



FORMULATION AND EVALUATION OF HERBAL PAIN RELIEF OIL

Vivek Chauhan^{*1}, Anu Kaushik² and Dr. Sudha³

¹Department of Quality Assurance/ BACFO Pharmaceuticals India Ltd, Noida, India.

²Department of Pharmacy / Teerthanker Mahaveer University, Moradabad, India.

³(Department Of Biotechnology / JJT University, Rajasthan, India).

***Corresponding Author: Vivek Chauhan**

Department of Quality Assurance/ BACFO Pharmaceuticals India Ltd, Noida, India.

Article Received on 23/02/2016

Article Revised on 14/03/2016

Article Accepted on 05/04/2016

ABSTRACT

A variety of herbs and essential oils can be used for pain and inflammation associated with sports and exercise, as well pain and inflammation associated with rheumatism, arthritis, surgery, or other medical conditions. Herbal pain relief oil is a perfect blend of oils like sesame oil and essential oil. and herbs like nirgundi and haldi. It gives quick relief from any type of ache in the body after rubbing on the body as a result no strains persist at the body. The objective of the present study is to prepare herbal pain relief oil and evaluate its parameter. Vitex negundo, and curcuma longa are well known for its medicinal value, two formulation F1 and F2 were prepared, F1 formulations consist of aqueous extract of curcuma longa (rhizomes), vitex negundo (leaves) and sesame oil as base oil, F2 formulations comprises of extract of curcuma longa, vitex negundo and sesame oil as base oil and essential oils. Both the formulation were evaluated for color, odour, pH (5.56-6.01), and density (0.921-.931gm/ml). Acid value (19.34-19.45), saponification value (115.24-194.33), refractive index (1.456-1.468). The result of accelerated stability studies revealed no physical and chemical changes in the herbal oil during three months. The herbal oil passes the microbial test herbal oil were free from fungal and bacterial growth. The massage oil samples comply for the requirements of acid value, peroxide value and saponification value. These methods are simple and reproducible. Present investigation was undertaken to standardize the herbal massage oils on physicochemical parameters. The herbal oil prepared were effective too. All the ingredients used are of natural origin. The essential oils used have many benefits when used effectively, they provide relief from pain, elevate mood, provide soothing effect to skin with enormous benefits.

KEYWORDS: curcuma longa, vitex negundo and sesame oil.

INTRODUCTION

Aromatic plants had been used since ancient times for their preservative and medicinal properties, and to impart aroma and flavor to food. Hippocrates, sometimes referred to as the 'father of medicine', prescribed perfume fumigations. The pharmaceutical properties of aromatic plants are partially attributed to essential oils. The term 'essential oil' was used for the first time in the 16th century by Paracelsus von Hohenheim, who named the effective component of a drug, 'Quinta essential'.^[1]

Since ancient times, essential oils are recognized for their medicinal value and they are very interesting and powerful natural plant products. They continue to be of paramount importance until the present day. Essential oils have been used as perfumes, flavors for foods and beverages, or to heal both body and mind for thousands of years.^[2]

Pathophysiology of pain

Two major types of pain exist: nociceptive and neuropathic. Nociceptors are free afferent nerve fibers

that distinguish noxious from innocuous stimuli. These are located in the skin, subcutaneous tissue, and visceral and somatic structures. Somatic nociceptive pain arises from bone, joint, muscle, skin, or connective tissue. Direct trauma to tissues is the typical cause of this type of pain. Visceral pain arises from visceral organs like the gastrointestinal tract or pancreas. Visceral nociceptive pain may arise from the organ or capsule or from obstruction of a hollow viscus causing intermittent, poorly localized pain. Somatic nociceptive pain is described as sharp, aching, throbbing, pressure, or vise like. Visceral nociceptive pain is often described as gnawing or cramping, or if due to obstruction of a hollow viscus, may be described as aching, sharp, or throbbing. This is the pain often associated with appendicitis, cholecystitis, or pleurisy.^[3]

The oral and nasal routes are the most common noninvasive paths for drug administration but are not suitable for some drugs, either due to stomach acidity or hepatic first-pass metabolism. Essential oils and their terpene constituents may be acceptable natural

alternatives to synthetic skin penetration enhancers. They are characterized by their relatively low price and promising penetration enhancing activities.^[1]

In the present work a massage pain oil is prepared with the help of essential oil: eucalyptus oil, gultheria oil, camphor oil, and castor oil as they are good penetration enhancer and arthritic property and sesame oil as base oil which is helpful in inflammation too, and few herbs haldi and nirgundi postulating anti inflammatory properties.

Benefits of Massage with Herbal Oil

1. Relief from pain

Herbal oil relieves from all kind of pain and muscular aches. It is very effective in the cure of rheumatoid arthritis, headaches, migraines, chronic back pain. Massage helps relieve muscle tension and stiffness.

2. Improved Circulation

It increases blood circulation, increasing life span and general sense of well being. Improved circulation also helps in pain relief.

3. Improved Flexibility

It provides greater joint flexibility and range of motion.

4. Athletic Performance

Massaging with pain oil improves athletic performance, speeds up healing of injury and strengthens bones.

ESSENTIAL OILS

“Essential oils” are the therapeutic, volatile oils that come from plants. In aromatherapy, the word “volatile” is not meant as “explosive” or “inconsistent.” Rather, this refers to the meaning: “evaporating readily at normal temperatures and pressures...[an oil that] changes readily from solid or liquid to a vapor [as in] ‘it was heated to evaporate the volatiles’.” Essential oils may be found in leaves, rinds of fruit, seeds, bark, heartwood of trees, flowers, and any other part of a plant, so long as the extracted oil has medicinal or otherwise therapeutic use.^[4]

Essential oils (also called volatile or ethereal oils, because they evaporate when exposed to heat in contrast to fixed oils) are odorous and volatile compounds found only in 10% of the plant kingdom and are stored in plants in special brittle secretory structures, such as glands, secretory hairs, secretory ducts, secretory cavities or resin ducts. Essential oils are hydrophobic, are soluble in alcohol, non polar or weakly polar solvents, waxes and oils, but only slightly soluble in water and most are

colourless or pale yellow, with exception of the blue essential oil of chamomile (*Matricaria chamomilla*) and most are liquid and of lower density than water (sassafras, vetiver, cinnamon and clove essential oils being exceptions). The amount of essential oil within a plant varies between 0.01% to over 10%.^[2]

Bioavailability of essential oils

Most essential oils are rapidly absorbed after dermal, oral, or pulmonary administration and cross the blood-brain barrier and interact with receptors in the central nervous system, and then affect relevant biological functions such as relaxation, sleep, digestion etc. Most essential oil components are metabolized and either eliminated by the kidneys in the form of polar compounds following limited phase I enzyme metabolism by conjugation. With glucuronate or sulfate, or exhaled via the lungs as CO₂.^[2]

The action of essential oils begins by entering the human body via three possible different ways:

- Direct absorption through inhalation,
- Ingestion or diffusion through the skin tissue.

Properties of essential oils.^[5,6]

1. Volatile.
2. Healing property.
3. Hydrophobic.
4. Penetrate the skin.
5. Antiseptic.
6. Stimulate white cell production.
7. Either stimulating or sedative.
8. Most are cell renewing.
9. Relieve from stress.

Examples of Essential Oils.^[7]

1. Lavender oil: is anti-inflammatory.
2. Chamomile is the best anti-inflammatory.
3. Cinnamon oil is our strongest anti-microbial oil.
4. Clove oil: the bacteria really causes pain.
5. Rosewood oil: Its loaded with the same thing lavender has and it's very healing to the skin.
6. Peppermint oil is the single best gargling oil – it leaves your mouth refreshed and kills bacteria.
7. Tea tree oil will kill ring worm in 24 hours – apply it non-stop.

FORMULATION OF HERBAL PAIN OIL MATERIALS AND METHOD

Various materials used in the preparation of herbal pain oil were procured from Bacfo pharmaceutical India Ltd.

Table 1:- Material and source of herbal oil

S. No.	Ingredients	Source
1.	Haldi	Arya vastu bhandar
2.	Nirgundi	Arya vastu bhandar
3.	Sesame oil	Orchid chemicals
4.	Gultheria oil	Orchid chemicals
5.	Eucalyptus oil	Orchid chemicals

6.	Camphor oil	Orchid chemicals
7.	Castor oil	Orchid chemicals
8.	Potassium dihydrogen phosphate	Scientific fischer
9.	Sodium hydroxide	Scientific fischer
10.	Nutrient agar	Titan biotech
11.	Sabaroud dextrose agar	Titan biotech
12.	Soya casein digest agar	Titan biotech
13.	Mannitol salt agar	Titan biotech
14.	Bismuth sulphite agar	Titan biotech
15.	Nutrient broth agar	Titan biotech
16.	Mc conkey broth	Himedia laboratories pvt ltd
17.	Salt meat broth	Titan biotech
18.	Distilled water	In house
19.	Methyl Paraben	Scientific fischer

PRE-FORMULATION STUDIES FOR HERBAL PAIN OIL

A. Determination of Foreign Matter.^[8]

Foreign matter is the material consisting of any or all of the following.

- Parts of organs from which the drug is derived other than the part named in the definition & description or for which limit is prescribed in the individual monograph.
- Any organs other than those named in the definition & description.
- Matter not coming from the source plant
- Moulds, insects and other animal contamination

METHOD

Weigh 100 to 500 g or the quantity specified of the original sample and spread it out in a thinner layer. Inspect the sample with the naked eye or with the 6X lenses and separate the foreign organic matter manually as completely as possible. Weigh and determine the % of foreign organic matter from the weigh or drug taken. Use the maximum quantity of sample for course or bulky drug.

B. Moisture Content

Weigh 2 g of sample & petri dish separately, Then heat in hot air oven at 105°C for 1 hour. Then put off the petri dish from oven & weigh.

Formula: $\text{Weight of petri dish} + \text{Weight of Sample} - \text{Dried weight} \times 100 / \text{Weight of Sample}$.

C. Ph ANALYSIS

Prepare 1 % w/v solution of sample in distilled water, mix it properly. Measure the pH with pH meter at 27°C ± 2°C.

Read the pH when temperature and pH reading remains constant on display.

D. DETERMINATION OF ETHANOL EXTRACTIVE VALUE

Macerate 5gm of air dried drug coarsely powdered with 100 ml of ethanol of specified monograph in a closed flask for 24 hrs. Shaking frequently for first 6hrs and allowing to stand for 18 hours, thereafter filter rapidly

taking care of loss of ethanol. Evaporate 25 ml of filtrate to dryness in a flat bottomed shallow dish, dry at 105°C and weigh. Calculate the %age of ethanol soluble extractive with reference to the air dried drug.

Formula: $\text{Weight of petridish} - \text{weight after drying} \times 100 / \text{weight of sample} \times \text{wt. of extract}$.

E. DETERMINATION OF WATER EXTRACTIVE VALUE :

Macerate 5gm of air dried drug coarsely powdered with 100 ml of chloroform water (2.5 ml chloroform in 1000ml water) of specified monograph in a closed flask for 24 hrs. shaking frequently for first 6hrs and allowing to stand for 18 hours, thereafter filter. Evaporate 25 ml of filtrate to dryness in a flat bottomed shallow dish, dry at 105°C and weigh. Calculate the %age of ethanol soluble extractive with reference to the air dried drug.

Formula : $\text{Weight of petridish} - \text{weight after drying} \times 100 / \text{weight of sample} \times \text{wt. of extract}$

F. DETERMINATION OF TOTAL ASH :

Incinerate about 2 to 3 g accurately weighed, of the ground drug in a tared platinum or silica dish at a temperature not exceeding 450° until free from carbon, cool and weigh. If a carbon free ash cannot be obtained in this way, exhaust the charred mass with hot water, collect the residue on an ashless filter paper, incinerate the residue and filter paper, add the filtrate, evaporate to dryness, and ignite at a temperature not exceeding 450°. Calculate the percentage of ash with reference to the air-dried drug.

G. DETERMINATION OF ACID INSOLUBLE ASH

Mix the ash obtained with 25ml of 2M HCl, collect the insoluble matter on an ash less filter paper, wash with hot water, ignite for 15 min at temp not exceeding 450°C, cool in a desiccator and weigh. Calculate the acid insoluble ash with reference to the air dried drug.

H. REFRACTIVE INDEX

The refractive index (n) of a substance with reference to air is the ratio of the sine of the angle of incidence to the sine of the angle of refraction of a beam of light passing

from air into the substance. It varies with the wavelength of the light used in its measurement.

Unless otherwise prescribed, the refractive index is measured at 25°(±0.5) with reference to the wavelength of the D line of sodium ($\lambda = 589.3$ nm). The temperature should be carefully adjusted and maintained since the refractive index varies significantly with temperature.

The Abbe refractometer is convenient for most measurements of refractive index but other refractometer of equal or greater accuracy may be used. Commercial refractometers are normally constructed for use with white light but are calibrated to give the refractive index in terms of the D line of sodium light.

To achieve accuracy, the apparatus should be calibrated against distilled water : which has a refractive index of 1.3325 at 25° .

The cleanliness of the instrument should be checked frequently by determining the refractive index of distilled water which at 25° is 1.3325.

I. WEIGHT PER MILLILITRE AND SPECIFIC GRAVITY

Weight per millilitre – The weight per millilitre of a liquid is the weight in g of 1 ml of a liquid when weighed in air at 25°, unless otherwise specified.

Method:

Select a thoroughly clean and dry pycnometer. Calibrate the pycnometer by filling it with recently boiled and cooled Water at 25° and weighing the contents. Assuming that the weight of 1 ml of water at 25° when weighed in air of density 0.0012 g per ml, is 0.99602 g. Calculate the capacity of the pycnometer. (Ordinary deviations in the density of air from the value given do not affect the result of a determination significantly). Adjust the temperature of the substance to be examined, to about 20° and fill the pycnometer with it. Adjust the temperature of the filled pycnometer to 25°, remove any excess of the substance and weigh. Subtract the tare weight of the pycnometer from the filled weight of the pycnometer. Determine the weight per milliliter dividing the weight in air, expressed in g, of the quantity of liquid which fills the pycnometer at the specified temperature, by the capacity expressed in ml, of the pycnometer at the same temperature.

RESULT AND DISCUSSION

Preformulation study results

Table 3:- preformulation test results

INGREDIENTS PARAMETERS	Nirgundi	Haldi	Sesame oil	Gultheria oil	Eucalyptus oil	Castor oil	Camphor oil
Foreign matter	0.7	0.3	nil	nil	nil	nil	Nil
Moisture	4.5	10	-	-	-	-	-
Water soluble extractive	25	17	-	-	-	-	-
Alcohol soluble extractive	13.58	11.35	-	-	-	-	-
Total ash	4.5	7.52	-	-	-	-	-
Acid Insoluble ash	0.87	0.33	-	-	-	-	-
Refractive Index	-	-	1.4659	1.536	1.462	1.523	1.469
Wt. per ml	-	-	0.920	1.180	0.915	0.945	0.923

Adopted Methodology

The formulation of herbal pain oil was done by following steps:

- All the herbs (haldi and nirgundi) were coarsely grounded and mixed with 500 ml of distilled water.
- Boiled on water bath till one fourth of the volume remains.
- The aqueous extract of herbs was filtered by muslin cloth and the by whattman filter paper 125mm pore size.
- Slowly added sesame oil(base oil) by continuous stirring
- Further heated the mixture to evaporate all the water content from the oil.
- Quantified amount of oil is checked for water content.
- Again filtered the oil.
- Added essential oils (Eucalyptus oil, Castor oil, Camphor oil, Gultheria oil).
- Finally filtered and added methyl paraben as the preservative.
- Stored in a clean and dried bottle.and analyzed physicochemical parameters.

Pain oil formulation

Two formulation was prepared formulation of pain oil comprises of haldi, nirgundi, sesame oil, gultheria oil , castor oil, camphor oil and eucalyptus oil. and preservative.

Table 2: Formulation of pain oil two batch (F₁, F₂)

Ingredients	Formulation F1	Formulation F2
Haldi	5 gm	5 gm
Nirgundi	10 gm	10 gm
Sesame oil	103 ml	100ml
Gultheria oil	0.5ml	1.5ml
Castor oil	0.5ml	1.0ml
Camphor oil	0.5ml	1.5ml
Eucalyptus oil	0.5ml	1.0ml
Total	120 ml	120 ml

Finished product evaluation results

Table 4: General Evaluation Of Pain Oil

S. NO.	TEST	FORMULATION	
		F1	F2
1.	pH Value	5.5	6.0
2.	Specific Gravity (wt/ml)	0.921	0.926
3.	Refractive index	1.487	1.456
4.	Thermal Stability	Ok	Ok
5.	Degradation of product	Nil	Nil
6.	Acid Value	19.34	19.45
7.	Saponification value	115.24	194.53
8..	Peroxide Value	nil	Nil

Table 5: Organoleptic Evaluation of Pain oil

S. NO.	SPECIFICATIONS	FORMULATION	
		F1	F2
1.	Physical Appearance	Oily liquid	Oily liquid
2.	Colour	Pale yellow	Pale yellow
3.	Texture	Slightly Viscous	Slightly Viscous
4.	Odour	Characteristics	Aromatic

Table 6: Microbiological parameters results

S.NO.	After 1-day	After 30- days	After 60 -days	After 90 –days
Formulation no. 1	<u>TMC</u> : less than 100 <u>YMC</u> : less than 100	<u>TMC</u> :less than 100 <u>YMC</u> : less than 100	<u>TMC</u> :less than 100 <u>YMC</u> : less than 100	<u>TMC</u> : less than 100 <u>YMC</u> : less than 100
Formulation no.2	<u>TMC</u> : less than 100 <u>YMC</u> less than 100	<u>TMC</u> less than 100 <u>YMC</u> : less than 100	<u>TMC</u> : less than 100 <u>YMC</u> : less than 100	<u>TMC</u> : less than 100 <u>YMC</u> : less than 100



Figure 1:-Microbial plate of herbal pain relief oil

Table 7:- Accelerated Stability Study data for herbal pain relief oil

MONTHS/ TESTS	F1				F2			
	Initial month	After 1 month	After 2 month	After 3 month	Initial month	After 1 month	After 2 month	After 3 month
Physical appearance	liquid	liquid	liquid	liquid	liquid	liquid	liquid	liquid
Texture	OK	OK	OK	OK	OK	OK	OK	OK
Colour	Pale yellow	Pale yellow	Pale yellow	Pale yellow	Pale yellow	Pale yellow	Pale yellow	Pale yellow
Odour	Characte ristics	Characte ristics	Characte ristics	Characte ristics	Aromatic	Aromatic	Aromatic	Aromatic
pH Value	5.560	5.55	5.58	5.67	6.02	5.99	6.02	6.00
Specific gravity	0.921	0.921	0.931	0.922	0.926	0.926	0.925	0.924
Refractive index	1.487	1.489	1.487	1.487	1.456	1.456	1.460	1.450
Thermal stability	OK	OK	OK	OK	OK	OK	OK	OK
Degradation of product	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Microbial count (cfu/gm)	less than 100	less than 100	less than 100	less than 100	less than 100	less than 100	less than 100	less than 100

CONCLUSION

The prepared herbal oil in two batch, one batch without essential oil and one with essential oil. Extract of vitex negundo, curcuma longa, and sesame oil as base oil along with essential oils (gutharia oil, camphor oil, castor oil and camphor oil.) Both the batch was subjected to stability test in order to check if any degradation or color change occur due to essential oil or base oil.

The density of herbal oils was found to be in the range of 0.921 to 0.926 gm/ml, pH ranges from 5.5-6, acid value ranges from 19.34 to 19.45, whereas peroxide value nil (meq/1000g). Saponification value ranges from 115.24 to 194.33 for f1 and f2 resp.

The stability study shows no physical and chemical changes for a period of 60 days. And microbial contamination was also not seen.

The F₂ batch was selected as it posses better skin penetration and less greasy, because essential oil contains volatile oils. The extract of curcuma longa vitex negundo act as anti inflammatory, antipyretic, antiarthritic, antiseptic, providing relief in general pain as well as in arthritic pain review revealed that essential oil as aroma flavor which help in massage therapy. Very effective in providing relief from pain, elevating mood, provide soothing effect to skin along with number of other benefits.

The present study suggested that herbal oil is beneficial as alternative treatment in pain and inflammation, as use of herbal preparation is devoid of side effects. Clinical studies demonstrate that many forms of arthritis and joint inflammatory conditions can be managed effectively through specific dietary and supplementation practices, in conjunction with other natural treatments including massage, exercise, etc. Unfortunately, many people rely exclusively on anti-inflammatory drugs as their only approach to managing these problems, This is where nutrition and supplementation can be of great value.

ACKNOWLEDGEMENT

I give my immense thanks to express my sincere thanks to BACFO PHARMACEUTICALS.

Conflict Of Interest

We declare that there is no conflict of interests regarding the publication of this paper.

REFERENCE

1. Amr E. Edris, "Pharmaceutical and Therapeutic Potentials of Essential Oils and Their Individual Volatile Constituents: A Review"; Phytotherapy Research, John Wiley & Sons, Ltd, 2007; 1-16.
2. Djilani Abdelouaheb and Amadou Dicko, "The Therapeutic Benefits of Essential Oils", 155-178.
3. James N. Dillard, "Complementary and Alternative Pain Therapy in the Emergency Department"; Emerg Med Clin N Am, 2005; 23: 529-549.

4. Ryan N. Harrison, MA, (<http://www.BeWholeBeWell.com>) "Aromatherapy & Essential Oils", 1-20.
5. Danny Cavanagh & Carol. "Everyday Ayurveda - the practical guide to healthy living" 2004; 1-14.
6. www.aromagregory.com, "essential oil reference guide", 1-3.
7. Rose Jeanne, "Fighting Back Herbs and Aromatherapy for Pain" 2006; 54-56.
8. Kumar A. and Baxi A.J., "Standardization of Ayurvedic medicated oil and effect of moorchan on the amount of marker in the oil", Indian drugs, 2007; 44(2): 122-127.