adverse side effects. Recently, herbal remedies are considered as safe as the synthetic one and herbal formulations are having growing demand in the global market.

Overall it can be concluded that, as the main objective of the study was to formulate and evaluate the basic physical parameter and stability check for pain balm containing menthol. We have attempted the same and the evaluation parameter results showed that, if the menthol formulated in the balm, it remains stable. The basic parameters were found to be within normal range except the color variation. The prepared formulation showed good physical characteristics. The eucalyptus oil has relieving pain property. Further evaluated by various evaluation parameters such as pH, Extrudability, Spreadability, Viscosity, Patch test and gives good result. Based on the study research it can be concluded that herbal components can be effectively formulated as in the form of balm which having excellent pain-relieving property.

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