A STUDY ON THE FORMULATION AND EVALUATION OF HERBAL MENSTRUAL PAIN RELIEF BALM.

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Abstract: Dysmenorrhea is a form of menstrual pain caused by uterine contractions due to both an increased production of prostaglandins and the release of the endometrial layers during menstruation. This research brings forward the development of a novel herbal menstrual pain relief balm with ingredients including clary sage oil, eucalyptus, peppermint, lavender, frankincense, and helichrysum, mixed with the base ingredients (beeswax, coconut oil, and Shea butter), tested through sensory assessment, patch test and feedback from users so as to ascertain that the product is able to address different types of pain associated with periods, as well as for other types of headache and backache; it seems to be equally effective for both men and women.

Key Word: Menstrual pain, Herbal remedy, Pain relief balm, Essential oils.

I. INTRODUCTION[1, 2, 3, 4]

The term dysmenorrhea refers to painful menstruation. Dysmenorrhea is a cramp labor-like pain in the lower abdomen that radiates to upper abdomen, waist and thighs and is sometimes accompanied by systemic symptoms like nausea, vomiting, diarrhea, headache and dizziness. In dealing with Dysmenorrhea, medications such as prostaglandin synthesis inhibitors, non-steroidal anti-inflammatory drugs and contraception pills are used irregularly because of fear of their side effects. Therefore, it seems necessary to find a new and simpler treatment for dysmenorrheal.

However, considering the side effects of modern medicine, there are increasingly and more women who prefer to rely on herbal treatment based on their own traditional/national medicine. Herbal medicines for women’s menstruation issues are used globally, and their efficacy and safety have been mentioned in previous reviews (Maleki-Saghooni et al., 2018).
Why Herbal[7]?

"Herbal" has common meaning that is considered as products (or items) obtained from plants and used in a medical way. These substances are made up of variously referred to bioactive compounds such as alkaloids, polyphenols, flavonoids, terpene, and phenols which have therapeutic effects on the body. The fields focusing on pharmacognosy, phytochemistry, and pharmacology are working to isolate and understand these bioactive compounds found in medicinal plants trying to find their biological applications. Research is the key to exploring the possibilities.

Including benefits of herbal medicine for certain health conditions, which are antibacterial, antioxidant, antimicrobial and soothing effect. Plenty of the cultures have an extensively recorded experience of employing herbal medicines to address the menstrual disorders. The natural treatments that pass down the generations through the ancient knowledge were usually created for the purpose of using them for menstrual cramps, regulating cycles and addressing all the other problems related to periods.

Herbal medicines are usually available as over-the-counter products. They can be more convenient and inexpensive than a prescription medicine for some people.

Development of the balm[8, 9, 10]:

This balm is formulated using a blend of natural ingredients, each one selected for their exceptional pain-relieving and anti-inflammatory properties. The blend includes key ingredients such as,

- Clary Sage essential oil, renowned for its Analgesic, muscle relaxant.
- Helichrysum essential oil is also included, which is widely regarded as an Anti-inflammatory, and skin-soothing.
- Eucalyptus essential oil is another essential component, as it possesses cooling and analgesic properties, making it a popular natural remedy for pain and inflammation.
- Frankincense essential oil is added to the blend, believed to have anti-inflammatory and pain-relieving properties, making it a popular choice for natural remedies.
- Lavender essential oil is added for their Pleasant scent and potential calming effect.
- Peppermint essential oil is added for their Cooling effect and pain alleviation.

How does the menstrual pain relief balm works?

The menstrual pain relief balm is an all natural product, which works by using the combination of essential oils and soothing base to relieve the menstrual pain when applied externally on your abdomen. When the skin's absorption process happen, it allows the essential oil like clary sage, helichrysum, eucalyptus, lavender, frankincense, and peppermint to penetrate deeply, thus, the anti inflammatory and pain agents are are able to target the pain at its source. Theses oils are naturally considered to have high anti-inflammatory, analgesic, and muscle-relaxing properties excelling in the alleviation of the tension and spasms which are usually associated with the menstrual cramps. Furthermore, Clary sage oil helps in hormone regulation, enabling a balance of hormones that cause pre-menstrual aggravation. When the balm is massaged into the skin, the calming and soothing effect is delivered by ingredients like lavender and frankincense that help you relax and reduce your stress. On the other hand, the moisturizing properties of Shea butter, coconut oil and beeswax allow the skin to remain hydrated and protected which in turn enhances the performance of the balm and provides mild relief for menstrual discomfort.

Goal:

Ultimately, our goal is to contribute to the growing awareness of natural pain management techniques and to promote safe and effective methods that improve overall well-being and quality of Life. By providing individuals with the ability to provide natural solutions to deal with menstrual cramps and muscle pain, we Aim to improve their ability to lead active and fulfilling lives.
II. MATERIAL AND METHODS.

A. COMPOSITION:

Table No.1: Formulation of Menstrual Pain Relief Balm

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Name of Excipients</th>
<th>Concentration / Quantity</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BEESWAX</td>
<td>25gm</td>
<td>Acts as a base, provides solidity. Forms a protective barrier, locks in moisture.</td>
</tr>
<tr>
<td>2</td>
<td>COCONUT OIL</td>
<td>15ml</td>
<td>Carrier oil, promotes absorption. Enhances skin moisturization, facilitates application of essential oils</td>
</tr>
<tr>
<td>3</td>
<td>SHEA BUTTER</td>
<td>35gm</td>
<td>Adds richness, soothes the skin. Soothes and softens the skin, reduces dryness and irritation.</td>
</tr>
<tr>
<td>4</td>
<td>CLARY SAGE ESSENTIAL OIL</td>
<td>8ml</td>
<td>Analgesic, muscle relaxant. Eases menstrual cramps, promotes relaxation and stress relief.</td>
</tr>
<tr>
<td>5</td>
<td>PEPPERMINT ESSENTIAL OIL</td>
<td>3ml</td>
<td>Cooling effect, pain alleviation. Refreshing sensation, aids in muscle relaxation.</td>
</tr>
<tr>
<td>6</td>
<td>LAVENDER ESSENTIAL OIL</td>
<td>3ml</td>
<td>Pleasant scent, potential calming. Adds soothing aroma.</td>
</tr>
<tr>
<td>7</td>
<td>FRANKINCENSE ESSENTIAL OIL</td>
<td>4ml</td>
<td>Anti-inflammatory, potential pain relief.</td>
</tr>
<tr>
<td>8</td>
<td>EUCALYPTUS ESSENTIAL OIL</td>
<td>3ml</td>
<td>Cooling sensation, muscle comfort. Refreshing scent, potential pain-relieving properties.</td>
</tr>
<tr>
<td>9</td>
<td>HELICHRYSUM ESSENTIAL OIL</td>
<td>4ml</td>
<td>Anti-inflammatory, skin-soothing. Soothes irritated skin.</td>
</tr>
</tbody>
</table>

B. INGREDIENT PROFILE:

B.1. BEESWAX\textsuperscript{[23,24]}:

Certainly! Beeswax, made from the workers' and the queens' wax glands, is a naturally processed substance from bees (Apismellifera). Those substances which are produced from the waxy glands in the abdomen of these insects is called the sweet secretion. It has the exact role of the glue which the bees use in making wax honeycomb combs which they use them in supplying broods and honey plus pollen. Beeswax has been used by people since time immemorial: first and foremost, in cosmetics such as lipstick, creams and lotions; it has been used to make candles and added to food as a natural emulsifier.

Figure No.1: Beeswax
Chemical Composition: Generally consisting of esters, hydrocarbons and fatty acids

Uses and Benefits:
- Cosmetics and skincare brands - This includes a long list of products ranging from hair care to nail care to lipstick to body butters and creams due to beeswax's hydrating, moisturizing, and protective properties. It acts as a super smooth and sealing agent, using such elements as pregnancy oil and extract from forest fruits to keep the skin supple and healthy. Furthermore, it prevents the evaporation of trans-epidermal water and thus could capture the harmful substance from the environment.
- Pharmaceutical and Medical Applications: Beeswax used some in the Pharmaceutical formulation to support the disintegration and solubility of some formulations and form the base. Besides, it might be used in the clinical area with some health-related devices and in orthodontics.

Overall, Beeswax is the main ingredient in this natural product because it serves various functions, such as repairing the skin, moisturising it and acting as a barrier

B.2. COCONUT OIL\[19, 20\]:

Botanical Name: Cocos nucifera

Source: Coconut oil is derived from the kernel or meat of mature coconuts harvested from the coconut palm.

Composition: Mainly medium-chain fatty acids among the composition of coconut oil is lauric acid that is a potent and inherent antibacterial and antiseptic compound. Lauric Acid: Roughly 45%-53% of coconut oil beholds Lauric acid content that goes into category of MCT (triglyceride medium chain) having antibacterial facets. Caprylic Acid: Caprylic acid comprises about 6-8% of coconut oil and This is responsible for fungal and bacterial eradication as well. Capric’s Acid: Lauric acid takes place round 5-7% in coconut oil and does the same thing as caprylic and capric’s acid are Microbicidal. Other MCFA’s: Another form of MCFA’s such as Myristic acid and Palmitic acid is also in coconut that give the significant impacts on health.

Health Benefits:
- Antimicrobial Properties: As well as the action of lauric acid together with the other MCFAs lay in the formation of antimicrobial properties. This remains to be coconut oil’s major roles in soothing the infection in the mouth and in fighting them because it has antibacterial properties
- Skin Moisturization: Coconut oil, particularly, is the most popular natural oil applied nowadays for skin hydration and its nourishment. This is why you are going to see it being used as one of the primary ingredients in products such as lotions, creams and balms meant for affording the skin moisture and making it homogenized.

Overall, coconut oil is a multi-purpose ingredient and provides help to cooking, as well as cosmetically, and it is also good for your health purpose. Therefore, coconut oil has wide applications. In the same way, moderation must be the key when employing it because of its high saturated fat that rises the cholesterol level if over consumed.
B.3. SHEA BUTTER\textsuperscript{[21, 22]}:

Botanical Name: Vitellariaparadoxa (formerly Butyrospermumparkii)

Source: A primarily African crop, the hard shea tree nuts were the source of shea butter.

Composition: Majorly consisting of triglycerides, which in turn have the main converse acids that are oleic acid(40-60%) and stearic acid (20-50%) in abundance. It is a compound consists of many other fatty acids but in smaller proportions; i.e. omega 6 (linoleic acid), saturated (palmitic acid) and polyunsaturated (arachidonic acid). Earlier, it was also observed that Shea butter is a treasure chest of bioactive compounds such as Phytosterols, Tocopherol, and Triterpenes.

Properties:
- Emollient: shea butter has moisturizing property and can help soften the skin.
- Anti-inflammatory: shed butter can help to alleviate skin conditions such as irritations and redness. It may just as well, besides the fact that it can soothe redness and swelling and itching that are the reactions of basically skin diseases.
- Antioxidant: The vitamin E functions like the antioxidant tocopherol in that it acts to hold the attack on the skin because of free radicals.

Benefits:
- Moisturizing: Shea butter is deeply moisturizing and nourishing, making it suitable for dry, rough, or chapped skin. It can help soften rough patches and improve skin texture.
- Soothing: Shea butter has a calming effect on the skin and can help soothe itching, irritation, and minor burns. It is often used to alleviate discomfort caused by eczema, psoriasis, and dermatitis.
- Healing: Shea butter promotes skin healing and regeneration, making it beneficial for treating scars, stretch marks, and minor wounds. It may also enhance the skin's natural barrier function, improving overall skin health.

Uses:
Skincare: Shea butter is commonly used in skincare products such as lotions, creams, balms, and moisturizers. It is suitable for all skin types, including sensitive and mature skin.

Overall, shea butter is a versatile and nourishing ingredient that offers numerous benefits for skin and hair health. Its moisturizing, soothing, and healing properties make it a popular choice in skincare formulations around the world.

B.4. CLARY SAGE ESSENTIAL OIL\textsuperscript{[25, 27, 28]}:

Botanical Name: Salvia sclarea

Extraction Method: Clary Sage essential oil is obtained mainly from the tops and leaves of the flowering plant Salvia Sclarea by way of steam distillation.

Chemical Composition:
The majority of constituents comprising clary sage essential oil possess the following bioactive compounds:
- Linalool: Known for its calming and sedative properties.
- Linalyl acetate: Provides a floral aroma and has relaxing effects.
Sclareol: Exhibits hormone-regulating properties and may help alleviate menstrual discomfort.
Germacrene D: Contributes to the oil's therapeutic benefits, such as anti-inflammatory and antimicrobial properties.

Therapeutic Properties:
- Analgesic: This could be a useful tool for period pain relief and other minor pains such as muscle sprains.
- Antispasmodic: May loosen contracted muscles which leads to a drop in cramping and gastrointestinal issues.
- Hormone Balancing: Does contain phytoestrogens that are probable to maintain the balance of hormone levels, especially estrogen, and thus it is of great importance in relieving signs of menopause.
- Antidepressant: It also features a natural anti-depressant role through the removal of stress and inducing relaxation, which lifts mood and emotional health.

Uses:
- Menstrual Relief: Clary Sage essential oil is as a general part of aromatherapy and topical application to reduce the menstrual cramps and discomfort.
- Stress Relief: In the act of heart, this fragrance can be considerably effective in the reduction of stress, anxiety, and the promotion of relaxation.
- Hormonal Balance: It can be used in synergy with other products for treating hormonal disorders, such as PMS or menopause. This application can be made in the form of blends or massage oils.
- Skincare: Being rich in the anti-inflammatory and antimicrobial components, Clary Sage oil is considered to be one of many components of the skin care products that may easily be applied to the irritated skin, and reducing the manifestation of inflammation.

Overall, Clary Sage oil brings a variety of therapeutical properties facilitating with menstrual cramps relief, emotional balance and skin condition enhancements. It is a dominating substance which can be mixed with many other aromatherapy blends, massage oils as well as skincare formulations.

B.5. PEPPERMINT ESSENTIAL OIL:\[13, 14\]:

Botanical Name: Mint, or menthapiperita.

Extraction: Mint essential oil is yielded through the dry distillation of the leaves and flowering top parts of the peppermint plant.

Chemical Composition: Main Components: The main active component with peppermint oil is menthol, that could be even 45% of the oil. Besides these main compounds they contain also menthone, menthofuran, 1,8-cineole and limonene.

Therapeutic Properties:
- Analgesic: peppermint oil is an ideal for stopping pain and discomfort. It is traditionally applied topically for the purpose of relieving headaches, muscle soreness, and menstrual cramps.
- Anti-inflammatory: Peppermint oil, on its part, possesses anti-inflammatory activities through which it can reduce the inflammation and swelling. It is often used for soothing the muscles that gave way to pain or acting as an analgesic.
Antimicrobial: The specific antibacterial properties of peppermint oil are demonstrated primarily by its high menthol content. It can be used to prove that it can suppress the growth of bacteria, fungi and viruses, and it is affecting such things as oral care and skincare.

Antispasmodic: Peppermint essential oil is a natural analgesic, which has the effect of relaxing smooth muscles, thereby relieving of spasm. It is a more commonly used remedy in addressing digestive issues such as bloating, flatulence and irritable bowel syndrome (IBS).

Therapeutic Uses:
- Pain Relief: People apply peppermint oil in cases of headaches, migraines, muscle aches among others. The refreshing and anesthetic effect of CBD provides instant relief from pain.
- Digestive Aid: Peppermint oil can be taken orally or inhaled to relieve digestive problems such as heartburn, bloating, and nausea. It is able to calm the digestive tract and thus reduce gastric uneasiness and discomfort.
- Respiratory Support: Breathing in peppermint oil, a natural decongestant, may relieve a stuffy nose, coughs, or respiratory infections. Its menthol component gives a cool feeling and an effect of refreshing your airways.

B.6. LAVENDER ESSENTIAL OIL\textsuperscript{[11,12]}:

Botanical Name: Lavandula latifolia

Extraction Method: The lavender essential oil is usually extracted by the distillation method from the narrow-leaved flower of the Lavandula spica plant.

Chemical Composition: Because of a number of factors such as cultivating conditions and mode of extraction, composition of caryophyllene in lavender oil may be invariably affected. However, some of the main components include: Nevertheless, there are aspects which ought to be considered as key points among others include:
- Linalool: To begin with, linalool is the main compound of lavender essential oil which is well known for its calming and peaceful nature.
- Linalyl acetate: Besides Linalyl acetate which gives lavendin oil floral and Body relaxing properties, Lavandin oil consists of various type of compounds.
- 1,8-Cineole: Along things about lavender oil is that it has camphor as well, which features to cool things and relieve Pain.
- Borneol: The borneol that lavender is abundant with may, among others, lead to a claming of the mind and easing Cramps.

Therapeutic Properties:
Lavender essential oil is renowned for its Lavender oil numerous therapeutic properties, including:
- Calming and Relaxing: Lavender oil has sedative effects, promoting relaxation and reducing stress and anxiety.
- Analgesic: Lavender oil can help alleviate pain, including headaches, muscle aches, and menstrual cramps.
- Anti-inflammatory: Lavender oil exhibits anti-inflammatory properties, making it beneficial for soothing skin irritations and reducing inflammation.
- Antimicrobial: Lavender oil has antimicrobial properties, helping to inhibit the growth of bacteria and fungi.
- Antioxidant: Lavender oil contains antioxidants that help protect cells from damage caused by free radicals.
Uses:

- **Aroma Therapy:** Lavender essential oil proves to be invaluable in aromatherapy and its effectiveness has been well proved to induce a peaceful state of mind and quality of sleep, as well as reduce anxiety and stress.
- **Skincare:** Oils distilled from lavender are employed by skin care formulations as they have the calming and moisturizing qualities of the flower.
- **Massage:** Lavender oil is most commonly incorporated in massage oils and lotions to bring in relaxation and discomfort reduction properties.

Overall, lavender is the most versatile and useful one as it has a number of therapeutic benefits, this makes it highly popular among people who seek efficient skincare products or natural healing alternatives.

### B.7. FRANKINCENSE ESSENTIAL OIL\[^{17, 18}\]:

**Botanical Name:** Boswelliacarterii (also known as Boswellia sacra or Boswelliaserrata, depending on the species)

**Extraction Method:** The essential oil of frankincense is acquired by the process of steam distillation where the tree resin of the tree species vastly belonging to the Boswellia tree is used.

**Main Chemical Components:** The chemical composition of frankincense essential oil can vary depending on factors such as species, geographical location, and extraction method. However, some of the main chemical components include:

- **Monoterpenes:** Pinene is the alpha-pinene and the beta-pinene, whereas the Limonene, which is also known as d-limonene.
- **Sesquiterpenes:** Indole, incensole
- **Monoterpenols:** α-terpineol.
- **Ketones & Esters:** Bornyl acetate.

**Properties:**

- **Anti-inflammatory:** Frankincense has been proven to have its boswellic acid compounds, anti-inflammatory components that stop the activity of the inflammatory enzymes called 5-lipoxygenase and leukotrienes, which carry the inflammation mediators.
- **Analgesic:** Through inhibition of pain perception transmission and/or the reducing of the release of the ones mediating inflammation, frankincense oil may show analgesic qualities that are similar to those of the pharmaceuticals.
- **Antimicrobial:** Biocide nature of frankincense oil is found to have learnt from some studies that it has capabilities of blocking the growth of some kind of bacteria and fungi.
- **Astringent:** The oil therefore acts as a shrinking agent, which is helpful in the firmer tightening of the skin.
- **Cytophylactic:** They claim that like cellular rejuvenation and regeneration, the essential oil of frankincense could be great for the use in skincare.
Frankincense essential oil offers a range of potential benefits for both physical and emotional well-being, making it a valuable addition to aromatherapy and natural health practices.

B.8. **EUCALYPTUS ESSENTIAL OIL**[^15] [^16]:

**Botanical Name:** T. globulus

**Extraction Method:** Steam distillation is done from the leaves and stems of the Eucalyptus globulus tree with the aid of the Eucalyptus essential oil.

**Chemical Composition:**
- 1,8-Cineole (Eucalyptol): The main ingredient of the eucalyptus essential oil is mainly known as has to treat some diseases such as respiratory illnesses, muscle aches, pains, and headache. Other Terpenes: Eucalyptus oil will not only provide you with good results for antifungal, floral and healing compounds as α-pinene, limonene and terpinen-4-ol but will also have the exquisite aroma and health benefits of the same.

**Therapeutic Properties:**
- **Anti-inflammatory:** It is well understood that eucalyptus oil, through the inhibition of those mediators, is a great anti-inflammatory just by itself. It stops the production of cytokines and of prostaglandins.
- **Analgesic:** Eucalyptus oil possesses pain go which is the reason it is frequently applied on the muscles or joints for pain relief.
- **Decongestant:** With their nose inhaling, they sucked the vapors of eucalyptus oil that dislodge icky nasal cells, allowing clean air to flow and removing congestions in their respiratory tract. This is one of the main ingredients present in the cold remedies medications.
- **Antimicrobial:** Eucalyptus oil can stop spreading of a wide range of different bacteria and also fungi because of its antibacterial effect. Eventually this may provide a good approach for use in treating infections and wound clearing.

**Health Benefits:**
- **Respiratory Health:** Eucalyptus oil is usually used by the people with colds, flue, sinusitis, bronchitis and other respiratory systems disorders. It helps the ease the symptoms. Reduction of mucus built up; relief of irritated airway and comfort in breathing are some of the benefits.
- **Muscle and Joint Relief:** The massage of eucalyptus oil into the muscles and joints paves the way for the reduction of the pain and the inflammation, which is great for arthritis, sprains and strains, as well as other conditions that are painful and inflammatory.
- **Mental Clarity:** The synergy of Eucalyptus oil fragrance is appreciated because it is believed to stimulate the mind and support focus and concentration and thus, it is commonly used in aromatherapy and diffuser blends.

Eucalyptus essential oil has been used for aromatherapy, massage, personal care products, and household cleaning because of its refreshing scent and repairing features.

B.9. **HELICHRYSUM ESSENTIAL**[^26]:

**Botanical Name:** Helichrysum italicum

**Common Names:** Helichrysum oil is also known as Immortelle oil or Everlasting oil due to the long-lasting nature of its flowers.
Extraction Process: Helichrysum oil is extracted from the flower of the Helichrysum italicum plant through steam distillation.

Chemical Composition: Helichrysum oil is a mixture of phyto-active substances like monoterpenes, sesquiterpenes as well as esters to make up the mixture. Some of the key constituents found in Helichrysum oil include: The main characteristics that are present in Helichrysum oil include: α-Pinene, β-Pinene, Neryl acetate, Italidone, γ-Curcumene, β-Caryophyllene, Italicene, Limonene, Linalool

Therapeutic Properties:

- **Anti-inflammatory**: At one time it has been called an elixir for the treatment of inflammation effects by its super-intensity act. It carries these anti-inflammatory properties that help in reduction of swellings associated with problems in joints like arthritis and also in muscle sprain and skin inflammation.
- **Analgesic**: the pain and discomfort relieving capability of Helichrysum essential oil is the main contributor to the interest and product demand. It can serve as a topical formula that performs functions such as migraine or muscle pain relief, cramps, or when going through menstruation.
- **Antioxidant**: Helichrysum oil for its rich in antioxidants it could be the good choice to use against the impact of free radicals, the major cause of oxidative stress, on the health of cells.
- **Antimicrobial**: Oil helichrysum is known to show its antibacterial activity, therefore skin may not be affected by infections and preserves normal flora on the skin.

Overall, Helichrysum oil is one of the widely beneficial and potent essential oils that carries along the role of enhancing healing and decreasing pain. Helichrysum essential oil is a favorite home remedy substance for people especially for its anti-inflammatory effects and pain relief.

C. METHOD FOR PREPARATION OF MENSTURAL PAIN RELIEF BALM[31,38]

- **Measure Ingredients**:
  For this purpose, get a sterilized measuring cylinder and take the signature amounts of coconut oil, beeswax, and shea butter as directed by the Formulation Table.No.1

- **Melt Beeswax, coconut Oil, and Shea Butter**:
  a. Weigh the beeswax, shea butter, and coconut oil and transfer them to a sterile beaker.
  b. Start with a triple boiler or a heating mental. Gently heat the beaker until the ingredients melt and combine.

  Stir with a sterile stirrer occasionally to achieve uniform melting.

- **Cool the Mixture**:
  Take the beaker off the heat and wait for the mixture to cool while maintaining a sterile environment during the experiment.

- **Add Essential Oils**:
  a. Using a sterile measuring cylinder, pour the measured amounts (as directed by the Formulation Table.No.1) of clary sage, peppermint, lavender, eucalyptus, helichrysum and frankincense essential oils one by one into the beaker containing the above mixture during cooling.
b. Mix the ingredients well with a sterile stirrer so that the essential oils are uniformly distributed.

➢ **Transfer to Container:**  
Once the essential oils are fully incorporated, pour the balm mixture into the sterile glass or plastic container using a sterile dropper or funnel in order to prevent contamination.

➢ **Cool and Solidify:**  
Let the balm cool and solidify at room temperature in a closed and enclosed environment. Moreover, keep the container tightly sealed so that the airborne contaminants cannot settle on it.

➢ **Label the Container:**  
Label the container with these basic information like product name, ingredients, concentration, expiration date, and any usage instructions or warning on the label.

➢ **Storage:**  
Make sure to store the pain relief balm in a clean and dry environment free from excessive sunlight and other extreme temperatures to ensure that its efficacy and shelf life is maintained.

![Figure.No.9: Preparation of herbal menstrual pain relief balm.](image)

![Figure.No.10. Prepared herbal menstrual pain relief balm.](image)
III. EVALUATION OF PREPARED HERBAL FORMULATION

1. PHYSICAL PARAMETERS:
   Clarity and color was checked by naked eyes against white background, the odour was smelled.

2. pH TEST:
   For making accurate pH reading by the use of pH meters, you must first calibrate the equipment with
   the instruction of the manufacturer. Once calibrated, the sample solution is prepared with the required
   analysis and it need to be devise to ensure the electrode adequately covers it. After ensuring the
   proper positioning of the electrode in the test solution, turn on the meter and remember not to contact
   any surfaces, except for the liquid. Also, avoid actively stirring the matter in order to obtain more
   precise results. Set the time for pH meter, so as to cause no error from variation. Keeping it the same,
   make sure the pH value shows on a meter and note all other additional parameters if any. Neglect of a
   regular maintenance of the electrode may result in poor long-term performance. In this case, the
   electrode needs to be immersed in distilled water and cleaned to remove any residues in the manner
   specified by the manufacturer.

3. SPREADABILITY TEST:
   For testing herbal balm sample we employed standard glass slider. The other side of the slide was
   coated with the herbal balm, but the other one was kept plain. The sample was spread over the slide
   surface by a small smear stick and between the end slide, a distance apart of 7.5 cm was spanned. To
   equally temper the beam, on the top slide, a 100g weight was positioned, thereby creating a thin layer
   when the balm was compressed. Then, the excess spreader and pest studying apparatus was wiped
   away as well. In order to ensure the flaps were stable, they were put in the stand, though the upper
   slide was the only one permitted to slide unhindered. The experiment was given a continuation by the
   addition of a 20g weight onto the top slide and timing how long it took for it to go through a 7.5cm
   distance and then detach owing to force on the bottom slide. The three replications were done to
   maintain a consistent plan, and an average time was reported.

4. GRITTINESS TEST:
   While a portion of the balm located on the facility was selected for the evaluation, a representative
   part of it was used. The balm had all visual defects like objects and roughness screened very carefully
   and anything felt in it would affect its quality. Later a physical examination was done by just applying
   a small quantity of the small lotion on between fingers to detect the existence or absence of grittiness
   or irregularities in texture. Sensory test continued, and the balm was applied for a deeper observation
   on the texture where any sort of roughness was taken into the account…feedbacks from trainees will
   be employed to refine and improve the training. The tests were repeated with obligatory recording of
   the observations of any peculiarities of grabbing, getting particles or grit. Regarding the grit materials
   properties these kinds of test were most important.

5. PATCH TEST:
   Participants for the study were chosen among the individuals with healthy and their normal skin type,
   while those with allergies or reported cases of sensitive skin were excluded to ensure that there were
   no adverse reactions to the ingredients in the balm. The site is typically selected as the inner forearm
   which is properly cleansed and all previous irritation or injury should not be present on the site. By
   using a patch test method, a small quantity of a balm was directed to a test area which were then
   sealed with a patch on top of. Afterwards, the experimenter neither touched nor left the paper for the
   specified observation period, usually being between 24 and 48 hours, during which the subjects were
   asked to follow the order and avoid wetting the area or exposing it to direct sunlight. After a
   substantial observation period, the patch was meticulously taken off, and the test area was
   scrupulously checked up for any suspicious signs of irritation such as redness, swelling, itching or any
   other type of adverse reactions in order to assess the product’s suitability for the skin.
6. **PHASE SEPARATION:**
Transferring the resultant balm into a tub made of wide bottom which is perfect for storage was performed. Then 24 hours after the oil preventive measures, oil and water phases were visually. The observing was done by looking for the visible layers with different textures which are associated with phase separation and phase instability. All detected phase separation happened was noted and saved. This technique is so intended to find out the formulation problems and it allows to do amendments in product to increase quality.

7. **CLINICAL ASSESSMENT:**
In a clinical assessment of the menstruation pain-relieving balm, 18 women experiencing lower abdominal pain were selected for participants. They were to use the medicated ointment by the way explained and writing down all the details of their painful unpleasantness, like severity of pain beforehand after the balm was put on, and any relief they felt. Further we distributed the balm to male participants experiencing with headache, neck pain, and back pain to check whether it is gender specific or not.

**IV. RESULT AND DISCUSSION**

The balm underwent analysis of its physicochemical attributes, including color, scent, appearance, pH level, spreadability, skin compatibility, grittiness, and phase separation. The evaluations revealed that the formulations excelled in appearance, overall quality, and maintained a skin-friendly pH level of 7.0, aligning with the skin's natural acidity.

The Clinical Assessment of Menstrual Pain Relief Balm has been found to provide a pain-relieving property, thus reducing menstrual pain for certain women. Women, on the other hand, achieved more lasting and significant relief from menstrual cramps backaches, and headaches following the use of the balm. According the investigation, there was no difference in gender-based effectiveness. The ointment, thus, markedly eases the menstrual pain and other types of pain, yet any individual reactions could be different.

![Figure No.11: Clinical assessment of herbal menstrual pain relief balm.](image)

<table>
<thead>
<tr>
<th>Gender</th>
<th>Used for What purpose</th>
<th>How much relief</th>
<th>Type of sensation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>Headache</td>
<td>65.6%</td>
<td>Dull</td>
</tr>
<tr>
<td>Men</td>
<td>Back pain</td>
<td>25.0%</td>
<td>Strong</td>
</tr>
<tr>
<td></td>
<td>Menstrual cramps</td>
<td>17.4%</td>
<td>Stiff</td>
</tr>
<tr>
<td></td>
<td>Neck pain</td>
<td>4.3%</td>
<td>Tense</td>
</tr>
</tbody>
</table>

**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>State</td>
<td>Semi-solid</td>
</tr>
<tr>
<td>3</td>
<td>Appearance</td>
<td>Smooth</td>
</tr>
<tr>
<td>4</td>
<td>Color</td>
<td>White</td>
</tr>
<tr>
<td>5</td>
<td>Odour</td>
<td>Aromatic</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>6.8</td>
</tr>
<tr>
<td>2.</td>
<td>Spreadability</td>
<td>7.2g. cm/sec, Easily spreadable.</td>
</tr>
<tr>
<td>3.</td>
<td>Grittiness</td>
<td>No Grittiness or Irregularities in texture.</td>
</tr>
<tr>
<td>4.</td>
<td>Patch Test</td>
<td>No Irritation, Redness, Swelling, Itching, or Other Adverse Reactions</td>
</tr>
<tr>
<td>5.</td>
<td>Phase Separation</td>
<td>No Phase Separation</td>
</tr>
<tr>
<td>6.</td>
<td>Clinical assessment</td>
<td>Balm gives mild to moderate relief with menstrual cramps for some women and also provide mild relief for person suffering with headache, back pain, joint pain etc, irrespective of gender</td>
</tr>
</tbody>
</table>

Figure No.12: Formulated herbal menstrual pain relief balm.

V. CONCLUSION
The production of the Herbal Pain Balm and its physicochemical properties as well as effects of their clinical tests have shown a positive impact on its development and application. Ointment was characterized by the following features: uniform structure, pleasant white color, and an attractive aroma. Also, it is believed to have a pH-level suitable for skin care products. Furthermore, it also got great amount of spreadability and it was not crumbly nor had any irregular texture.

Besides that, also the results of the clinical testing show that the balm has the ability to provide relief from menstrual cramps and some women mentioned minimum to medium reduction in pain level. Also, broad spectrum pain relieving effects of this product were proved by its ability to alleviate headache, back or joint pain regardless the gender of the pain sufferer. The outcome of this study points out that the Pain Balm from Herbs is a hopeful safe and effective natural product for pain management.

In conclusion, the herbal pain balm looks great. It has wonderful features such as smoothing the skin, sense with a good fragrance, and the right pH level for proper skin care. Practitioners reported that this practice brought reliefs from problems like menstrual cramps and headaches. Also, it helped with backaches. This type of the concept seems to work equally as well for both men and women. This puts forward the possibility that the balm could be a viable treatment for alleviating menstrual cramps and even other types of pain. On balance, this seems tool may be a viable alternative/add-on to placebo for many consumers.

VI. REFERENCE


