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# Preparation And Evaluation Of Herbal-Roll On For The Management Of Migraine

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***Abstract:*** Migraine headaches can be debilitating, significantly impacting quality of life. This study investigates the development and evaluation of a topical herbal roll-on formulation designed for the rapid relief of migraine symptoms. Herbal roll-ons are natural liquid/semi-solid preparations containing essential volatile oils and herbal extracts used to relieve pain and stress in migraines. Literature review and studies reveal that essential oils such as camphor, eucalyptus, lavender, and peppermint, along with herbal extracts like feverfew, saffron, chamomile, ashwagandha, and ginger, are commonly used in migraine treatment. This roll-on format offers a convenient and non-invasive alternative to traditional oral medications, providing targeted delivery of these active herbal ingredients. While herbal capsules, tablets, nasal drops, gels, and ointments exist, the roll-on offers a unique advantage for on-demand relief. Specifically, this formulation incorporates feverfew and chamomile as key ingredients. Feverfew is known for its potential to reduce migraine frequency and intensity through anti-inflammatory and analgesic actions. Chamomile provides calming effects, helping to mitigate stress and anxiety, common migraine triggers. Together, they aim to alleviate pain and discomfort associated with migraines. The roll-on was evaluated for its physicochemical properties, including viscosity, Spreadability, and stability. In vitro drug release studies were conducted to assess the rate and extent of active ingredient permeation. Additionally, sensory evaluation and patient acceptability were assessed. The results demonstrate that the developed roll-on formulation exhibits desirable physicochemical characteristics and provides sustained release of active ingredients. Furthermore, preliminary patient feedback indicates a high degree of user satisfaction and perceived efficacy in reducing migraine symptom severity. This topical herbal roll-on presents a promising option for the on-demand relief of migraine symptoms, offering a practical and patient-friendly approach.

**Keywords –** Aromatherapy, Natural relief, Essential oils, Headache Management

## I. INTRODUCTION

Migraines are extremely frequent affecting more than one out of every ten individuals. Migraine headache begins in major part in meninges, blood vessel, particularly dural arteries. While it was once thought that dilatation of these arteries was the trigger for migraine headache, neurogenic inflammation involving trigeminal nerve and inhibition of 5-HT1B/1D receptors are the primary causes of the condition. Many vasoactive neuropeptides such as serotonin, calcitonin gene related peptide (CGRP), pituitary adenylate cyclase

Figure 1: Herbal roll-on

activating peptide, histamine are key regulators of the neurogenic inflammation in migraine. The brainstem, hypothalamus and cerebral cortex all have a role in migraine pain and aura modulation. Cortical spreading depression is a phenomenon that occur when a wave of neuronal alteration washes throughout the cerebral cortex causing a hypersensitive state throughout neural networks due to which migraine occur. [1]

Herbal Roll On: they are the natural liquid or semisolid preparation containing essential volatile oil and herbal extract used to relief pain and stress in migraine. Herbal roll on is novel topical dosage form. There is need to develop such dosage form in order to overcome difficulties faced by conventional dosage form like tablet and capsule for migraine. Roll on can be apply topically on skin very easily. Herbal roll-on is natural liquid preparation containing volatile oil used to relieve from migraine, pain and stress. These volatile oils are essential oil which has aromatic odour and used for mental, spiritual and physical healing. These oils are found from the leaves, barks, flower, stem etc. are used to prepare pain relieving formulation. A roll-on of feverfew and chamomile as main ingredients can be effective in management of migraines.[1]

## II. MATERIALS AND METHODS FOR PREPARATION

### II.I MATERIALS USED IN FORMULATION:

**1. FEVERFEW**

Biological source – Feverfew flowers and leaves of *Tanacetum parthenium L.*
Family – Asteraceae
Chemical constituents – Parthenolide
Uses – Migraine relief, digestive issues, menstrual pain, arthritis management

Figure 2: Feverfew leaves

**2. CHAMOMILE**

Biological source – Chamomile flowers and leaves of *Matricaria chamomilla*
Family – Asteraceae
Chemical constituents – Flavonoids (luteolin, rutin, apigenin) Uses – Mild anti-depressant and insomnia

Figure 3: Chamomile flowers

**3. PEPPERMINT OIL**

Biological source - Leaves and stems of *Mentha piperita*
Family – Lamiaceae
Chemical constituents – Menthol, Menthone, Menthofuran, Menthyl acetate Uses – Soothing effect and muscle relaxant

Figure 4: Peppermint oil

**4. LAVENDER OIL**

Biological source – Flowers of *Lavandula angustifolia*
Family – Lamiaceae
Chemical constituents – Linalool, Linalyl acetate Uses – Aromatherapy

Figure 5: Lavender oil

**5. EUCALYPTUS OIL**

Biological source – Leaves of *Eucalypti aerherolum*
Family – Myrtaceae
Chemical constituents – Eucalyptol, Pinene, Citronellal, Limonene Uses – Anti-inflammatory

Figure 6: Eucalyptus oil

**6. CAMPHOR**

Biological source – Wood and bark of camphor laurel tree, *Cinnamomum camphora*
Family – Lauraceae
Chemical constituents – D- camphor, Linalool, Cineole, Camphene and Terpineol Uses – Cooling sensation and preservative

Figure 7: Menthol crystals

## II.II METHODS AND PREPARATION OF HERBAL ROLL-ON

Cold maceration – It's a technique for extracting active compounds from plant materials by soaking them in a solvent at room temperature or low temperatures without the application of heat. This method is particularly effective for thermolabile substances, allowing for the separation of active ingredients while preserving their integrity. It is commonly used to prepare extracts, such as the ethanolic extract of herbal leaves or flowers.

**(a) Extraction procedure of chamomile flower [7]:**

- Take the dried chamomile flowers.
- Then make the dried flowers in powder form with the help of food mixer.
- Then weigh 2.5 gm of powder in conical flask and prepare 5% w/v suspension in hot boiled water.
- Then kept the flask in flask shaker for 4 hours under the speed of 200 rpm and maintained temperature at 37 degrees Celsius.
- Essentially similar procedure was used for organic solvent extraction using methanol, ethanol, and propanol (5% w/v) and kept on shaker for 4 h at 200 rpm.
- After shaking, the flask was brought to room temperature.
- Then pass this mixture through series of Whatman filter papers (0.22-micron filter).
- then store the extract at 20 degrees Celsius.

**(b) Extraction procedure of feverfew leaves [8]:**

- Collect leaves from 7-month-old feverfew plants (micropropogated & conventionally grown).
- Wash and air-dry for 30 min at room temperature and then oven dry at 40 degrees Celsius for 72 hours.
- Then grind dried leaves into powder using a food mixer.
- Weigh 0.5 g of leaf powder and place in a 150ml conical flask (covered with aluminum foil).
- Then add 25ml of solvent (ethanol, acetone hexane or distilled water) and shake at 25 degrees Celsius, 300 rpm, in the dark for 1 hours using a shaker.
- Filter the solution using Whatman filter paper use the filtered extracts for Parthenolide quantification.
- Dissolve 0.248 mg Parthenolide (98% pure) in 5 ml HPLC-grade methanol (99.9%).
- Transfer to 25 ml volumetric flask and fill to volume with methanol to prepare a 10-ppm stock solution.

**II.III Method of preparation for herbal roll-on**

- In the beaker take 2ml of feverfew extract and chamomile extract and stir it gently.
- In another beaker take 1ml from each peppermint oil, eucalyptus oil and lavender oil and dissolve 1gm of camphor in it.
- Add 2 gm of menthol and dissolve it completely.
- Then add dropwise each 1ml of glycerine in the above solution.
- Now add the prepared extract mixture into the above prepared mixture and lastly add 2ml of polyethylene glycol. Stir the mixture properly.
- The prepared mixture is now transferred inside the ambered colored bottle.

## III. MATERIALS USED FOR FORMULATION:

| Sr no. | Material | Category |
|---|---|---|
| 1. | Feverfew leaves | Frequency and intensity of migraine attacks |
| 2. | Chamomile flowers | Mild anti-depressant and insomnia |
| 3. | Peppermint oil | Soothing effect, Muscle relaxant |
| 4. | Lavender oil | Aromatherapy |
| 5. | Eucalyptus oil | Anti-inflammatory |
| 6. | Camphor | Preservative |
| 7. | Polyethylene glycol (PEG 200) | Humectant |
| 8. | Menthol | Cooling sensation |
| 9. | Glycerine | Base |

Table 1: Materials used for formulation

**III.I BATCH OPTIMIZATION:**

| Sr no. | INGREDIENT | F1 | F2 | F3 | F4 | F5 |
|---|---|---|---|---|---|---|
| 1. | Feverfew extract | 2 ml | 2 ml | 2 ml | 2 ml | 2 ml |
| 2. | Chamomile extract | 2 ml | 2 ml | 2 ml | 2 ml | 2 ml |
| 3. | Eucalyptus oil | 1 ml | 1 ml | 1 ml | 1 ml | 1 ml |
| 4. | Peppermint oil | 1 ml | 1 ml | 1 ml | 1 ml | 1 ml |

| | | | | | | |
|---|---|---|---|---|---|---|
| 5. | Lavender oil | 1 ml | 1 ml | 1 ml | 1 ml | 1 ml |
| 6. | Polyethylene glycol (PEG 200) | 2 ml | 2 ml | 2 ml | 2 ml | 2 ml |
| 7. | Menthol | 2 gm | 2 gm | 2 gm | 2 gm | 2 gm |
| 8. | Camphor | 1 gm | 1 gm | 1 gm | 1 gm | 1 gm |
| 9. | Base: Castor oil Olive oil Glycerine Bees wax Yellow soft paraffin | 1 ml | - | - | - | - |
| | | - | 1 ml | - | - | - |
| | | - | - | 1 ml | - | - |
| | | - | - | - | 1 ml | - |
| | | - | - | - | - | 1 ml |

Table 2: Different batches of Herbal roll-on


Figure 9: Extract in different bases

- The formulation F1, F2, F4 and F5 of herbal roll-on prepared using different bases, failed to adequately solubilize the herbal extracts also causing inconsistent release of active ingredients, potential instability and separation issues.
- In contrast, F3 formulation which utilizes Glycerine as base, successfully solubilizes the herbal extracts leading to improved Spreadability, absorption, enhanced stability, optimal pH and viscosity.

## IV. EVALUATION PARAMETERS

**IV.I Organoleptic test:** Organoleptic evaluation test standard for Herbal-roll on typically evaluating the product sensory characteristics such as appearance, colour, odour and texture.it also provide valuable information about sensory characteristics of product helping ensure quality standards, user satisfaction, and suitable use in pharmaceutical application

**IV.II Homogeneity test:** Homogeneity Test ensures that the active ingredient and excipient are uniformly distributed throughout the product. Product is uniform composition which is essential for maintaining quality, efficacy and safety. Homogeneity test plays crucial role in ensuring the integrity and reliability of herbal roll on. Herbal Roll-on product uniform and consistent throughout it.

**IV.III Spreadability study:** The Spreadability test was performed by filling the product inside the amber colored roll-on and was applied gently on skin. The product was spread evenly on skin without leaving any residue and non-greasy.

**IV.IV FTIR spectroscopy:** It's a technique that utilizes infrared light to identify the functional groups of the extract. The active components are separated based on its peak value. The FT-IR test of Chamomile powder (figure 10), Feverfew powder (figure 11) extract, Lavender oil (figure 9), Feverfew + Chamomile powder (figure 10) and Lavender oil + Feverfew powder (figure 11) were done in CENTRE OF EXCELLENCE, Vapi. The FT-IR spectra were observed in the range of 400-4000 cm-1.

**IV.V Preliminary Phytochemical screening test:** The method used to identify the presence and types of specific chemical compounds within a plant extract. These tests help determine the composition of the extract. Secondary metabolites are the compounds that are not directly engaged in the normal growth and development but do have some ecological function within the body. It provides protection against
pathogen.

*Test for flavonoids*

a. Alkaline reagent test: Two to three drops of sodium hydroxide were added to 2 mL of extract. Initially, a deep yellow colour appeared but it gradually became colorless by adding few drops of dilute HCL, indicating that flavonoids were present.
b. Lead acetate test: 1 ml lead acetate solution treated with 0.5 ml of extract. Formation of a yellow precipitation indicates the presence of flavonoids.

*Test for terpenes*

a. Salkowski test: Extract shaken with chloroform and conc.H2SO4 was added along the walls of test-tube. The upper layer turns red and the H2SO4 layer shows yellow colour which indicates the presence of terpenes
b. Tollen's test: 1-2 drops of Tollen's reagent treated with 0.5 ml extract. The dark brown precipitation indicates presences of terpenes

*Test for coumarins and phenolic compounds*

a. Ferric chloride test: 2 ml of FeCL3 solution treated with 1 ml of extract. The dark blue colour is obtained indicating the presence of coumarin.

**IV.VI Measurement of pH**: The pH of the formulation influences the stability of Herbal roll-on. The pH of prepared herbal roll-on was measured using a digital pH meter at room temperature (25°C ± 5°C). For this purpose, 10ml of content was taken in a beaker, and the pH was noted.

**IV.VII Stability test**: Stability test of Herbal-roll on is crucial to ensure their quality, efficacy and safety. Stability studies based on different storage conditions that affect the factor such as temperature, humidity and light. Temperature range such as room temperature (25-30℃), hot temperature (45℃) and freezing temperatures (-1 to -5℃). Stability study maintains a steady state in the face of external disturbance. It also includes physical appearance study, chemical composition study and microbial growth

**IV.VIII Viscosity measurement:** Viscosity of Herbal roll-on was carried out using Brookfield viscometer. As the system is Newtonian spindle no. 94 was used. Viscosity was measured for fixed time min at 20 rpm at room temperature (25 °C ± 5 °C).

## V. RESULT AND DISCUSSION

### V.I Organoleptic and Homogeneity tests:

| Sr no. | Properties | Observation |
|---|---|---|
| 1. | Colour | Light yellow |
| 2. | Odour | Mint like |
| 3. | Appearance | Slightly viscous |
| 4. | Texture | Liquid |
| 5. | Homogeneity | Uniform distribution |

Table 3: Organoleptic and homogeneity evaluation

### V.II Spreadability study:

The study of herbal roll-on formulation demonstrated that the product exhibits excellent Spreadability characteristics as evenly spread without leaving any residues behind, ensuring the effortless application and uniform coverage on the skin.

**V.III FTIR interpretation**:

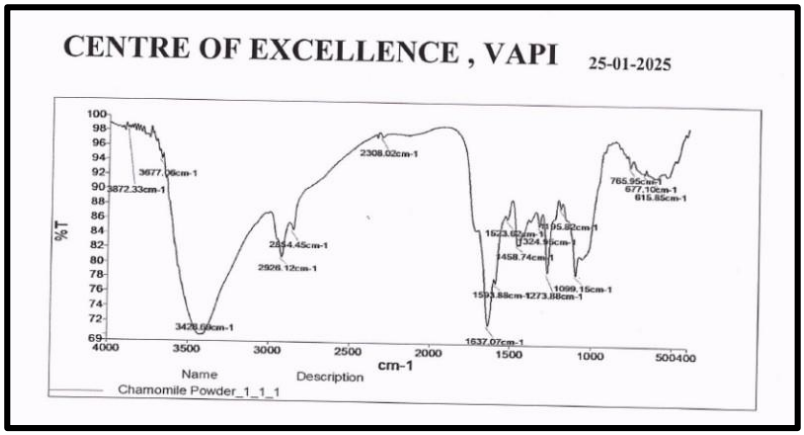


Figure 10: FTIR graph of chamomile powder

| Sr no. | Functional group | Standard frequency value (cm-¹) | Observed frequency value (cm-¹) |
|---|---|---|---|
| 1. | - OH | 1200-1500 | 1458.74 |
| 2. | C=O | 1620-1680 | 1637.67 |
| 3. | C-C | 1000-1300 | 1273.88 |
| 4. | C=C | 1500-1600 | 1523.62 |

Table 4: FTIR value of chamomile powder

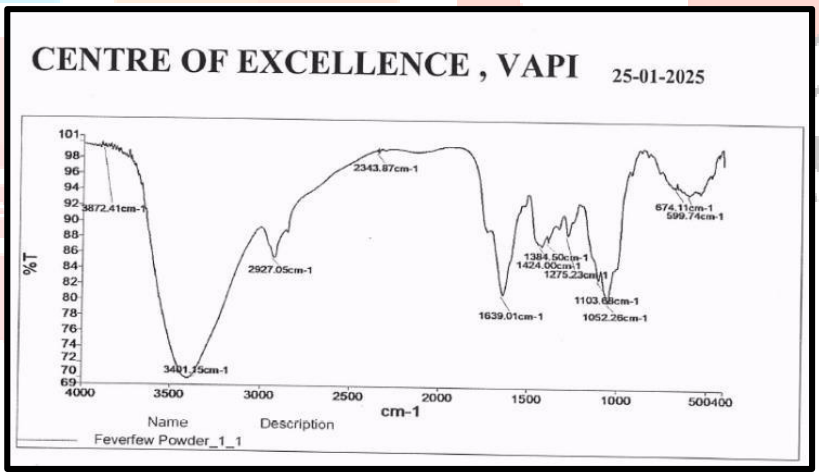


Figure 11: FTIR graph of Feverfew powder

| Sr no. | Functional group | Standard frequency value (cm-¹) | Observed frequency value (cm-¹) |
|---|---|---|---|
| 1. | C=O | 1640-1750 | 1639.01 |
| 2. | C=C | 1620-1680 | 1639.0 |
| 3. | C-H | 2850-2960 | 2927.05 |
| 4. | C-O | 1000-1300 | 1052.26 |

Table 5: FTIR value of Feverfew powder

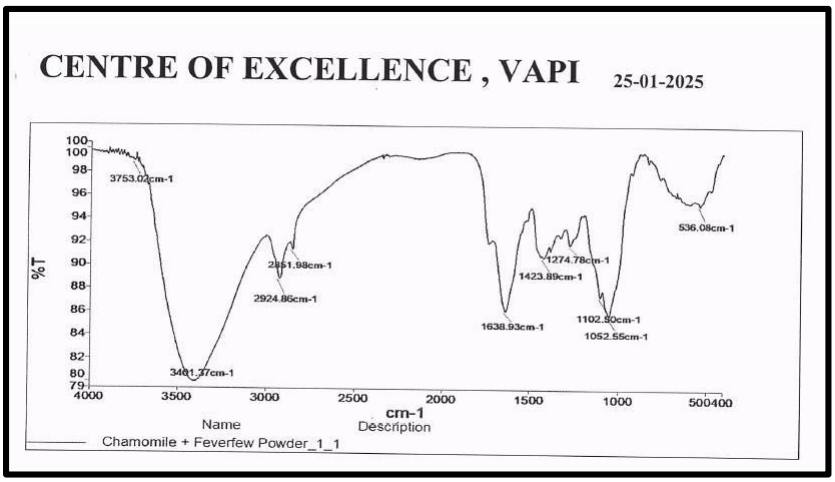


Figure 12: FTIR graph of Chamomile and Feverfew powder

| Sr no. | Functional group | Standard frequency value (cm-¹) | Observed frequency value (cm-¹) |
|---|---|---|---|
| 1. | - OH | 1200-1500 | 1423.89 |
| 2. | C=O | 1200-1500 | 1638.93 |
| 3. | C-C | 1000-1300 | 1102.50 |
| 4. | C=C | 1620-1680 | 1274.78 |
| 5. | C-H | 2850-2960 | 2924.86 |

Table 6: FTIR value of Feverfew and chamomile powder

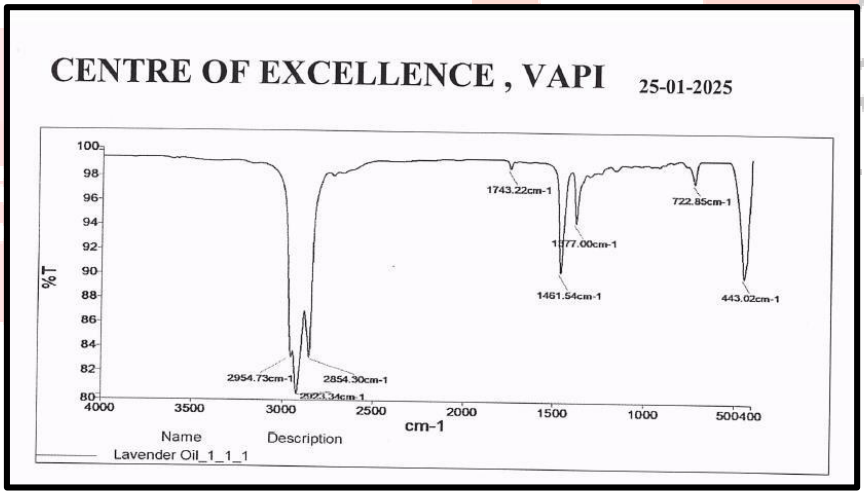


Figure 13: FTIR graph of Lavender oil

| Sr no. | Functional group | Standard frequency value (cm-¹) | Observed frequency value (cm-¹) |
|---|---|---|---|
| 1. | C-H | 2850-2960 | 2954.73 |
| 2. | -OH | 1200-1500 | 1377 |

Table 7: FTIR value of Lavender oil

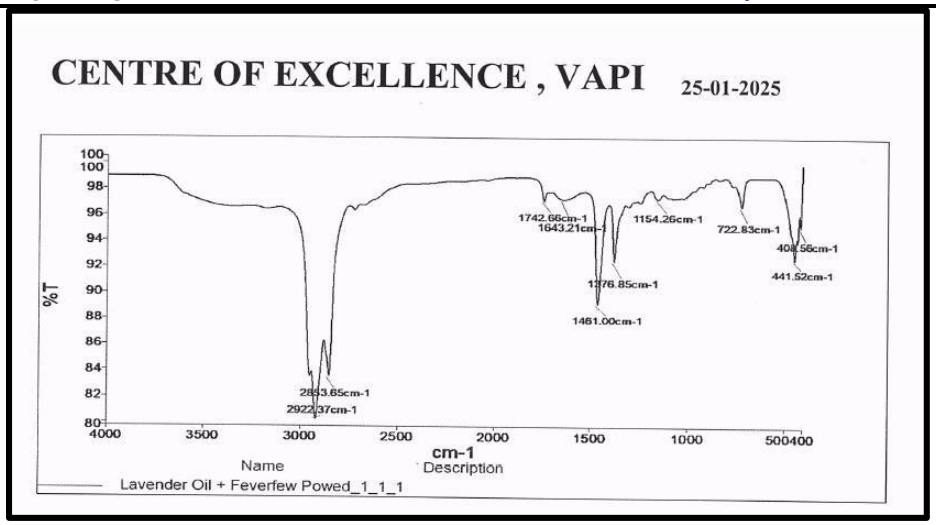


Figure 14: FTIR graph of Lavender oil

| Sr no. | Functional group | Standard frequency value ($cm^{-1}$) | Observed frequency value ($cm^{-1}$) |
|---|---|---|---|
| 1. | C=O | 1200-1500 | 1742.66 |
| 2. | C=C | 1620-1680 | 1643.21 |
| 3. | C-H | 2850-2960 | 2922.37 |
| 4. | C-O | 1000-1300 | 1154.26 |
| 5. | -OH | 1200-1500 | 1461.00 |

Table 8: FTIR of Lavender oil and Feverfew powder

**V.IV Phytochemical screening:**

| Sr no. | Test | Inference | |
|---|---|---|---|
| | | Feverfew | Chamomile |
| 1. | Test for flavonoids | | |
| | a. Alkaline reagent test | ✓ | ✓ |
| | b. Lead acetate test | ✓ | ✓ |
| 2. | Test for terpenes | | |
| | a. Salkowski test | ✓ | ✓ |
| | b. Tollen's test | ✓ | ✓ |
| 3. | Test for coumarins and phenolic compounds | | |
| | a. Ferric chloride test | ✓ | ✓ |

Table 9: Chemical tests

**V.V Measurement of pH**:

In the Herbal roll-on pH is used for the main parameter is pH. The herbal formulation was found to be non-irritable and pH within the standard value as mentioned below.

Standard value – 4.7 – 5.75 pH

Observed value – 5.03 pH

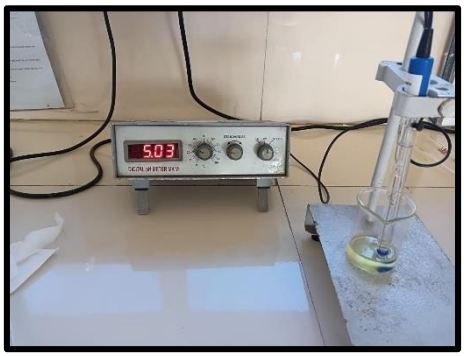


**Figure 15: pH meter**

**V.VI Stability study:**

The stability study of herbal roll-on formulation revealed that the product remains stable over a long period of time. The result suggest that the herbal roll-on formulation is stable and can be safely used for its intended purpose.

| Sr no. | Duration | Observation |
|---|---|---|
| 1. | 1 week | No change in Color, Odour, Spreadability, Appearance, Viscosity and Fragrance |
| 2. | 15 days | |
| 3. | 30 days | |

Table 10: Stability observation

**V.VII Viscosity measurement:**

| Sr no. | Duration | Observed value (cp) |
|---|---|---|
| 1. | 1 week | 562.4 |
| 2. | 15 days | 562.5 |
| 3. | 30 days | 562.4 |

Table 11: Viscosity measured value

- The average viscosity of prepared formulation was found to be 562.43 cp.

**VI. LABEL FOR PRIMARY AND SECONDARY PACKAGING:**


Figure 16: Label for primary packaging


Figure 17: Label for secondary packaging

## VII. CONCLUSION

The aim is to formulate and evaluate roll-on for management of migraine, stress, insomnia, fast acting with soothing effect, aromatherapy with better patient compliance. The prepared roll-on formulation was found to be an excellent approach for all type of age group. Rollon formulation was found to be advantageous as well as they more patient compliances. Pre formulation studies were conducted on extract of chamomile, feverfew and lavender oil such as determination, FTIR, batches (F1-F5) of prepared roll-on were subjected to the evaluation for appearance, pH, Viscosity, stability, chemical test for microbial growth, Spreadability, after feel test, irritancy, removability.

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