Formulation And Evaluation Of Herbal Pain Relief Balm

Pratiksha Salunke, Shital Markad, Komal Magar,
Department of pharmaceutical Quality assurance
Vidya Niketan College of Pharmacy, Lakhewadi,
Indapur. 413103.Maharashtra, Indian

ABSTRACT
In line with the advancement of our understanding of pain mechanisms, there has been a growing emphasis on the creation of novel drug delivery systems that can offer patients individualized treatments without compromising the effectiveness of analgesics. Acute pain serves as a warning, but chronic pain is a syndrome that necessitates careful selection of highly bioavailable analgesic medications for longterm treatment. Topical drugs are designed to address these issues by providing a stable plasma level, allowing for gradual delivery of the active ingredient, and having a high safety profile. The most popular medications' topical formulations for the treatment of pain are reviewed here, along with new research findings. Tension headaches are one symptom of the stress of modern living. Since ancient times, there has been a strong need for cosmetics; however, these days, the emphasis is primarily on derived cosmetic items. In addition to cosmetics, skin care products are also preferred because of their convenient application. Of all dermal medication delivery treatments, pain balm formulations provide the fastest local effect. Menthol is a naturally occurring, plant-derived cyclic terpene alcohol that has been used for therapeutic purposes since ancient times. It is widely used in dermatology, where it is commonly found in topical preparations for anti-pruritic, antibacterial, analgesic, and cooling purposes. Although menthol is widely used, the mechanism by which it produces the same chilly feeling has just lately come to light. The Identification of the TRPM 8 receptor provided an explanation for the feeling of low temperature. Despite the fact that “this receptor was discovered nearly five years ago, many dermatologists are still unaware of menthol’s true target.[1,2].

KEYWORDS: evaluation of herbal pain balm, dermatology is ubiquitous, Castor oil, Mentha oil, Eugenol (clove), Camphor, Rose oil, Bees wax.
INTRODUCTION

The way the pain balm functions is based on the counterirritancy principle, which suppresses pain perception by creating irritation to the extent that it prevents pain from being felt. formulation has been used. In common parlance, a balm is a semisolid composition intended for external application that typically contains medication. One such formulation is a pain balm, which is meant to be applied for the alleviation of mild to moderate pain. Tension headaches are quite frequent, impacting as many as 78% of the population. Regrettably, they are also among the most neglected and challenging kinds of headaches to manage. Plant-based menthol is a naturally occurring chemical that has a cooling effect. One common natural remedy for pain treatment in sports injuries, arthritis, and other unpleasant disorders is menthol, while peppermint is utilized in many other formulations. Analgesic, antipruritic, counterirritant, and rubefacient, camphor is a naturally occurring substance made from the wood of the Cinnamomum camphora tree. The necessity of applying drugs topically to achieve therapeutic effects has grown in the modern period. Camphor absorbs easily through the skin and is very volatile. Colonoscopies are examples of diagnostic tests where it is important to prepare the colon before the procedure. Because castor oil works well for bowel evacuation, it may be used in these kinds of operations. Nevertheless, patients usually experience greater satisfaction and outcomes from these operations when using additional laxatives, including sennosides, polyethylene glycol, and other bisacodyls. According to definitions, pain is an unpleasant sensory and emotional experience that is linked to or characterized by tissue damage, whether it is actual or potential. In addition to being mildly soluble in water, menthol is highly soluble in ether, alcohol, chloroform, and hexane. Similar to peppermint, menthol is an alcohol that is present in mint oils and has cooling qualities, a white crystalline structure, and a refreshing scent. Menthol has the chemical formula C10H20O and a molecular weight of 156.37g/mol. Many topical pain relievers contain menthol because of their anti-irritant and localized anesthetic qualities. When applied topically to the skin, menthol's ability to provide a cooling feeling is widely recognized. The safety profile of menthol in excess of concentration is excellent. Beeswax is used in pharmaceuticals as a consistency, bindingagent, time release mechanism, and drug carrier in pills, capsules, ointments, and salve. [3,13].

REVIEW OF LITERATURE

1. Md. Ikram Ahmed and Syed Safiullah Ghor (et al. 2015) Since ancient times, herbal therapy has been used for many ages. Effective pain and inflammation therapy is necessary in today’s world. Investigating novel biomolecules from natural sources is necessary in the hunt for new treatment alternatives. The goal of this study was to assess OFCMT’s (oily formulation of camphor, menthol, and thymol) analgesic and anti-inflammatory properties. Essential oils and other compounds found in various plant parts are among the most significant and useful components of herbal plants. Essential oils are substances that are soluble in oil and possess a strong aroma. They are extracted using solvents and enzymatic hydrolysis, and they are separated using water and steam distillation. The naturally cooling substance found in peppermint, menthol, is frequently utilized in remedies for arthritis,
sports injuries, and other painful ailments. Thymol is a naturally occurring monoterpenic phenol derivative known as cymene, which is isomeric with carvacrol. It is extracted as a white, crystalline material with a pleasant, aromatic smell and potent antibacterial qualities from Thymus vulgaris and numerous other types of plants.

2. Ghode Shweta P, Chatur Vibhavari M, and Choudhari Pooja (et al. 2019) Cosmetics have been in high demand since antiquity. These days, attention is focused more on Cosmetics that are derived. Because they are so simple to use, skin care products are just as important as cosmetics. Pain balm is the most popular dermal medication delivery product. It is preferable to utilize formulations to provide a quicker local effect. The primary goal of the current study was to create a pain salve with paracetamol, a medication utilized in the therapy for the alleviation of mild to moderate pain, including headache, toothache, and backache. When taken as directed, paracetamol is thought to be safe. Therefore, the primary goal of the current study was to produce a paracetamol-based pain balm and determine the drug’s physical compatibility and stability in the balm formulation before evaluating it using the fundamental key.

3. Bogdanov, Stefan (et al., 2009). In ancient Egypt, beeswax was used to create figures and religious artifacts. Stingless-beeswax figurines were common in areas where stingless bees were produced in Australia and other South American nations. An essential component of early seals was beeswax. Initially, only pure beeswax was used; resin and color were added later. The first documented tablet made of beeswax in ancient Egypt dates to approximately 1300 BC. In Europe, writing tablets were still in use well beyond the Middle Ages. Before paraffin wax was introduced in the 19th century, beeswax and beeswax candles were a profitable industry to produce and sell. Although it is no longer as exclusive, beeswax is still the most expensive material today.[14]

AIM
Evaluation and formulation of herbal pain balm.

OBJECTIVE

- To ease the patients’ joint and muscular pain.
- To Greatly Improve Headache Patients’ Experience.
- To treat common colds in comparison to other product types.
- To reduce tension and encourage rest.
- Temporarily relieves the minor aches and pains of muscles and joints associated with: arthritis. Sprains. Muscle strains.
### Table 1. Causes of pain

<table>
<thead>
<tr>
<th>Types of pain</th>
<th>Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>Irritated, inflamed or damaged nerves</td>
</tr>
<tr>
<td>Foot pain</td>
<td>Arthritis, a fractured or broken bone, gout, tendinitis, plantar fasciitis</td>
</tr>
<tr>
<td>Arthritis pain</td>
<td>Enough damage can result in bone grinding directly on bone</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>Ongoing cause of pain, such as arthritis or cancer</td>
</tr>
<tr>
<td>Muscle pain</td>
<td>Tension, stress, overuse and minor injuries</td>
</tr>
<tr>
<td>Neck pain</td>
<td>Poor posture</td>
</tr>
</tbody>
</table>

**Fig. 1 Types of pain**

**MATERIAL**

**Eugenol (Clove)**

- **Synonyms:** Caryophyllum; Clove flower; Clove bud; Laung, Eugenia cariophylata
- **Biological Source:** Cloves consist of dried flower buds of Eugenia caryophyllus,
- **(Family: Myrtaceae).** It should contain not less than 15% (v/w) of clove oil.
- **Scientific name:** Syzygium aromaticum Family: Myrtaceae
- **Chemical constituents** – The drug contains about 15 to 20% of volatile oil; 10 to 13% of tannin (gallotannic acid), resin, chromone and eugenin. The volatile oil contains eugenol (about 70 to 90%), eugenol acette, methylamylketone, Caryophyllenes and small quantities of esters and alcohols.

---

Menthol

- **Scientific Name:** Hexahydrothymol.
- **Synonym:** Peppermint camphor.
- **Family:** Lamiaceae.
- **Botanical Source:** It is the oil obtained by the distillation of Mentha piperita, belonging to family Labiatae.
- **Chemical Constituents**

  The chief constituent of Peppermint oil is Menthol, along with other constituents like menthyl acetate, isovalerate, menthone, cineol, inactive pinene, limonene, and other less important bodies. Menthol separates on cooling it to a low temperature (−22°C). The flavouring properties of the oil are due to both the ester and alcoholic constituents, whereas the medicinal value is...
Castor oil

- **Synonyms**: Castor bean oil, castor oil seed, oleum ricini, ricinus oil, oil of palma christi, cold-drawn castor oil.
- **Scientific name**: Ricinus communis
- **Synonym**: Ricinus oil.
- **Family**: Euphorbiaceous
- **Biological Source**: Castor oil is the fixed oil obtained by cold expression of the seeds of Ricinus communis Linn.
- **Family**: Euphorbiaceous.
- **Chemical Constituents**: Castor oil consists of glyceride of ricinoleic acid, isoricinoleic, stearic, and dihydroxy stearic Acids. Ricinoleic acid is responsible for laxative property. Castor oil also contains vitamin F. 90% Of the fatty acid content is ricinoleic acid. The ricinoleic acid is an 18-carbon acid having a double Bond in the 9–10 position and a hydroxyl group on the 12th carbon. This combination of hydroxyl Group and unsaturation occurs only in castor oil.
- **Uses**: Castor oil is mild purgative, fungistatic, used as an ointment base, as plasticizer, wetting agents, As a lubricating agent. Ricinoleic acid is used in contraceptive creams and jellies; it is also used as An emollient in the preparation of lipsticks, in tooth formulation, as an ingredient in hair oil. The Dehydrated oil is used in the manufacture of linoleum and alkyl resin. The main use of castor oil Is the industrial production of coatings, also employed to make pharmaceuticals and cosmetics in The textile and leather industries and for manufacturing plastics and fibres.
Camphor

- **Scientific name:** Cinnamomum camphora.
- **Family:** Lauraceae.
- **Synonyms:** Gum Camphor, Japan Camphor, Alcanfor
- **Biological Source:** Camphor is a solid ketone, obtained from the volatile oil of Cinnamomum camphora (L.) Nees et Eber, belonging to family Lauraceae. Synthetic camphor, which is optically inactive, is prepared from turpentine and would probably have completely replaced the natural product.
- **Uses:** Camphor is used externally as a rubefacient, counterirritant and internally as a stimulant, carminative and antiseptic. It is a topical antipruritic and antiinfective, used as 1–3% in skin medicaments and in cosmetic. It is also used to manufacture some plastics, celluloid, in lacquers, var-nishes, explosives, pyrotechnics, as moth repellent, and in embalming fluids.
- **Chemical Constituents:** Camphor oil contains camphor, cineole, pinene, camphene, phellandrene, limonene, and diterpenes. Camphor is entirely a monoterpenic ketone. Its basic carbon framework is related to bofneol.
Rose oil

- **Scientific name**: Rosa centifolia L
- **Synonyms**: Essential oil, Attar of rose
- **Family**: Rosaceae
- **Biological Source**: Rose oil is extracted from the flowers of Rosa damascene.
- **Use**: Used in the preparation of soaps, body lotions, face cream etc.
- **Used as moisturizer**: Soothes dry skin
- **Chemical constituents**: Rose oil contains citronellol, geraniol, nerol, linalool, phenyl ethyl Alcohol, pinene, limonene and p – cymene

Bees wax

- **Scientific name**: Ceraalba.
- **Synonym**: Yellow wax.
- **Family**: Apidea
- **Chemical constituents**: Myricylpalmitate (80%), free cerotic acid (15%), melissic acid Cerolein.
- **Uses**: Used as antibacterial, antifungal, anti-inflammatory and anti-allergic properties.
METHOD

Stem and hydro Distillation

The plant (100 g of powdered and dried clove buds) was hydrodistilled for 4-6 hours in a 500-ml Flask and Subjected to 810 hours of steam distillation. Up until no oil dropped out, the volatile distillate was gathered. Sodium chloride was used to stabilize the Distillate, and ether was also added. The hydrogel layer and ether layer were then divided using Funnel. The ether layer was dehydrated using anhydrous sodium sulfate and then heated to 60 degrees Celsius in a water bath to concentrate the oil and recover the ether. The oil was weighed and chilled before examination.
Extraction of solvents

After weighing and quantitatively transferring the 30 g of pulverized clove bud samples onto a filter paper extraction thimble, put them into a 500ml reflux flask. In a Soxhlet apparatus, the mixture was then extracted using 250 ml of pure ethanol for roughly six hours (Quan et al., 2004). Extracts were concentrated using a rotary vacuum evaporator at 50°C following Soxhlet extraction.

![fig.8 Soxhlet Extraction Of Clove](image)

**FORMULA**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity Given</th>
<th>Quantity Taken</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eugenol</td>
<td>0.5 gm</td>
<td>1.0 gm</td>
<td>Carminative, anti-inflammatory</td>
</tr>
<tr>
<td>Mentha oil</td>
<td>2.5 gm</td>
<td>5.0 gm</td>
<td>Counter irritant</td>
</tr>
<tr>
<td>Castor oil</td>
<td>2.7 gm</td>
<td>5.4 gm</td>
<td>Anti-Inflammatory</td>
</tr>
<tr>
<td>Camphor</td>
<td>0.6 gm</td>
<td>1.2 gm</td>
<td>Antiseptic</td>
</tr>
<tr>
<td>Rose oil</td>
<td>0.4 gm</td>
<td>0.8 gm</td>
<td>Soothes dry skin</td>
</tr>
<tr>
<td>Bees wax</td>
<td>3.3 gm</td>
<td>6.6 gm</td>
<td>Base</td>
</tr>
</tbody>
</table>

**Table.2 Formula**
PROCEDURE

The essential botanical components for making a herbal pain-relieving balm were carefully weighed using a digital balance.[16]

- Weigh all the ingredients and blend menthol, beeswax, castor oil and Rose oil.
- Heat the mixture to 80°C with stirring to melt the ingredients. Mix till homogeneous.
- Cool the content with 65°C with continuous mixing.
- Add the camphor at 60°C and mix well.
- Add the Eugenol to the above mixture with continuous stirring, till the uniform mixing.
- Fill the mixture into the container when hot.
- Allow to cool in the container and close it with tight lead.

EVALUATION TEST

Following evaluation parameters were preferred to ensure superiority of prepared pain relieving balm.

Organoleptic Evaluation

Organoleptic Evaluation such as colour and clarity was done by sensory and visual inspection.

- **Colour:** cream yellow
- **Odour:** characteristic
- **Appearance:** pain relief stick
- **Texture:** smooth

**PH**

The PH of the prepared formulation was determined by using digital PH meter by preparing 10% solution & dipping the glass electrode completely into the Solution system to cover the electrode. The measurement was carried out in triplicate and the average of the three readings was recorded.

**Viscosity**

Viscosity of balm was determined using brook filled viscometer (S-62, model LVDV-E) at 25°C with a spindle speed of the viscometer rotated at 12rpm.
Phase Separation:

The prepared balm was transferred in a suitable wide mouth container. Set aside for storage, the oil phase and aqueous phase separation were visualizing after 24h.

Consistency

Smooth and no greeting is observed.

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.[17-19]

\[
S = \frac{M \times L}{T}
\]

S = Spreadability.
M = Weight applied to slides.
T = Time taken to separate the slides.

Fig.9 Spredability
Solubility

Soluble in boiling water, miscible with alcohol and Ether.

Fig. 10 solubility

Non-irritancy

Prepared formulations was applied to the skin of human being and observed the effects.[17-19]

Fig. 11 Non-irritancy
Washability

Balm was applied to the skin then washability with Water was checked[17-19]

![Image of hand washing](image)

**Fig.12 washability**

**RESULT**

The physicochemical parameters of the prepared balm were determined parameters such as Color; odour, appearance and PH were tested. The formulations exhibited good in appearance Quality as well as PH was found in the range 7.0 which is the desired PH of the skin.[20].

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Cream yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>Characteristics</td>
</tr>
<tr>
<td>Appearance</td>
<td>Pain balm</td>
</tr>
<tr>
<td>Texture</td>
<td>Smooth</td>
</tr>
<tr>
<td>PH</td>
<td>6.2</td>
</tr>
<tr>
<td>Viscosity</td>
<td>3256 cps</td>
</tr>
<tr>
<td>Phase separation</td>
<td>No phase separation</td>
</tr>
<tr>
<td>Consistency</td>
<td>Smooth</td>
</tr>
<tr>
<td>Spredability</td>
<td>7.2gm cm/sec</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in boiling water</td>
</tr>
<tr>
<td>Non-irritancy</td>
<td>No irritation</td>
</tr>
<tr>
<td>washabilitiy</td>
<td>Easily washable</td>
</tr>
</tbody>
</table>

**Table.3 Result**
DISCUSSION

Pain relief balms achieve progressive delivery of active components while maintaining stable plasma levels and ensuring a good safety profile through various formulations. Topical medications address the challenges of selecting analgesic drugs with high bioavailability for long-term use, ensuring a tailored treatment approach for chronic pain. Additionally, sustained release pharmaceutical formulations utilize water-miscible and hygroscopic network-forming materials to disperse active ingredients effectively, enhancing the sustained release mechanism for pain management. Furthermore, specific analgesic balms are formulated with a combination of natural ingredients that synergistically provide strong pain relief effects, allowing for prolonged pain relief and healing benefits. These formulations may also include components like capsaicin, bromelain, and menthol to enhance pain relief and anti-inflammatory properties.

CONCLUSION

Adverse side effects are produced when allopathic medications are taken often to treat acne vulgaris. Herbal remedies are now regarded as secure as the demand for synthetic and herbal formulations is rising on the international market. In summary, the primary aim of the research was to develop and assess the fundamental physical parameters and stability assessment of menthol-containing pain relief products. After making the same attempt, the assessment parameter results indicated that, provided the menthol formulation in the balm, stays steady.

Herbal balm was prepared by using Hot Melt Processing Technique and was found to be Without particles transparent components which are used in formulation are having good Compatibility without any significant changes. The clove oil have relieving pain Property. A clove leaves extracts used to relieve Arthritic pain, cures high fever and This herbal balm show good physical properties. Based on the study research it can be Concluded that herbal components can be effectively formulated as in the form of balm by Using Hot melt Processing Technique which having excellent pain-relieving property.

REFERENCE

1. Formulation and evaluation of herbal pain reliving balm Jagruti S Bidgar, Shivam S Bamankar, Kajal K Katkar, Samadhan K kodalkar Department of B. Pahramcy, Mandesh Institute of Pharmaceutical Science and Research Center Mhaswad, Maharashtra, India.


