

“Formulation & Evaluation Of Pain Relief Natural Miracle Balm By Using Plant Vitex Negundo”

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Abstract:-

Ancient time *vitex negundo* is also use to treat arthritis and gout pain relief but *vitex negundo* leaf extract using prepare balm is new formulation. Herbal Balm is a semisolid dosage form, sweet-smelling oil extracted from tropical trees and used to produce swelling & pain-relief Balm. Pain balm formulations are preferably used so as to get the faster local effect. New & improved Balm leaves the skin it shows first cooling effect then it shows counter irritant principle. Pain management when it comes to pain relief, balms have a unique pharmacological effect; however, the amount of pressure applied and the movements play a crucial role. It also relieves of aches and pains in the muscles and joints. Pain relief Balm with its mixture of useful ayurvedic ingredients that also work organically and reduce any chances of side effects. The Balm's role includes providing a local analgesic & anti-inflammatory effect. Pain relief that is free of side effects and gentle enough to use on a daily basis. Arthritis & Gout pain discomfort can also be alleviated by the use of Balm. Topical preparations are believed to avoid issues associated with oral or intravenous routes such as gastric disturbances, first-pass hepatic metabolism, and variable serum concentrations. Topical medications aim to overcome, allowing progressive delivery of active component, maintaining stable plasma levels, with a good safety profile.

Keywords:-

Nirgundi oil, Eucalyptus oil, Osteoarthritis ,First pass Hepatic metabolism, anesthetic.

Introduction: -

Herbal balm composition comprising *Vitex negundo* leaf extract, organic essential oils, bees wax & other desired herbal components has medicated topical preparations for application to skin to relieve pain & swelling. Pain is an unpleasant feeling often caused by intense or damaging stimuli. Pain balm is something that is comforting & soothing. Pain balms generally contains three components namely methyl salicylate, menthol and camphor all these are easily absorbed through the skin.

The other ingredients in the pain relief balm essential oil, petroleum jelly, beeswax. Although these pain relief balms have a special pharmacological effect in relieving pain, it is actually the amount of pressure applied and the movement that plays a significant role. Role of the balm includes a local anesthetic & Anti-inflammatory effect and finally provides a comfortable stage. These products do not have any side effect or allergic reactions such as skin rashes or darkening of the skin. Inflammation and Rheumatism remain serious problems in the present era. Inflammation is a complex Immune response to vascular tissues injury or infection caused by pathogens, clinically characterized by Signs of swelling, redness, pain, warmth and loss of function.

Vitex negundo extract as well as anti-inflammatory ingredients like Menthol may reduce this type of pain. Menthol crystal or methyl salicylate is made from mint extracts. They're common anesthetics and work by constricting muscles to help decrease muscular and joint pain. It may soothe arthritis and other inflammatory pain. When used as directed balm is unlikely because in some cases, it may to cause side effects. So, it's a good idea to do a patch test before applying Balm to a small area of the body. To do this, apply Balm to the inside of your elbow. Wait a couple of days to see if you have any adverse reaction. If this isn't the case, you're likely safe to use balm for pain on other parts of your body. Balm is considered safe for adults when used as directed. Don't cover the application area with heat pads, cold packs, or bandages. It store in a well-closed wide mouth container at room temperature¹.

PLANT PROFILE:-

1. Vitex Negundo Linn.

Vitex Negundo Linn family (Lamiaceae) is popularly known as 'Nirgudi' or 'Nirgundi' (Hindi) and 'Five leaved chaste tree' (English). Vitex negundo is an erect shrub or small tree growing from 2 to 8 m (6.6 to 26.2 ft.) in height. The bark is reddish brown. Its leaves are digit ate, with five lanceolate leaflets, sometimes three. Each leaflet is around 4 to 10 cm (1.6 to 3.9 in) in length, with the central leaflet being the largest and possessing a stalk. The leaf edges are toothed or serrated and the bottom surface is covered in hair. The numerous flowers are borne in panicles 10 to 20 cm (3.9 to 7.9 in) in length. Each is around 6 to 7 cm (2.4 to 2.8 in) long and is white to blue in color. The petals are of different lengths, with the middle lower lobe being the longest. Both the corolla and calyx are covered in dense hairs. The fruit is a succulent drupe, 4 mm (0.16 in) in diameter, rounded to egg-shaped. It is black or purple when ripe².



Fig.No.1.Vitex Negundo plant

Fig.No.2. Parts of Vitex Negundo plant

2. Distribution

It is a perennial tree distributed throughout the great outer part of Himalayas, India ascending to an altitude of approx.1500 meters. Highly distributed in the hill region of Afghanistan, Bangladesh, Bhutan, Cambodia, China, Indonesia, Malaysia, Nepal Myanmar, Pakistan, Philippines, Sri Lanka, Taiwan, Thailand, and Vietnam.³

3. Taxonomical Classification:-

- Kingdom - Plantae
- Sub Kingdom - Tracheobionta - Vascular plants
 - Super division - Spermatophyta - Seed plant
- Division - Magnoliophyto - Flowering plants

- Class- Magnoliopsida-Dicotyledons
- Subclass - Asteridea
- Order - Lamiales
- Family- Lamiaceae
- Genus - Vitex Linn.
- Species - Vitex negundo Linn. (Chaste tree).⁴

4. Botanical Discription:-

Plant: It is a branched shrub or tree grown up to 5 meters tall, cylindrical with thin gray bark.

Leaves: Mostly trifoliate, occasionally pentafoliate, palmate compound petiole up to 2.5:3.8 cm long; in trifoliate the leaflets are lanceolate or narrowly lanceolate, middle leaflet 5 cm to 10 cm long and 1.6:3.2 cm broad with 1 cm to 1.3 cm long petiolule and remaining two sub-sessile; in pentafoliate leaf inner three leaflets have petiole and remaining two sub-sessile; on top of surface glabrous and tomentose in bottom with leathery texture.

Roots: Cylindrical, hard, longitudinal, narrow, cracks and small rootlets, tough with irregular fractures; the cork region shows grayish brown, middle region greyish-white, and xylem region cream colored.

Flowers: Small, bluish-purple, cymes peduncle, large forming terminal, often pyramidal panicles.

Fruit: The fruit is light brown to black with rounded drupe, 1 mm to 3 mm in diameter, 1/3rd to 3/4th of its size surrounded by a dull grey cup-like, persistent calyx along with pedicel; calyx cup may show one or two vertical splits; two locales each containing two seeds; smooth texture with uncharacteristic taste and odour .

Bark: Used for relieving intermittent fever, thirst & body pain. Bark is used in toothache.⁵

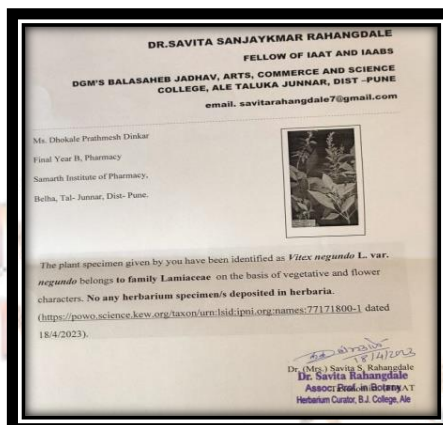
5. Traditional use:-

- Herbal medicine focuses on curing the root cause of the disease, rather than its symptoms.
- It is used to treat Swelling & Joint pain.
- Vitex Negundo use treatment of Rheumatoid Arthritis, Gout.
- Nirgundi decoction used for steam bath for joint pain.
- Dried leaves when smoked also said to relieve swelling and headache.

MATERIAL AND METHOD

1. Selection of plant

In the present study I have selected the plant of *Vitex Negundo* linn plant.



2. Collection of plant material

The leaves of *Vitex Negundo* were collected from village of Garkhindi, Ahmadnagar district, Maharashtra. The plant was Identified and Authenticated by DGM'S Babasaheb Jadhav, Arts, Commerce & Science College, Ale Tal-Junner, and Dist.-Pune

3. Preparation of plant material

For the present study the fresh plant material was taken and it was wash and dried in shade. The Leaves were dried for 15-20 days for proper drying.

4. Preparation of powder:-

After drying it was pounded to coarse powder. Powdered drug was stored in air tight And light resistant container for the study.

5. Preparations of extract:-

Preparations of methanolic extract by using maceration method.

MATERIAL AND METHOD FOR BALM PREPARATION

API AND CHEMICALS:-

Vitex negundo extract, Eucalyptus oil, Clove oil, Coconut oil, Sesame oil, Petroleum jelly, Menthol, Camphor, Methyl salicylate, Sodium benzoate, Bees wax.

INSTRUMENT AND EQUIPMENT:-

Iodine flask, Water bath, Stand, Beaker, Stirrer, Weighing balance, Digital pH meter, Brook Filled viscometer.

1) COCONUT OIL:-

Coconut oil also called Copra oil is show cooling effect and edible oil extracted from the kernel or meat of mature coconuts harvested from the coconut palm (*Cocos nucifer*). It has various applications. Because of its high saturated fat content, it is slow to oxidize and thus resistant to rancidification. Coconut oil one of nature's super foods and a truly essential nutrient in any diet or beauty regime. Coconut oil is unique when compared to other oils because it is composed predominantly of a group of fat molecules known as medium chain fatty acids. Animal research suggests that antioxidants called polyphenols found in coconut oil may be able to relieve some symptoms of arthritis.

Scientific Name: *Cocos nucifera*

Family: Arecaceae

Sub-family: Arecoideae

Genus: *Cocos* L.

Species: *Nucifera*

2) EUCALYPTUS OIL:-

Eucalyptus oil is useful in easing your joint and muscle pains. Combine 1-2 drops with Coconut carrier oil and rub it on the sore space in a very circular motion for higher results. Eucalyptus oil is anti-inflammatory and soothing, ideal for treating sore, over-exercised muscles. It helps relax stiff muscles, allows pain relief and eases muscle movement. It relieves pain and inflammation; Owing to the strong analgesic, anti-inflammatory and pain relieving properties of the active component eucalyptol, this oil is extensively used for providing relief from pain and inflammation in case of arthritis and joint pain. Being a natural vasodilator, it is also used to treat painful muscle spasms, sore muscles as well as neuralgia. Its property to calm and soothe the mind also makes it useful in case of headache and other inflammatory conditions.

Scientific Name: *Eucalyptus globulus* Labill

Kingdom: Plantae

Order: Myrtales

Family: Myrtaceae

Sub-family: Myrtoideae

Genus: *Eucalyptus* L her

Species: *Eucalyptus obliqua*⁷

3) CLOVE OIL:-

Clove oil is relieves pain, counter irritant & local stimulating effects that treat swellings.

Pain management: Clove essential oil is well-known for its use in musculoskeletal system pain relief blends. Clove bud oil can be used in a massage oil blend or as a Balm to help relieve symptoms of arthritis, sprains, strains, and muscle pain, as well as rheumatism.

Skincare: Clove oil is used in the skincare industry to treat acne, provide anti-aging benefits, rejuvenate the face, moisturize dry skin and lighten blemishes. To summarize, the therapeutic properties of clove essential oil include: Antioxidants

Analgesic (reduce pain sensation) Anthelmintic (kills intestinal parasites) antimicrobial and antiseptic, Anti-neuralgic (counteracts neuralgia) Carminative (relieves flatulence, easing abdominal pain and bloating) Spasmolytic (eases muscle spasm).⁸

4) SEASAME OIL:-

Topical application of sesame oil could reduce pain severity and frequency of received NSAIDs in patients with upper or lower extremities trauma. Therefore, it is recommended to use this oil in complementary medicine for pain relief due to low cost, easy usage and lack of adverse effects Sesame oil has been another herbal extract useful as external administration in management of pain in previous studies Sesame oil is derived from the plant species *Seasame indicum* L., an herbaceous annual belonging to the Pedaliaceae family. Sesame oil has been long used in traditional medicine of Iran and many other countries due to its antioxidant, anti-inflammatory and anti-bacterial significant effects. In traditional medicine, sesame oil was used to relief pain in people with joint pain, toothache, premenstrual syndrome, scrapes and cuts Sesame oil is anti-inflammatory properties, using it to treat joint inflammation, toothaches, scrapes & significantly decreased joint pain.⁹

5) METHYL SALICYLATE AND MENTHOL:-

Menthol and methyl salicylate combination topical is used to relieve minor pain caused by arthritis, simple backache, bruises, cramps, muscle strains, or sprain. This medicine is a topical analgesic. Menthol and methyl salicylate are known as counter irritants. They work by causing the skin to feel cool and then warm.

Methyl Salicylate:-

Odor; liquid having the characteristic odor of wintergreen.

Taste; liquid having the characteristic taste of wintergreen.

Density; 1.174

Boiling point; 423° at 760 mm Hg

Melting point; 16.5° F

Solubility; less than 1 mg/ml at 66°F

USES;

Food additives: flavoring agents

Industry uses;

1. Not known or reasonably ascertainable
2. Odor agents¹⁰

7) SODIUM BENZOATE:-

Sodium benzoate powder is accepted as a preservative by some of the world's toughest natural product certification. Using sodium benzoate as a preservative is a safe and effective technique to protect against bacteria and mold forming the bottles.

Type of ingredient; Preservative

Main benefits; Sodium benzoate is also an effective product stabilizer commonly used in pain.¹¹

8) CAMPHOR: -

It is a common ingredient in pain relief medications, including topical analgesics. It may help treat muscle aches and pains. Camphor oil can also help reduce chronic muscle and joint pain over longer periods. Camphor is derived from the wood of camphor laurel and other related trees of laurel family. Camphor is bicyclic mono Terpenoids. It is a white crystalline substance with strong odor and pungent taste. It is a waxy flammable substance obtained from steam distillation, purification and sublimation of wood, twigs and bark of the tree.

Uses

Topical analgesic

Antiseptic

Muscle relaxant

Anti- inflammatory

Contraceptive

Cough suppressant¹²

9) BEES WAX:-

Bees wax obtained from the honey comb of the bees *Apis mellifera* and other species of *Apis* belonging to the family *Apidae*. Order *Hymenoptera*. It is also known as yellow wax, *Ceraalba*. It is yellow to yellowish – brown in colour. Insoluble in water and soluble in alcohol, Ether, chloroform, carbon uses; In preparation of ointments, plasters and polishes Also used in the manufacturing of candles, moulds in dental and

electronic industries, Cosmetics, lip sticks. Is an ingredient of paraffin ointment. Beeswax is a natural wax produced in the bee hives of honey bees. It is a tough wax and formed from a mixture of several compounds. Its main components are palmitate, palmitoleate, hydroxypalmitate and oleate esters. It is natural and developed from renewable sources and biodegradable¹³

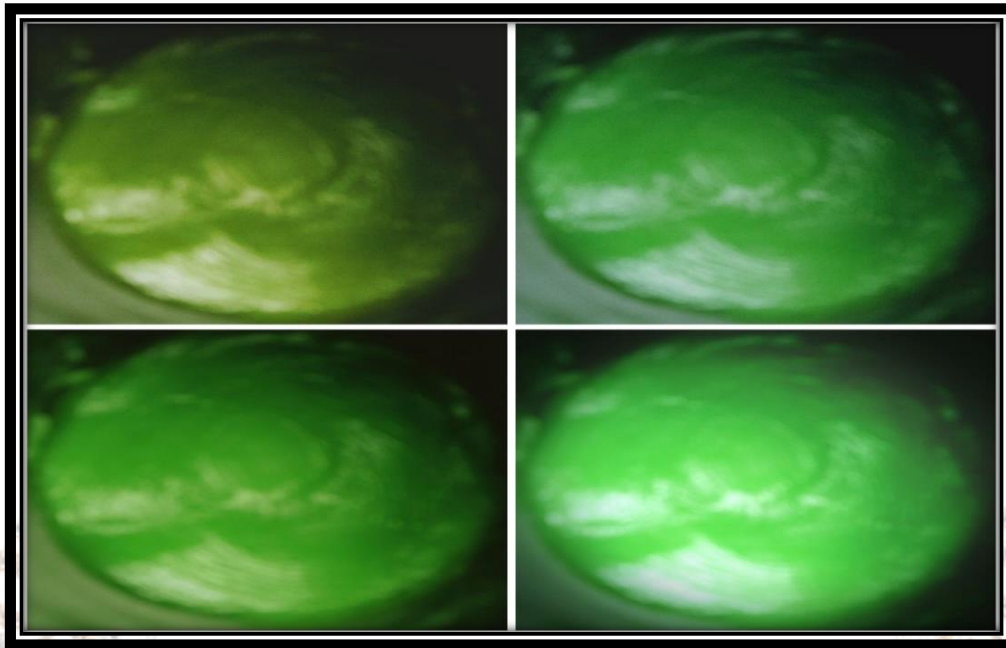
TABLE: 1 MATERIALS USED IN FORMULATION OF HERBAL BALM

INGREDIENTS	QUANTITY	MEDICINAL USES
Vitex negundo extract	5 ml	Relieve arthritis pain
Methyl salicylate	1 ml	Analgesic skin absorbent
Petroleum jelly	2 gm	Relieves dry skin, healing
Bees wax	5 gm	Thickeners
Menthol crystal	2 gm	Cooling and soothing effect
Eucalyptus oil	0.5 ml	Pain reliever
Clove oil	1 ml	Counter irritant
Seasame oil	1 ml	Pain reliever
Camphor	0.5 gm	Topical analgesics
Coconut oil	1.5 ml	Solvent
Sodium benzoate	0.5 gm	Preservative

PROCEDURE

- Take one container in that weigh and add petroleum jelly, place the container in a hotplate and boil it until all the amount of petroleum jelly completely dissolved.
- Measure & add Methyl salicylate and boil the solution in hot plate. In the dissolved petroleum jelly solution weigh and add bees wax stir it and boil until the bees wax added completely dissolve in the petroleum jelly.
- After that, weigh and add menthol crystals to the above solution and boil it until the Menthol completely dissolved.
- Measure & add clove oil and Coconut oil stir the solution and boil the solution.
- Measure & add 6ml of eucalyptus oil and Seasame oil stir the solution and boil the solution.
- Weigh sodium benzoate and add it to the solution, stir it well and boil the solution, for complete dissolution of the solution.
- Measure & add Vitex Negundo extract, properly mixing is essential.
- When all the added ingredients were completely dissolved & turn into the liquid form then take the solution out of the hot plate & pour wide mouth container the herbal Balm solution for cooling finally the prepared solution cools down & turn into a semisolid herbal Balm

Fig.No:03 Herbal pain relief balm formulations TABLE: 2 PREPARATION OF



HERBAL PAIN RELIEF BALM

(10 BATCHES)

Formula	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Petroleum jelly	2gm	2gm	2gm	2gm	2gm	2gm	2gm	2gm	2gm	4gm
Methyl salicylate	1ml	1ml	1ml	1ml	1ml	1ml	1ml	1.5ml	1ml	2ml
Bees wax	1gm	3gm	2gm	5gm	5gm	5gm	5gm	5gm	5gm	10gm
Menthol	1gm	2gm	2gm	2gm	1gm	1gm	1gm	1.5gm	2gm	4gm
Camphor	0.5gm	1gm	1gm	1gm	1gm	1gm	1gm	0.5gm	0.5gm	1gm
Clove oil	1ml	1ml	1ml	1ml	1ml	1ml	1ml	1.5ml	1ml	2ml
Coconut oil	2ml	1.5ml	1.5ml	1.5ml	1.5ml	1.5ml	1.5ml	1ml	1.5ml	3ml
Eucalyptus oil	1ml	1ml	1ml	1ml	1ml	1ml	1ml	0.5	0.5	1ml
Seasame oil	1ml	2ml	2ml	1ml	1ml	1ml	1ml	1ml	1ml	2ml
Sodium benzoate	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm	1gm
V.N. extract	-	-	-	-	2ml	4ml	4ml	5ml	5ml	10ml
V. N. oil	-	5ml	5ml	3ml	2ml	-	-	-	-	-

Hard paraffin	-	-	1 gm	-	-	-	-	-	-	-
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Fig. No. 4: Preparation of pain relief balm (10 batches)

EVALUATION TEST FOR HERBAL BALM

1. PHYSICAL PARAMETERS

Clarity and colour was checked by naked eyes against white background, the odour was smelled.¹⁴

2. SKIN IRRITATION

After applied this new & improved Balm leaves the skin it show first cooling effect then it show counter irritant effect.

ADR:-No side effect shown in this balm.

Conclusion:-After this experiment I say that this balm is very potent and effective Arthritis and Joint Pain.

3. pH

The pH of the prepared formulation was determined by using digital pH meter by dipping the Glass electrode completely in to the gel system to cover the electrode.

pH-test procedure:-1gm of balm dissolved in 100ml of water. The pH value must be 5 - 6.9. The 1gm of balm with 100ml of water placed for 2hr and then dip the glass Electrode. The measurement of pH value was 5.99.¹⁵

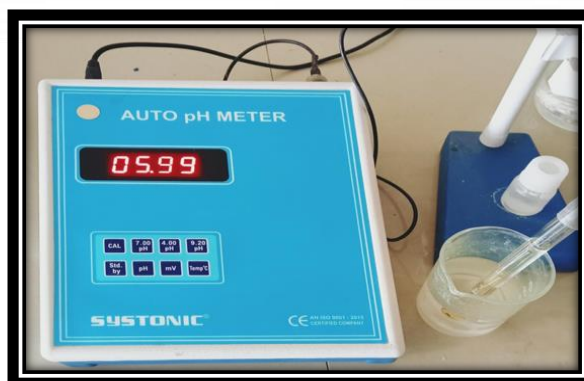


Fig.No.5: pH of herbal Balm4. PHASE SEPARATION

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 24hr.

5. SPREDABILITY

Two sets of glass slides of standard dimensions were taken. The herbal 1gm Balm formulation was placed over one of the slides. The other slides was placed on the top of the balm, such that the Balm was sandwiched between the two slides in an area occupied by a distance of 7.5 cm along The slides. 12 g weight of balm was placed on the upper slides so that the Balm was between the two slides was pressed uniformly to form a thin layer. The weight was removed and the Excess of Balm adhering to the slides was scrapped off. The two slides in position were fixed to a stand without slightest disturbance and in such a way that only upper slides to slip off freely by the force of weight tied on it. A20 g weight was tied to the upper slide carefully. The time taken for the upper slide to travel the distance of 7.5 cm and separated away from the lower under the influence of the weighed was noted.¹



Fig.No.6 Spreadability Test

6. STABILITY STUDIES

For this formulation the stability study was carried out over a period for 2 months by keeping the formulations at normal room temperatures so as to check the basic physical parameters such as the physical appearance, pH value, Spreadability, Viscosity, skin irritation, Patch test which is the basic objective of this study.¹⁶

Accelerated stability testing of prepared herbal balm formulation was at room temperature studied for one week, at $50^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 3 months. The herbal balm formulation were kept both at room and elevated temperature and observed on 0th, 15th, 20th, 30th, 40th, 50th, 60th, 70th, 80th and 90th day for the following parameters.

7. PATCH TEST

- 1) Skin where a person is unlikely to accidentally wash or rub it away. Good areas may include the inside of the arm or bend of the elbow.
- 2) Apply the product to a quarter-sized patch of skin. A person should apply the product as thickly as they would when using it regularly.

3) leave the product on the patch of skin for as long as it would normally be on the skin. If a person is testing a product that they would usually wash off, such as a cleanser, they should keep the patch on for 5 min. or as long as the instructions advise.

4) Repeat the patch test twice a day for between 7–10 days. A reaction may not happen immediately, so it is important to continue applying the product for this length of time.

5) If a person’s skin reacts to the product, they should wash it off as soon as possible and stop using it. A person can use a cool compress or petroleum jelly to relieve the skin if needed.¹⁷

5. VISCOSITY

Viscosity of Balm was determined using brook filled viscometer spindle no.2 (S-62, model LVDV-E) at 25°C with a spindle speed of the viscometer rotated at 12 rpm.¹



Fig. No.7 Viscosity determination

RESULTS AND DISCUSSION;-

TABLE NO: 2 RESULT OF STABILITY STUDIES (4 BATCHES)

FORMULATION	PERIOD	TOLERANCE LIMIT	COLOUR	pH	SPREADABILITY	PHASE SEPARATION	VISCOSITY	PATCH TEST
F7	Room temp.	15 day	Dark green	5.99	7.5	No phase separation	25330	No Allergic
F8	25°C ± 2°C	30 day	Dark green	5.93	7.5	No phase separation	39010	No Allergic

F9	30°C ± 2°C	1month 15day	Light green	5.97	7.5	No phase separation	24900	No Allergic
F10	30°C ± 2°C	2Month	Light green	5.79	7.5	No phase separation	25290	No Allergic

The physicochemical parameters of the prepared balm were determined parameters such as colour, odour, appearance and pH was tested.

TABLE: 3 PARAMETERS OF HERBAL PAIN BALM

SR. NO.	ORGANOLEPTIC CHARACTERS	HERBAL BALM	MARKETED BALM
1	Formulation	Pain balm	Pain balm
2	Colour	Light green	White
3	Odour	Fragrant	Fragrant
4	Appearance	Good	Smooth
5	State	Semisolid	Semisolid

TABLE: 4 EVALUATION TEST RESULT OF PAIN BALM

SR. NO.	PARAMETERS	RESULT
1	pH	5.99
2	Spreadability	7.5g. cm/sec
3	Phase separation	No phase separation
4	Viscosity	25330 cps
5	Patch test	Non allergic

Spreadability (S):- = $M \times L \div T$
 = $12 \times 5 \div 8$
 = 7.5g.cm.sec.

Inference:- Easily Spreadable

Viscosity:-

Rotor:- No.2

Revs./Speed:- 12 rpm

Viscosity:- 2533mPa.S

Angle:- 95.3%

Viscosity:- 2533×10
 = 25330 cps

SUMMARY AND CONCLUSION

- Ancient time vitex negundo is also use to treat arthritis and gout pain relief but vitex negundo leaf extract using prepare balm is new formulation
- Herbal balm was prepared by using Double boiling “Hot 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 eucalyptus leaves extracts have relieving pain property, vitex negundo leaves extracts used to relieve arthritis pain, cures high fever and alleviates menstrual cramps.
- The prepared formulation showing good physical characteristics.
- Further evaluated by various evaluation parameters such as pH, Spreadability, Viscosity, skin irritation, Patch test and gives characteristic 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 Processing Technique which having excellent pain-relieving property.

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