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Formulation And Evaluation of Herbal Pain Relief Balm

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ABSTRACT:
Herbal balms are topical used ayurvedic preparations made from a combination of herbs, oils and waxes. They are designed to be applied to the skin for various therapeutic purposes, such as soothing muscle aches, relieving from skin irritation, cold, chest congestion, sour throat and promoting relaxation. The efficacy of herbal balms often stems from the active compound present in the chosen herbs, which can possesses Anti-inflammatory, analgesic, antiseptic or emollient properties. Herbal pain relief balm is a semi-solid topical preparations formulated using natural plant-derived ingredients for the relief of pain and inflammation. It's commonly used in the management of conditions such as muscular pain, joint stiffness, backache, sprains, headache and minor inflammatory disorders. This study focuses on the formulation and evaluation of a herbal pain relief balm that includes active ingredient like camphor, menthol, tulsi, eucalyptus oil, thymol combined with a base of beeswax and coconut oil. The formulated balm was evaluated through various methods such as pH, organoleptic properties, patch test, spreadability, washability. In ancient times, herbal preparations are used to cure the population. Nowadays, synthetic preparations are commonly used to treat the most of the diseases but most of the chemical preparations possess mild to moderate side effects. Our main aim to formulate the herbal pain relief balm instead of synthetic formulation to reduce the number of doses taken orally to cure headache and backache.

Keywords: Herbal Pain Relief Balm, Natural Plant Derived Ingredients, cold balm.

I. INTRODUCTION:

Herbs , the term herb is derived from Latin word Herba and old French word Herbe. Herb can be defined as "any plant which leaves, stem, flowers, roots and seeds:used for different purpose like food, medicine, flavoring, perfume". Botanically, herb is any seed – bearing plant which does not have a woody stem and dies down to the ground after flowering or completion of life cycle. [1]

Balm, is a traditional or ayurveda form of topical semi- solid, anhydrous preparation, commonly used for relieving bodyaches and pain. Usually, balm requires friction and must be rubbed or massaged into the skin for proper application. They are normally thicker in consistency than ointment. Balms are preferrable for topical use as they are water impermeable, occlusive, moisture protecting, chemically, physically stable even without preservative and longer acting with slow absorption. The demand for the utilization of herbal medicine is rising due to their high efficacy, affordability, ease of use, weather adaptability with human body and lesser side effects. There is a progressive demand for topical drug route over the other routes due to various advantages of topical drug delivery system such as reduced risk of systemic adverse reactions, avoidance of first pass metabolism and gastrointestinal tract variability, direct administration to desired site of action, known -invasiveness and prevention of drug interaction.[2] They provide simple therapeutic regime, which is easily terminated by simple removal of the application from the surface of the skin. Analgesic herbal balm is an ayurvedic formulation of powerful essential oils for quick relief from headache, backache, cold and in relieving pain. Herbal balm composition comprising organic essential oils, organic beeswax and other desired herbal components has medicated topical preparations for application to skin of human beings. These balms contain counter irritant chemical compounds such as camphor crystals, thymol crystals, eucalyptus oil, menthol, beeswax, tulsi and turmeric. Pain is an unpleasant feeling often caused by intense or damaging stimuli, such has stubbing a toe, burning a finger, putting alcohol on a cut. According to international association for the study of pain, pain is a complex phenomena that includes modulation, affective reactions, nociception afferent to the central nervous system, endogenous analgesia, behavioural changes and shifts in social roles. Pain is

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an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or describe in terms of such damage. When pain relief balms are rubbed, on the area where the pain exits, the pressure and movement produced excess of sensory input that blocks the pain sensation. A cure for pain doesn't exist. To cure pain, the condition causing your pain must be anatomically removed from your body through surgery and in most cases this simply is not feasible nor possible, nor label as a cure for pain. In order to achieve pain relief and pain control your task is to find the wrights product, methodology or pain relief treatment that allows here dramatic reduction of your painful condition. Traditional pain balm offers safe, accessible and effective, alternative especially in rural and semi urban areas where the allopathic options may be limited. This production venture not only promotes healthcare access but also strengthen the local rural economy through herbal value chain development. [3]

1.1 Discrepancies between herbal and synthetic balms :

Serial Number	Herbal Balm	Synthetic Balm
1.	These are obtained from plants or parts of plants such as : flowers, roots, stems, leaves etc.	They rely on petroleum jelly, parabens and artificial fragrances etc.
2.	These have less or no side effects.	They produce mild to moderate side effects.
3.	They are inexpensive.	These are expensive.
4.	On Applying topically, they do not cause any irritation or allergic reaction.	Sometimes on applying it may cause irritation and burning sensation on the skin.
5.	They improves skin texture, natural healing and offer anti oxidant protection.	They may cause long – term dryness or skin issues.

1.2 Types of pain:

Pain is usually transitory lasting only until the noxious stimulus is removed or the underlying damage or pathology has healed. But some painful conditions, such as rheumatoid arthritis, peripheral neuropathy, cancer and idiopathic pain may persist for years. Psychogenic pain is pain caused, increased or prolonged by mental emotional or behavioral factors. Acute pain is usually managed with medications such as analgesics and anaesthetics. Management of chronic pain, however is much more difficult and may require the coordinated efforts offer pain management team.

- Acute pain
- Chronic pain
- Neuropathic pain
- Nociceptive pain[4,5,6]

1.3 How does the pain relief balm works?

Pain relief balm works on the principle of counter irritant instead of actually relieving the pain. They work on the principle of suppressing the pain by causing irritation on the point where the pain relief balm is applied. Pain balms generally contains 3 component mainly namely thymol camphor and menthol all of these are easily absorbed through the skin. A combination of these 3 active ingredients is useful in case of headache and rheumatic pains. The other ingredients in the pain the pain relief balm are eucalyptus oil, petroleum Jelly, bees wax and tulsi. Role of balm includes a local anaesthetic effect and finally provides a comfortable stage. These products do not have any side effect or allergic reactions such as irritation or darkening of the skin or cause inflammation on the point of application. Hence the consumer develops a liking for the chosen product.

Herbal pain relief balm work through its combination of ingredients, such as camphor, menthol and essential oils. These ingredients work together to provide pain relief and reduce inflammation.

Source: The ingredients in the balm such as camphor and menthol, increase blood circulation to the surface of the skin and vessels. Herbal balm extracts of organically certified herbs, organic essentials form a medicated topical application. This application is used for quick relief from pain such as headache, backache and arthritic pain. [7,8]

1.4 How to apply?

1.4.1. Clean the area: Wash and dry the skin where you'll apply the balm.

1.4.2. Use a small amount: Gently rub a little balm on the affected area until it's absorbed

1.4.3. Repeat as needed: Apply 2 -3 times a day for the best results.

1.4.4. Cover the affected area : After applying the balm cover the affected area with the cloth which keep the affected area warm.

1.4.5. Take proper rest : after applying the balm rest properly so that it will show rapid action.

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 3, May-June 2026, pp:854-868 www.ijprajournal.com ISSN: 2456-4494

II. IDEAL PROPERTIES

2.1. Analgesic and Anti – inflammatory : The balm should deliver herbs / essential oils that provide analgesia(pain relief) and Anti – inflammation action locally (At the site of application) .

2.2 Good penetration and local bioavailability: The active herbal or essential oil components must reach the target tissues (muscle, joints and superficial nerves) via skin. The balm should have an effect within a reasonable time (example : tens of minutes to a few).

2.3. Herbal profile/ synergy : since we are working with herbal formulation, the choice of plant / essential oil actives is important : they should have analgesic/ anti – inflammatory/ anti- oxidant / circulation promoting activities.

2.4 Safety and tolerability : Because this is topical, the formulation must be non irritant (and ideally non sensitising) for majority of users. The balm should be safe on normal intact skin and appropriate warnings for broken skin etc. The balm should avoid systemic side effects like methyl salicylate or Salicylate derivatives .[9, 10]

III. ADVANTAGES:

Natural ingredients: The use of tulsi, mint leaves and eucalyptus oil as natural ingredients can provide a safe and more sustainable alternative to synthetic ingredients.

Potential therapeutic applications: The herbal balm may have potential therapeutic applications for the relief from headache, backaches, pain, inflammation etc.

Cost effective: The use of natural ingredients and simple formulation methods can make the herbal balm a cost effective option.

Produce calming sensation : It must provide cool and calm feeling at the affected areas.

Reduce number of reactions: Herbal balm shows less side effects as compared to the synthetic balms

Treatment of cold: To treat common colds in comparison to other product type.

Relieve pain : Temporarily relieves the minor aches and pain of muscles and joints associated with : arthritis, sprains, muscle strains.[11,12]

IV. INDIAN REGULATIONS FOR HERBAL MEDICINES:

In India, herbal medicines are regulated under the Drug and Cosmetic (D and C) Act 1940 and rules 1945, where regulatory provisions for Ayurvedic, Unani, Siddha, medicine are clearly laid down. Ministry of Ayurvedha, Yoga, and naturopathy, Unani, Siddha , homeopathy (AYUSH) is the regulatory authority and mandate that any manufacture or marketing of herbal drugs have to be done after obtaining manufacturing licence, as applicable.

The main focus of this department is on development of education and research in Ayurveda, yoga, and naturopathy, unani, siddha and homeopathy systems. Laws and regulations on herbal medicines are partly the same as those for conventional pharmaceuticals.

The Drug and Cosmetic Act extends the control over licensing, formulation, composition, manufacture, labelling, packaging, quality, and export.

Schedule “T” of the act lays down the good manufacturing practices requirements to be followed for the manufacture of herbal medicines. The official pharmacopoeias and formularies are available For the quality standards of the medicines. First schedule of the drug and Cosmetic Act as listed authorised texts, which have to be followed for licensing any herbal product under the two categories:

- Ayurvedic, siddha &unani drugs
- Patent or proprietary medicines [13,14,15]

4.1 New Guidelines for Herbal Medicines:

- AYUSH providing time to time new revised regulations for ASU drugs . Before there is no such guidelines for conducting clinical trials ,but in March 2013 Ayush public new GCP guidelines for clinical trials on ASU drugs.
- Good clinical practice is a set of guidelines which incorporates the design , conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects.
- The fundamental Tenet of GCP that in research on man, the interest of science and society should never take precedence over consideration related to the well-being of the study subjects.
- It’s intention to ensure that the studies are scientifically and ethically sound and that the clinical properties of the ASU medicine under investigations are properly documented.
- The guidelines seek to establish two cardinal principles: protection of the rights of human subjects and authenticity of ASU medicine clinical trial data generated.

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 3, May-June 2026, pp:854-868 www.ijprajournal.com ISSN: 2456-4494

- These guidelines are formulated based on CDSCO document on GCP guidelines (2001) for clinical trials on pharmaceutical products.
- They should be followed for carrying out all ASU medicine research in India at all stages of drug development whether prior or subsequent to product registration in India.
- These GCP guidelines have to be followed during a clinical trial, if this not follow than clinical trial will be suspended by the regulatory authorities.
- GCP guidelines also provide the compensation related guidelines for participants if any unwanted results or death of participants occur during clinical trial.
- From 2017 onwards, it's also mandatory that there must be expiry and manufacturing date present on product label.[17,18]

V. Herbal Components:

5.1. Camphor:

Synonym: Kapoor, karpura
Biological Source: *Cinnamomum camphora.*
Family: lauraceae[19,20,21,22]

Chemical constituents: camphor is derived from the wood of camphor laurel and other related trees of laurel family. Camphor is bicyclic monoterpenoid. It is a white crystalline substance with strong odour and pungent taste. It is a waxy flammable substance obtained from steam distillation, purification and sublimation of wood, things and bark of the tree. Camphor oil contains camphor, cineole, pinene, camphene, phellandrene, lomonene and diterpenes. Camphor is entirely a monoterpenic, ketone. It's basic carbon framework is related to bofneol.

Uses: Camphor is used externally and internally as a stimulant, carminative and antiseptic.

Used as topical analgesic.

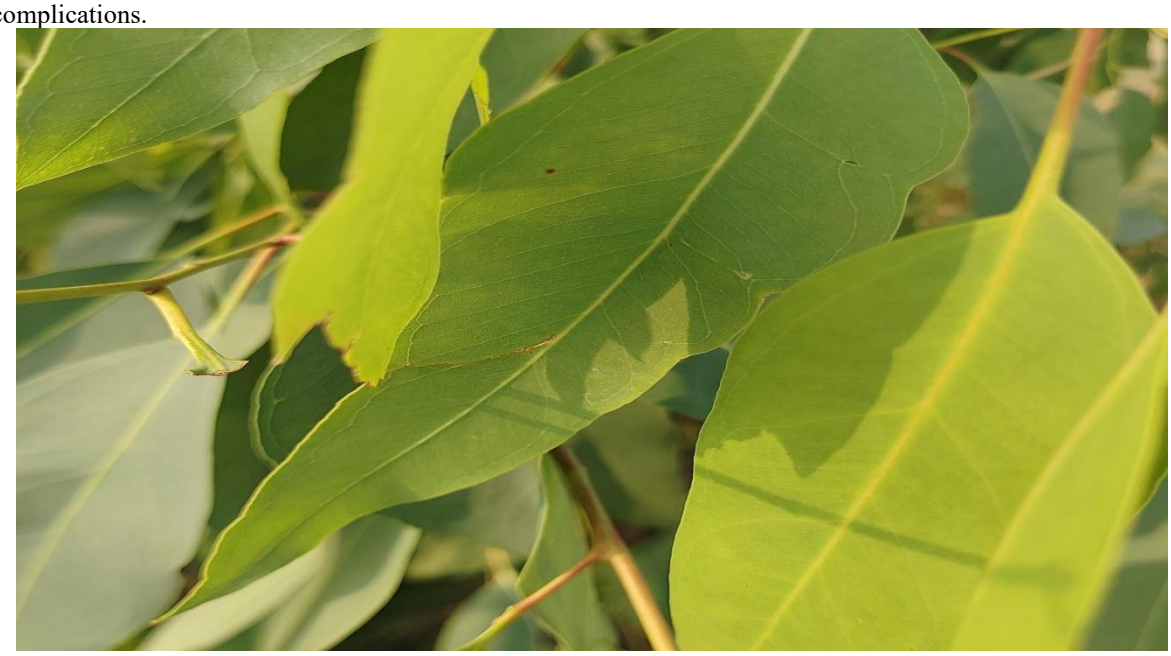
Cough suppressant.

Camphor is served as a natural insecticide to repel insects and pests. [23,24,25]

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 3, May-June 2026, pp:854-868 www.ijprajournal.com ISSN: 2456-4494

5.2. Menthol:
Synonym: peppermint camphor
Biological source: It is obtained by the distillation of *Mentha piperita,*
Family: lamiaceae[26]
Chemical constituents: The chief constituent of peppermint oil is Menthol, along with other constituents like menthyl acetate, isovalerate, methone, cineol, inactive pinene, limonene and other less
Uses:
Menthol provides a cooling sensation when applied to the skin, which help relief pain in the tissues underneath the skin.
Menthol topical is used to provide temporary relief of minor arthritis pain, backache, muscles or joint pain
Painful bruises.
Menthol improves blood flow to the skin wherever it is applied, bringing life back to dull and tied complications.
It reduces the production of inflammatory cytokines and prostaglandins to help improve red and inflamed skin.[27,28]

5.3. Eucalyptus oil:
Synonym : Blue gum leaf oil, eucalypti aetheroleum, nilgiri oil
Biological source: Eucalyptus oil is made from the fresh leaves and branch tops of the *Eucalyptus teriticornis*
Family: Myrtaceae
Chemical constituents: The main chemical constituents are 1,8-cineole(63.1%), peimene(7.7%),apinene
(7.3%), and a -limonene (6.9%).[29, 30]
Uses: Auguments skin and hair .
Reliefs pain and Inflammation .
To treat rheumatoid arthritis.
Also used as room freshener .[31,32,33]



5. 4. Tulsi:
Synonym: Holy basil, Tulasei,tulsi,tulasi.
Biological source: Tulsi consists of the fresh and dried leaves of ocimum species like *Ocimum santum L.*and *Ocimum basilicum L.* etc
Family: Lamiaceae

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 3, May-June 2026, pp:854-868 www.ijprajournal.com ISSN: 2456-4494

Chemical constituents: Eugenol , Methyl Eugenol,linalool. Tulsi offers numerous health benefits and is often taken as an herbal tea , dietary supplements,or extract .It is also commonly utilised in traditional ayurvedic treatments.

Uses: Antioxidant: The polyphenol rosmarinic acid found in tulsi serves as a strong antioxidant, safe guarding bodily cells against damage caused by free radicals. Excessive oxidation can lead to cell harm , and this acid helps prevent that.

Antifungal: Research indicates that the compounds linalool and Methyl chavicol extracted from tulsi essential oil exhibit antifungal properties against dermatophytes isolated from clinical settings.

Antibacterial: Tulsi contains antibacterial agents such as carvacrol and terpene , along with the sesquiterpene B-cariophyllene, which serves similar functions.This constituent, recognise as an FDA – approved food additive , plays a role in protecting the body from illness – inducing bacteria.

Anti-Inflammatory : Beyond its antioxidant capabilities , rosmarinic acid also provides anti-Inflammatory benefits. Another compound pegenin contributes similarly.However, the primary anti-Inflammatory agent in tulsi is Eugenol which also helps regulate blood sugar level by enhancing pancreatic beta cell function and insulin secretion.

Anti-stress: Studies have shown that the leaves of O. sanctum exhibit anti-stress properties in rabbits.[34,35,36,37,38]

5.5. Beeswax:

Synonym: yellow wax (cera flava),white wax(sera alba)

Biological source: Purified wax obtained from the honeycomb of *Apis mellifera* and
Other species of Apis.

Family: Apidae[39, 40]

Chemical constituents: Reach in saturated fatty acids (~95%), caprylic acid (2%),
Capric acid (50-80%), lauric acid (3%), myristic acid (1%)

Uses:

It is used as a natural base in ointment and topical preparations.
It is used to lubricate instruments and moulds during pharmaceutical processing.
It is also used in manufacturing of candles or electronic industries, Cosmetic,
It is an ingredient of paraffin ointment.
Show emollient characteristics
In preparation of plaster or polishes.[41,42,43]

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 3, May-June 2026, pp:854-868 www.ijprajournal.com ISSN: 2456-4494

5.6.Thymol:
Synonym: Thyme camphor, thymic acid,Ajwain.
Biological source: Ajwain is obtained from the dried ripe seeds of *Trachyspermum ammi (L.) Sprague.*
Family : Apiaceae [44,45]
Chemical constituents: Thymol is consist of carvacrol, p-cymene (upto21%), Terpinene and other components are linalool, caryophyllene, and Beta myrcene.

Uses:
It is used as an antiseptic and antimicrobial agents.
It provides soothing and cooling effect.
It helps to control fungal infections.
It is used as a natural pesticides and insect repellent.
It can inhibit the growth of bacteria and fungi helping to prevent spoilage.
Thymol is used as a flavouring agent in food industry.[46,47,48]

5.7 Turmeric :
Synonym: Haldi**,** Indian saffron, Haridra
Biological source: Turmeric consist of dried rhizomes of *Curcuma longa*
Family: Zingiberaceae

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 3, May-June 2026, pp:854-868 www.ijprajournal.com ISSN: 2456-4494

Chemical constituents: Turmeric contains yellow colouring matter known as curcuminoids.The chief constituent of yellow colouring matter is curcumin 1 (60 %) in addition with small quantities of curcumin 2, curcumin 3 and dihydrocurcumin.
Uses: anti-Inflammatory action
Boost immunity
Pain relief action
Anti oxidant action
Boost brain function.[49,50,51,52,53]

6. Mechanism of Action :

- **Counter irritant effect:** Ingredients such as Menthol and camphor stimulate nerve endings in the skin , producing sensations (cooling/ balming) that distract the brain from the underlying pain.

- **Increased blood flow:** Rubefacients (like camphor) dilate blood vessels at the application site, increasing blood flow to soothe aching muscles and reduce stiffness .

- **Local analgesic action:** Many balms act as mild anaesthetics, numbing the immediate area to reduce pain from muscle aches , arthritis and strains .

- **anti-Inflammatory properties:** Certain ingredients (such as eucalyptus oil and specialised compounds) help to reduce the swelling in joints and tissues . [54,55]

7. Method of preparation:

7.1 Extraction of eucalyptus oil : firstly clean eucalyptus leaves , removing any dirt or debris. Lightly bruise the leaves to help release the oils.

- Place the RBF (round bottom flask) on the heating mantle .
- Add the dried eucalyptus leaves into the Round bottom flask , and half fill the RBF with distilled water.
- Position the condensation tube to allow steam to flow through it , into a separate vessel .
- Attach the inlet and outlet pipes to the condenser so that water enter into the condenser through inlet pipe . Water is drained through outlet pipe.
- Heat the RBF on a low to medium setting. As the water boils , The steam will pass through the leaves, carrying the volatile oil. This steam condenses in the condenser and flows into the collection vessel.
- Once a significant amount of Liquid has been collected , carefully turn off the heat. Allow the RBF to cool down considerably before disassembling .
- The collected liquid will have two distinct layers – A layer of Eucalyptus oil on top and a layer of hydrosol below . Use a separating funnel to carefully separate the oil from the hydrosol .
- Transfer the eucalyptus oil to a dark glass bottle and store it in a cool , dark place.[56]

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 3, May-June 2026, pp:854-868 www.ijprajournal.com ISSN: 2456-4494

The hydrosol : The remaining hydrosol carries a faint fragrance of eucalyptus and can be used as a room freshener or a gentle toner for the skin.

7.2 Extraction of Menthol : Collect the fresh mint leaves from the garden and wash it under running water.

- Place the RBF (round bottom flask) on the heating mantle .
- Add the dried mint leaves into the Round bottom flask , and half fill the RBF with distilled water.
- Position the condensation tube to allow steam to flow through it , into a separate vessel .
- Attach the inlet and outlet pipes to the condenser so that water enter into the condenser through inlet pipe . Water is drained through outlet pipe.
- Heat the RBF on a low to medium setting. As the water boils , The steam will pass through the leaves. This steam condenses in the condenser and flows into the collection vessel.
- Once a significant amount of Liquid has been collected , carefully turn off the heat. Allow the RBF to cool down considerably before disassembling .
- Collect the menthol extract in the separate beaker .[56]

International Journal of Pharmaceutical research and Applications
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7.3. Melting phase

- Take beeswax in a beaker.
- Melt on a water bath (60 – 70°C) until a clear liquid forms.

7.4. Incorporate Active ingredients:

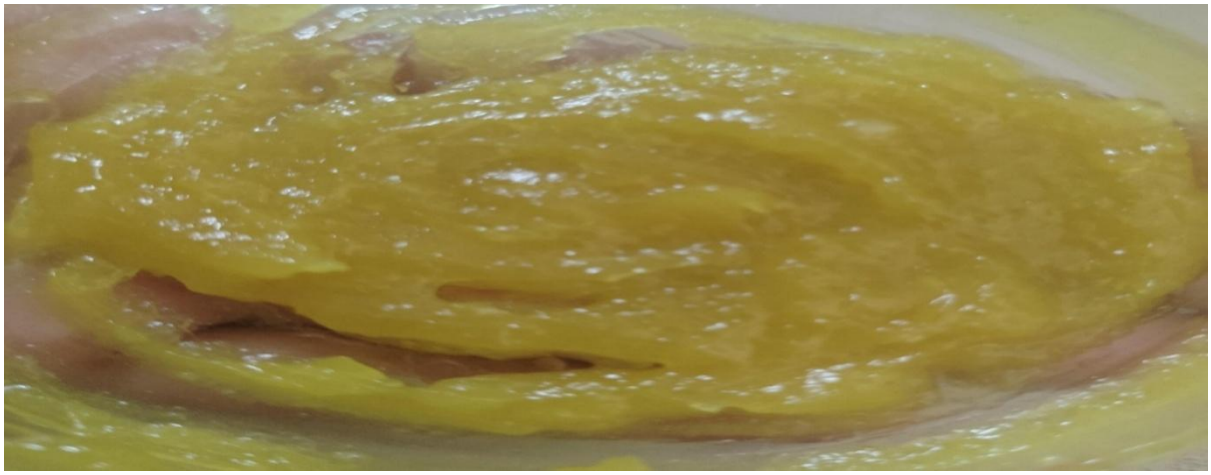
- Remove from heat.
- Add camphor, Menthol , thymol and tulsi one by one with continuous stirring.

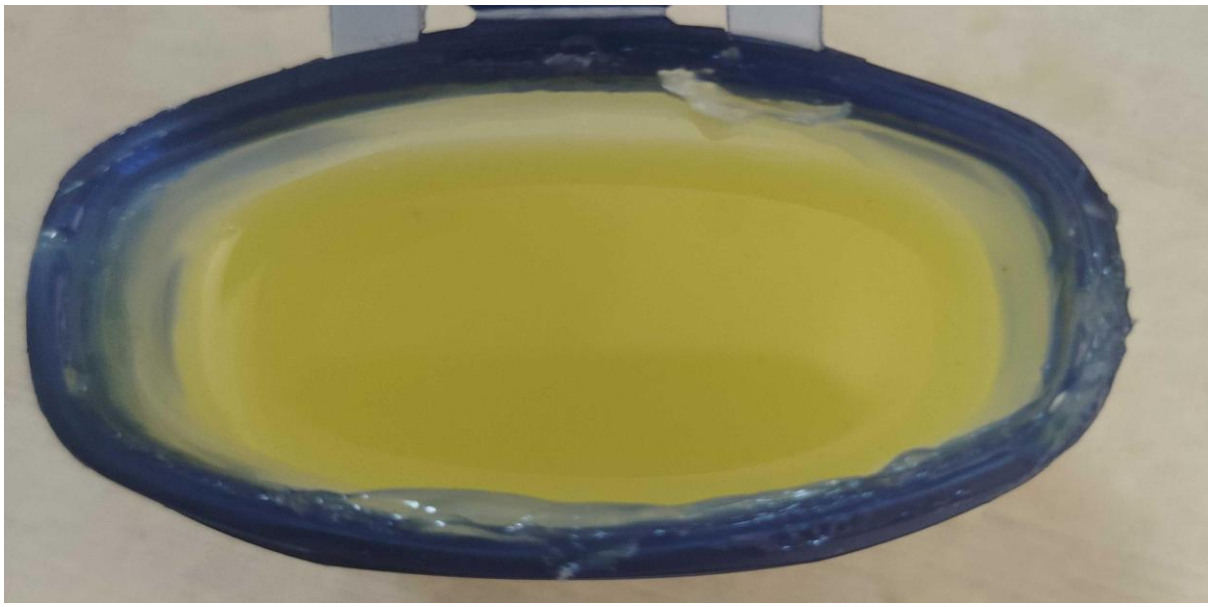
7.5. Add Herbal oil:

- Add eucalyptus oil and turmeric powder when the temperature drops below 40°C to preserve fragrance .

7.6. Filling and Cooling:

- Pour the uniform mixture into the clean , sterile container while still semi-solid.
- Allow to cool and solidify at room temperature.
- Then fill into the suitable container.





8. Experimental work :

Collection of Material / Ingredients
↓
Weighing properly all ingredients
↓
Formulation of herbal balm
↓
Evaluation test of Herbal balm

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 3, May-June 2026, pp:854-868 www.ijprajournal.com ISSN: 2456-4494

↓
Packaging of herbal balm

9. Method Apparatus :

Serial Number:	Glassware and Apparatus
1.	RBF (Round bottom flask)
2.	Condenser
3.	Heating Mantle
4.	Collecting vessel
5.	Weighing balance

10. Evaluation parameters:
Evaluation of Herbal pain relief balm includes:

10.1 Organoleptic evaluation parameters:

Serial Number:	Characteristics	Observation
1.	Colour	Creamy light yellow
2.	Odour	Mild astringent
3.	Consistency	Semi solid
4.	Texture	Smooth

Clarity and colour were assessed visually against the white background and the odour was evaluated through sensory organs (nose via smell)

10.2 Phase separation Test :
The balm was placed in a suitable container for storage . After 34 – 48 hours , any separation between the oil phase and aqueous phase was observed .

- Observation: No phase separation found in the balm.

10.3 PH Test :
Take the pH paper and placed in the sample of herbal pain relief balm and test the pH of the sample with the help of pH paper or digital pH meter .

- Observation: The pH of the balm is approximately between 5 – 6 .

10.4 Homogeneity Test:
Homogeneity test tells about the equal / uniform distribution of essential oils extract, active ingredients (Menthol, camphor , eucalyptus oil) and excipients within the formulation and that the physical properties remain consistent.[58]

10.5 Patch Test (Skin irritation Test) :
In This, take small amount of herbal balm onto our finger tips and apply it on the skin and observe the irritation, redness, itching , burning sensation on the skin.

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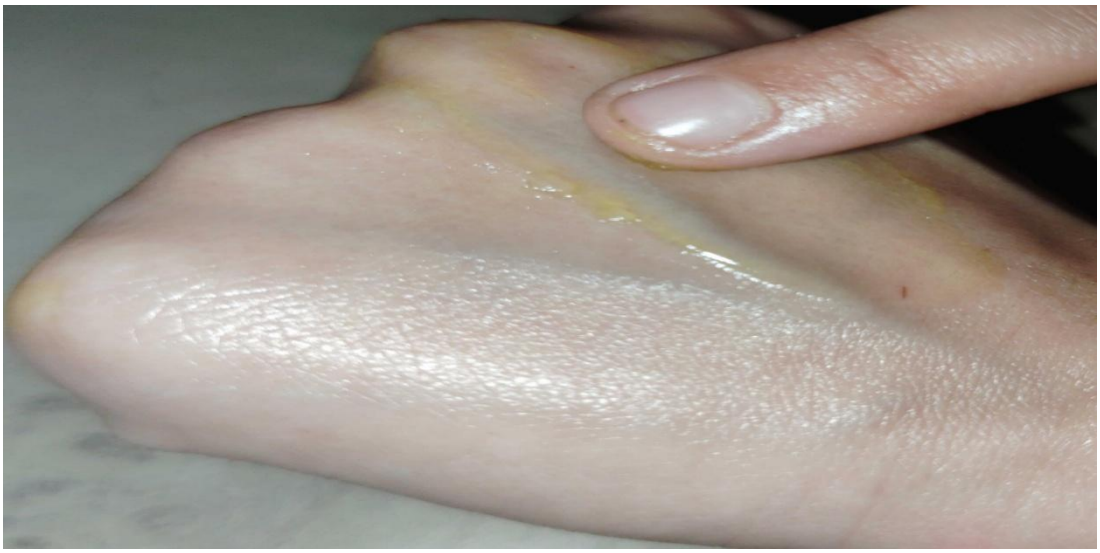


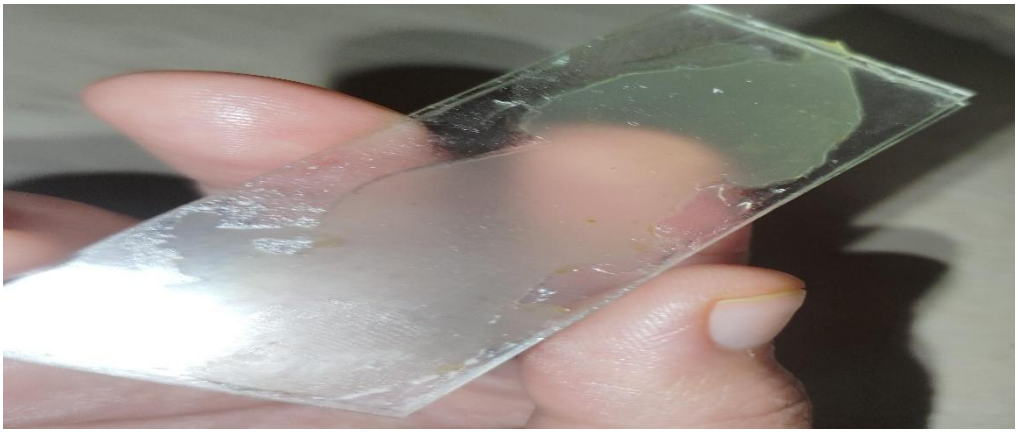
Testing for skin irritation or redness is essential to confirm dermatological safety . Particularly essential oils like camphor can be irritating in high concentration. So patch test conducted on human volunteers to evaluate symptoms like redness , itching , irritation , burning sensation or inflammation .

An effective herbal balm should cause little to no irritation, making it appropriate for frequent topical applications .[59]

- Observation: It was observed that no irritation, burning, redness or itching produced on the skin and herbal balm may produce soothing or cooling effect on the skin .

10.6 Spreadability Test:

- Take two clean glass slides and apply the small amount of herbal balm on one glass slide.
- Then put the second slide on to the first slide which cover the first slide properly.
- After that put a 100 gm of weight on the glass slides for 30 – 40 seconds .
- Then remove the weight from the slide after few seconds.
- Now observe the spreadability of the balm on the slide.
- observation: It was observed that the balm will easily spread on the glass slide .



10.7 Washability Test:

Washability refers to the easiness with which the balm can be removed from the skin using water or mild soap . Products with high wax content may adhere more strongly, which makes washability a key factor for user's convenience.

Effective washability helps avoid residue, build up and lower the chances of pore blockage or irritation.[60]

International Journal of Pharmaceutical research and Applications
Volume 11, Issue 3, May-June 2026, pp:854-868 www.ijprajournal.com ISSN: 2456-4494

- Observation: It was observed that there will be easy removal of balm from the skin complete by using soap and water.

10.8 Stability Test:

Stability test is performed to ensure the shelf life by exposing the herbal balm to the environmental factors like temperature, humidity and light etc.

- Real time stability Testing : Herbal balm is stored under required temperature to check the shelf life of the herbal balm .
- Accelerated stability Testing : Herbal balm is exposed to higher stress conditions (example: high temperature or humidity) to predict the shelf life more quickly. Typical conditions include 40°C ± 2°C and 75% ± 5% relative humidity.

VI. RESULT:

The herbal pain relief balm made from natural components like camphor, bees wax, Menthol, Thymol , Tulsi and eucalyptus oil which exhibited suitable physico-chemical properties . It had a creamy/ Burgundy colour, smooth texture, mild astringent odour and semi-solid consistency. No phase separation had been found in the herbal balm . The pH of the herbal balm had been found to be between 5-6 (approximately) . No itching, irritation or redness had produced on the skin. It was recorded that the herbal balm will easily spread on the skin. The balm will easily remove from the skin after washing. These observations ensure that the herbal balm should be safer to use .

VII. CONCLUSION:

Herbal balms represent a significant integration of traditional ayurvedic knowledge with modern topical drug delivery systems. Derived from plant based ingredients like camphor, Menthol, eucalyptus oil, Tulsi, Thymol and bees wax . They offer natural, cost effective and accessible alternative for managing pain , inflammation and musculoskeletal discomfort . Unlike many synthetic balms , herbal formulations provide therapeutic benefits such as analgesic , anti inflammatory and counter irritant actions with fewer or no side effects and better skin tolerability . Their occlusive , anhydrous base ensures stability prolonged action and targeted relief without systemic absorption or first pass metabolism. The rising demand for herbal balms reflects a broader shift towards natural health care solutions that are affordable, sustainable and culturally relevant especially in rural and semi urban areas .

In essence Herbal pain relief balms bridge traditional medicine and contemporary needs , providing safe symptomatic relief while promoting holistic wellness and economic development through indigenous resources.

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