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Formulation and Evoluation of Pain Relief Balm by using Vitex Negundo and Ginger Offecinalis

Shete A.R[1*]; Sargar R.S.[2]; Kalebhag A.M.[3]; Dhole M.S.[4]; Pukale A.B.[5]; Pawar S.V.[6]; Panaskar A.N.[7]; Panaskar B.A.[8]

[1,2,3,4,5,6,7,8]Padmini College of Pharmacy, Dighanchi, Tal-Atpadi, Dist-Sangli, Maharashtra, India

Corresponding Author: Shete A.R.[1*]

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Abstract: Improved and new balm has a cooling effect on the skin following application. Though the amount of pressure and mobility are important factors, balms have a special pharmacological effect when it comes to pain alleviation. One of the balm's functions is to provide a local anesthetic effect, which eventually results in comfort. It is possible to cure congestion and headaches right away, as well as aches, pains, and stiffness in the muscles, joints, feet, and stress and fatigue. In this research paper. The potential benefits of ethanolic extract of Vitex Negundo leaves in inflammatory and pain diseases have been extensively researched, While ginger oil helps with circulation, warming, and muscle relaxation because it contains bioactive compounds like gingerol. The results suggest that the combination of Vitex negundo and ginger oil offers a promising, natural alternative to synthetic pain relief formulations, with potential for further development and clinical validation.

Keywords: *Pain, Vitex Negundo, Gingerol, Potential, Inflammatory.*

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I. INTRODUCTION

According to Meuss, phytotherapy, also known as herbal drug, is the study of treating ails with herbal remedies. According to reactionary exploration, people have been using shops as drugs for at least 60,000 times. Sauces were used in numerous traditional medical systems, including Greek Unani, Chinese traditional drug, Japanese Kampo, and Indian Ayurveda. For artistic reasons, Native Americans and Africans also used them in mending observances. still, when new chemical logical ways surfaced in the 19th century, allowing scientists to produce synthetic medicines, the fashionability of traditional drug began to decline. Herbal specifics are getting more and more popular these days because they're less precious, entirely natural, and have no significant side goods. According to estimates from the WHO, 80 of people worldwide still admit their medical care through traditional means. VN is among the most significant shops employed in traditional drug. It's a woody, ambrosial shrub that grows to a slender tree and is a member of the Verbenaceae family. Its quadrangular branches, which bear tri or penta- foliate leaves with five circulars arranged like a win, are also appertained to as the Five- Leaved Chaste Tree(1). It's known as" sarvaroganivarani" in Indian traditional drug, which means" the remedy for all conditions." Because of its antioxidant rates, nirgundi may help control diabetes by raising insulin situations. Because of itsanti-inflammatory parcels, it also aids in the operation of seditious responses by precluding the exertion of specific intercessors(2). Analgesic herbal attar is a comforting and soothing product. It's the bone that causes the pain. The term" relief" is thus essential in the term" herbal pain attar ," which is defined as asemi-solid medication that's applied externally as a remedy or to soothe and irritate. It can also relate to any of a number of sweet resinous composites set up in a medication intended to soothe and heal(3). An Ayurvedic combination of potent essential canvases , analgesic herbal attar provides immediate relief from snap, headaches, and backaches. Natural essential oil painting, organic beeswax, and other favored herbal accoutrements make up the herbal attar expression, which also contains remedial topical curatives for mortal skin operation. Topical specifics called redolences are used to treat skin stiffness and pain(4). In indispensable drug, Zingiber officinale(Zingiberaceae family) has long been used to treat osteoarthritis and rheumatoid arthritis. gusto is also constantly used as ananti-inflammatory and to treat toothaches and casket and stomach pain. One of the medicinal shops with positive health goods that's constantly used in food and drug is Zingiber Officinale. Its pharmacological goods are well- known due to its crude excerpt. Throughout

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history, gusto rhizome has been used considerably in traditional drug and is constantly added to food as a spice or taken as a salutary supplement(5). The rhizome of gusto(Zingiber officinale) has long been used as a medicinal condiment. The chemical factors of gusto, which include antioxidants andanti-inflammatory agents with the eventuality to serve as immunomodulators, are known tohave positive health effects.Zingerone, paradol, shogaols, and gingerol give gusto its anti-inflammatory and antioxidant rates(6). Ayurvedic drug uses Vitex negundo and gusto officinale's to treat arthritis because of its anti-inflammatory and antioxidant properties(7).

II. MATERIAL AND METHOD

➢ *Material:*

Vitex Negundo,Ginger, Bees Wax,Menthol, Coconut Oil , Eucalyptus Oil ,OilveOil ,Camphor, Triethanolamine, Alovera Gel , Pipperment Oil, Almond Oil ,Propyl Paraben.

Fig 1: Soxhalet Extraction Process of Vitex Negundo

Method of extraction of VitexNegundo Collect the fresh leaves and clean them and dry the leaves in shade.Triturate the dried leaves into fine powder.use suitable solvent like water,ethanol or methanol.Then use Soxhalet extraction(6-8hrs).filter the extract by using whatman filter paper.keep the filtered extract at 4°C in tightly sealed container..[9],[10],[11].

Fig 2: Extraction Process of Ginger Oil

Fig 3: Ginger Oil

➢ *Method of Extraction of Ginger Oil:*

Fresh ginger rhizomes should be cleaned, peeled, and then chopped into little pieces. In order to extract oil using a Clevenger device, dry the slices to reduce the moisture content. Then, put the ginger in a distillation unit, pass steam through it, and utilize the vapor to separate the oil from the water.then gather the oil and store it at a cold temperature in an airtight container. [13]

III. PROCEDURE FOR PREPRATION OF HERBAL BALM

The raw ingredients used in this experiment, including the medicine, excipient, and chemicals, came from a variety of sources.

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Table 1: Formulation table of Pain Relief Balm

Sr.no	Ingredient	Formulation (F1)	Formulation (F2)	Formulation (F3)
1	Vitex Negundo Extract	0.8gm	0.6gm	0.7gm
2	Ginger Oil	1ml	1ml	1ml
3	Bees Wax	3gm	3gm	3gm
4	Coconut Oil	1ml	1ml	1ml
5	Olive Oil	1ml	1ml	1ml
6	Alomand Oil	1ml	1ml	1ml
7	Eucalyptus Oil	1ml	1ml	1ml
8	Pipperment Oil	1ml	1ml	1ml
9	PropylParaben	0.5gm	0.5gm	0.5gm
10	Menthol	Q.S	Q.S	Q.S
11	Camophor	Q.S	Q.S	Q.S
12	Triethanolamine	1drop	1drop	1drop
13	Alovera Gel	Q.S	Q.S	Q.S
14	Perfume	Q.S	Q.S	Q.S

Third formulation is **more stable** than first two formulation.

IV. PROCEDURE

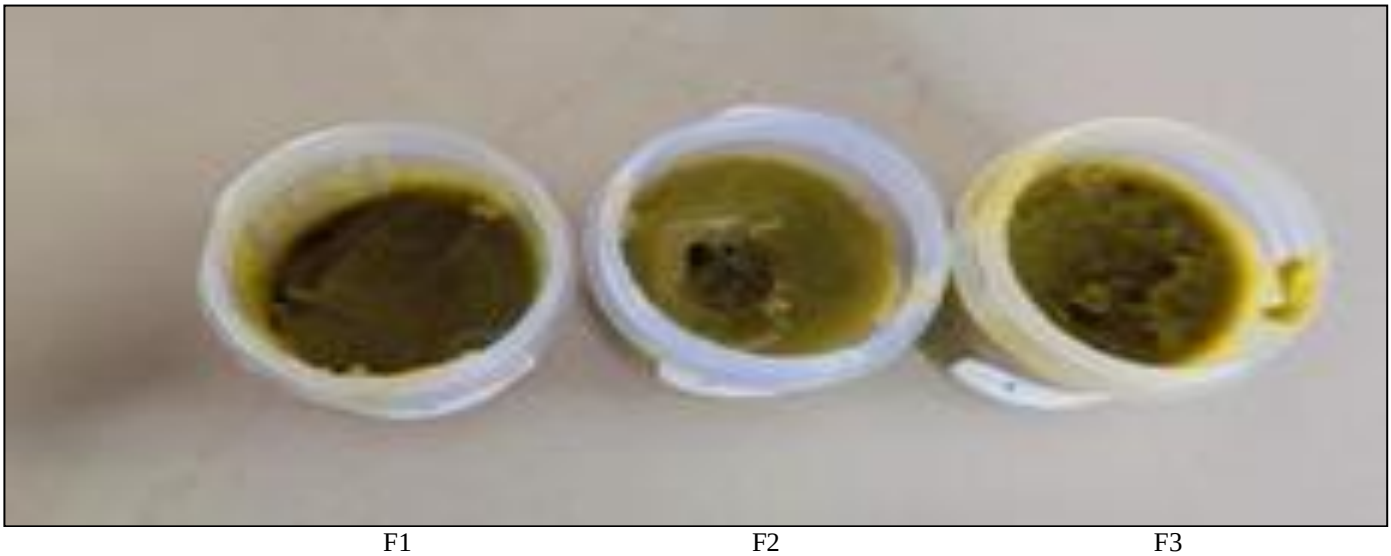
➢ *Prepare the Double Boiler Setup*
Set up a double boiler.

➢ *Melting The Base*
Add bees wax, coconut oil, Eucalyptus Oil and olive oil, Almond Oil, Pipperment Oil. Gentely heat until completely melted stirring occasionally.

➢ *Incorporating the Herbal Extracts*
Once the base is melted, lower the heat slightly. Add Vitex negundo extract and Ginger Oil and stir well. Add Triethanolamine, camphor and menthol; stir until dissolved.

➢ *Add preservative and Aloevera Gel*
Remove from heat. Let the mixture cool slightly (around 40–45°C), then add Preservative and Aloevera Gel. Then add perfumes in it. Stir thoroughly to ensure uniform distribution.

➢ *Pour and Set*
Pour the mixture into clean, dry containers (e.g., glass jars or balm tins).Let it cool and solidify at room temperature.



F1 F2 F3

Fig 4: Formulation of Balm

V. EVALUATION TEST OF BALM

In compliance with standard procedures, a variety of parameters were used to assess the manufactured balm.

- **Physical evaluation**: Color, texture, and odor were noted throughout this examination.
- **PH**: Using a digital PH meter, the formulation's PH was measured by making a 10% solution and fully submerging the glass electrode in the solution system to cover it. Three readings were taken during the measurement, and the average of the three was noted.
- **Washability:** Water was used to test the balm's washability.

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- **Phase separation:** A suitable container was used to transfer the created balm. After 24 hours, the oil phase and aqueous phase separation was seen; set away for storage.
- **Spreadability**: A sample was implanted to test the spreadability. between two glass slides that were crushed for a set period of time to obtain a consistent thickness. The time needed to separate the two slides was measured. Spreadability increases as two slides are separated in less time, according to the formula

$$S = M * L / T \; S =.$$

- **Consistency:** smooth, no greetings.
- **Non-irritation**: Human skin was treated with created formulations, and the results were monitored.
- **Viscosity:** The viscosity of balm at 25°C was measured using a brook-filled viscometer (S-62, model LVDV-E) with a spindle that rotated at 12 rpm.
- **Greasiness:** Balm formulations F3, F5, and F6 appear slightly oily. [14]

➢ *Chromatography:*

- **Thin layer chromatography:** (TLC) in chromatography: This chromatographic technique separates the components of a mixture using a thin stationary phase supported by an inert backing. The goal of TLC is to obtain distinct, well-separated spots.
- **Retention factor:** RfValue = (Solute Traveled Distance)/(Solvent Traveled Distance) is the retention factor.

A thin layer chromatography test was performed on the ethanolic extract of Vitex Negundo leaves to identify the presence of several compounds, which were subsequently verified by chemical testing. TLC spot color and RF value in ethanol: Acetic acid: water (3: 2: 5). These TLC locations with the RF value and color are in the table, and the TLC plate is depicted in the figure below.

- **Paper chromatogaraphy:** Paper chromatography is a method for separating chemical mixtures by using variations in the mobility and solubility of substances in a mobile phase (solvent) on a stationary phase (paper).
- **Retention Factor:** RfValue = (Solute Traveled Distance)/(Solvent Traveled Distance) is the retention factor.

To find the existence of several compounds that were verified by chemical testing, the ethanolic extract of Vitex Negundo leaves was put through a paper chromatography test. RF value and color of the chloroform TLC spot: Acid acetic: Ethyl Acetate: Ethanol (10: 3: 5: 2) These TLC locations with the RF value and color are in the table, and the TLC plate is depicted in the figure below.

VI. RESULT AND DISCUSSION

In order to determine the anti-inflammation activity of the balm , the current study was conducted to formulate and asses a herbal anti-inflammation balm employing ethanolic extract. By using thin layer chromatography and phytochemical screening, the ethanolic extract of Vitex Negundo and Zingiber Officinale was also asses. A range of physical evaluation factor including Physical characterstic ,pH , Phase seperatioin , Spreadability , Washability, Consistency , Nonirritancy , Patch test , Viscocity , Greasiness , were applied to the formulations. The following are the outcomes of the same.

➢ *Phytochemical Analysis:*

Table 2: Phytochemical Screening Vitex Negundo

Sr. No.	Component	Test	Inference
1.	Alkaloids	a)Mayer's test b)Wagner's test	Positive
2.	Flavonoids	a) Shinoda test b)Alkaline reagent test	Positive
3.	Saponins	Froth test	Positive
4.	Tannins	Ferric chloride test	Positive
5.	Phenols	Ferric chloride test, tannins	Positive
6.	Glycosides	a)Keller-Killiani test for cardiac glycosides	Positive
7.	Terpenoids	Salkowski test	Positive
8.	Steroids	Liebermann-Burchard test	Positive
9.	Carbohydrates	a)Molischs test b)Benedict's Test	Negative
10.	Protine and Amino acid	Ninhydrin test	Positive

Alkaloids, Flavonoids, Saponins, Tannins, phenol, Glycosides , Terpenoids , Steroids, Carbohydrates, Protine and Amino acid are all present in the ethanolic extract of Vitex Negundo according to phytochemical screening

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Table 3: Phytochemical Screening Ginger Oil

Sr . No .	Component	Test	Inference
1.	Alkaloids	Mayer's Test	Positive
2.	Flavonoids	Shinoda Test	Positive
3.	Phenols	Ferric chloride Test	Positive
4.	Terpenoids	Salkowski Test	Positive
5.	Steroids	Liebermann–Burchard Test	Positive
6.	Tannins	1% Ferric chloride Test	Positive
7.	Saponins	Froth Test	Positive
8.	Glycosides	Keller-*Killiani* Test	Positive

- *Evaluation of Balm:*
- *Physical Evaluation:*

Table 4: Physical Evaluation

Sr.No.	Parameters	Formulation (F3)	Formulation (F5)	Formulation (F6)
1.	Colour	Dark bottle green	Dark bottle green	Dark bottle green
2.	Odour	Pleasant	Pleasant	Pleasant
3.	Texture	Smooth	Smooth	Smooth
4.	State	Semisolid	Semisolid	Semisolid

Based on visual observation, the created formulation of balm F3 , F5 and F6 were seen to have smooth texture , pleasant smell, and a homogenous dark green colour.

- *pH:*

Table 5: pH

Sr. No.	Formulation	pH
1.	Formulation (F3)	5.08 - 6.04
2.	Formulation (F5)	5.05-6.02
3.	Formulation (F6)	5.07 - 6.0 8

The pH of all three of the formulation – F3, F5, and F6, -was determined to be between 5.08 to 6.04, which is a suitable range for skin pH , based on the results. All of the balm formulations had pH values between 5 – 7, which is closer to what the skin requires.

- **Wash Ability:** When applied to Skin , the created formulation balm F3, F5, and F6 can be removed with water , indicating that they are washable.

Table 6: Wash Ability

Sr. No.	Formulation	Wash ability
1.	Formulation(F3)	Washable
2.	Formulation(F5)	Washable
3.	Formulation(F6)	Washable

- **Phase Separation:** The prepared balm was stored at room temperature , hidden from light , in a covered container. After then , phase separation was examined every day for 30 days. The findings showed that none of the three formulations showed signs of phase separation

Table 7: Phase Separation

Sr. No.	Formulation	Phase separation
1.	Formulation(F3)	No phase separation
2.	Formulation(F5)	No phase separation
3.	Formulation(F6)	No phase separation

- **Spreadability:** Out of the three formulation , F3 takes less time for the two slides to separate, which is good for Spreadability since, as the evaluation test description states , less time is needed for the two slides to separate . In light of this , F3 demonstrated the expected Spreadability in comparison to F3 , F5 .

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Table 8: Spreadability

Sr. No.	Formulation	Time (sec)	Spreadability (g×cm/sec)
1.	Formulation(F3)	12	23.6
2.	Formulation(F5)	07	29.2
3.	Formulation(F6	20	17.9

- **Non – Irritancy:** The developed formulation balm F3 , F5, and F6 exhibit nor any irritation impact .
- **Viscosity:** Balm Viscosity was measured using a Brookfield viscometer at 27 ℃ and spindle number seven running at 100 RPM . Based on the finding , the balm viscosity fell between 11810 to 21020 Cps.

Table 9: Viscosity

Sr. No.	Formulation	Viscosity
1.	Formulation(F3)	21020
2.	Formulation(F5)	11810
3.	Formulation(F6	18820

- **Greasiness:** Upon observation , the created formulation balm F3 , F5 , and F6 have a little greasy nature .

Table10: Greasiness

Sr. No.	Formulation	Greasiness
1.	Formulation(F3)	Slightly- greasy
2.	Formulation(F5)	Slightly- greasy
3.	Formulation(F6	Slightly- greasy

➢ *Thin Layer Chromatography:*

Table 11: Thin Layer Chromatography of Vitex Negundo

Mobile Phase	Extract	Rf Value	Colour of Spot
Ethanol : Acetic acid : Water (3 : 2 : 5)	Ethanolic	0.81	Green
		0.77	Light Green

The ethanolic extract of Vitex Negundo was subjected to thin layer chromatography ,with Ethanol : Acetic acid : Water (3 : 2 : 5) serving as the mobile phase . The current study displays several coloured dots that have travelled from the origin. The displayed Rf value ranges from 0.81 to 0.77

➢ *Paper Chromatography :*

Table 12: Paper Chromatogratphy

Mobile Phase	Extract	Rf Value	Color of Spot
Chloroform : Ethanol: Ethyl acetate : Acetic acid (10 : 3 : 5 : 2)	Ethanolic	0.96	Light yellow
		0.8	Light Green

The ethanolic extract of Vitex Negundo was subjected to Paper chromatography ,with Chloroform : Ethanol : Ethyl acetate: Acetic acid (10 : 3 : 5 : 2) serving as the mobile phase . The current study displays several coloured dots that have travelled from the origin. The displayed Rf value ranges from 0.96 to 0.8

VII. CONCLUSION

Pain relief balms can be an effective tool for managing and lowering pain when created correctly with safe and effective components, especially in cases of headaches, muscular aches, and arthritis. These balms often work on the counterirritation principle, creating a momentary feeling of warmth or cold to distract from the underlying discomfort. While ginger oil, which includes bioactive chemicals like gingerol, helps with warming, circulation, and muscle relaxation, numerous studies have looked at the potential benefits of ethanolic extract of Vitex Negundo leaves in inflammatory and pain diseases. The results show that Vitex negundo and ginger oil work well together as an all-natural alternative to pharmaceutical painkillers, albeit more study and clinical approval are needed.

In order to guarantee the effectiveness and safety of a human pain relief balm, both in vitro (laboratory) and in vivo (live creature) evaluations are required. While in vivo research use animal models or human clinical trials to test the

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balm's analgesic effects, skin penetration, and possible adverse effects, in vitro studies concentrate on evaluating the balm's physical attributes, such as consistency, stability, and release characteristics.

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