

## Formulation and evaluation of herbal anti-inflammatory Emulgel prepared from *Vitex negundo* leaves extract

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World Journal of Biology Pharmacy and Health Sciences, 2022, 12(03), 119–124

Publication history: Received on 26 October 2022; revised on 07 December 2022; accepted on 10 December 2022

Article DOI: <https://doi.org/10.30574/wjbphs.2022.12.3.0226>

### Abstract

Topical drug delivery system is dosage forms which are applied directly to skin to cure various disease. In comparison with the other semisolid formulation the use of gel seen to be more advantages both in cosmetics and pharmaceutical preparation. Emulgel have emerged as a promising drug delivery system for the delivery of hydrophobic drugs. The objective of the study was to prepare from the leaves of *Vitex negundo* plant using Carbopol 940 as a gelling agent. Eucalyptus oil and menthe oil were used as penetration enhancers. Propylene glycol amount of distilled water. The skin pH was maintained by addition of tri-ethanolamine. The formulation was evaluated for spread ability, Viscosity, in vitro release drug content pH, physical stability etc. On this experimental work prevalent that the herbal gel of leaves extract from leaves of *Vitex negundo* found good gelling property and it will be useful as anti-inflammatory gel as per the literature.

**Keywords:** Anti-Inflammatory; Emulgel; Enhancer; Penetration; Topical drug delivery; *Vitex negundo*

### 1. Introduction

The drug is administered to a human body through different route such as oral, parenteral, rectal, and sublingual etc. The oral route is the best route for the administration of the drug but the topical route is preferable to avoid the first pass metabolism. Emulgel are the basically emulsion which are w/o or o/w type that are gel in which gelling agent is use for mixing. Emulgel are the best vehicle for the hydrophobic drug. The emulgel has an ability to deliver both lipophilic as well as hydrophobic drug as they contained to phase, aqueous and oily phase. The emulgel are apply to the skin suitably as it non- greasy easily spreadable as compared to other topical formulation that require excess rubbing. (1)

Gel which are used for dermatological properties have a few positive properties for example being emollient, greaseless, easily removable, non-staining, and compatible with various excipient. The emulgel may provide a better option when it is concerned with topical delivery of poorly water-soluble drug. It is provided better and stable vehicle for poorly water soluble or hydrophobic drug. (2)

The topical drug delivery system has followed the first pass metabolism there the chances of degradation of medicament. From the gastro intestinal tract and the bother of intravenous therapy in avoided emulgel formulation has been fruitful importance in the pharmaceutical field under the category of semisolid dosage form. (3)

The Gel formulation topically show higher drug release than ointment and creams. It has many advantages of emulsion and gels. Major disadvantages are their inability to deliver hydrophobic drug and instability during storage. Such type

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of problem can be overcome by using the emulsion-based approach that is emulgel preparation and thereby hydrophobic drug are successfully incorporated and have a unique property of gel. (4)

Several analgesic preparations are available in the market as different topical preparation. *Vitex negundo* are effective and use as an anti-inflammatory and analgesic agent. The *Vitex negundo* contain an essential oil isolated from the leaves and contain a  $\beta$ -caryophyllene, viridifloral 4-terpeniol are the chemical constituent which produce anti-inflammatory and analgesic effect. The emulgel prepare from natural ingredient hence it is completely free from irritation or side effect as compared to the synthetic gel. This emulgel contain peppermint oil and eucalyptus oil enhance the penetration and menthol increase the cooling effect. As compared to ointment and cream the gel formulation faster drug release. There is no marketed topical formulation of *Vitex nigundo* available. It is available in the form of oil only not any pharmaceutical preparation is available in market. The emulgel have many advantages like greaseless, easily spreadable, easily removable, emollient and have good skin penetration long shelf life. (5)

### 1.1. Advantages

- Incorporation of hydrophobic drugs
- Better loading capacity
- Better stability
- No intensive sonication
- Avoiding first pass metabolism
- Avoiding gastrointestinal incompatibility
- More selective for a specific site
- Improved patient compliance
- Convenient and easy to apply [1]

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## 2. Introduction about *Vitex negundo*

*Vitex negundo* is a woody, aromatic shrub growing to a small tree and is a much-branched shrub up to 5 m tall or sometimes a small, slender tree with thin, gray bark. *Vitex negundo* is mentioned in Ayurveda as useful in treatment of arthritic disorders. Ayurveda mentions several plants acting as anti-inflammatory agents in arthritic disorders. *V. negundo* is a reputed drug in Ayurveda and is beneficial in inflammatory disorders. *V. negundo*, commonly known as *Nirgundi* is a widely available plant all over India. The leaves were washed and dried in oven at a temperature not exceeding 50°C and ground to obtained from sieve no.40# powder. *Vitex negundo* is a much-branched shrub up to 5 m tall or sometimes a small, slender tree with thin, gray bark. [6]

- Family: -Lamiaceae
- Genus: - vitex
- Species: -*V. negundo*
- Kingdom: -Plantae

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## 3. Material and methods

### 3.1. Plants materials

The plant of *Vitex negundo* was obtained from the farm.

### 3.2. Vehicle

The vehicle use for the formulation of emulgel must possess properties such as should effectively deposit and evenly distribute the drug. E.g.: -Water, and alcohol.

#### 3.2.1. Aqueous phase

The aqueous phase of the emulsion is formed by using aqueous material alcohol and water are commonly used.

#### 3.2.2. Oil phase

Eucalyptus oil & menthol oil are used in oily phase to enhance the penetration.

### 3.3. Emulsifier

The emulsifying agent are used to reduce interfacial tension between two phases such as water oil. E.g., Span 60, tween 80.

### 3.4. Gelling agent

e.g. Consistency and the gelling property can be increase by using various gelling such as Carbopol 940.

### 3.5. Preservative

e.g. The substance which preserves the preparation for long period such as Methyl paraben and propyl paraben.

### 3.6. Method of preparation

#### 3.6.1. Extraction Method

40g of dried leaves sample weighed and extracted in an extracted in a Soxhlet device with 250 ml solvent at room temperature for 8 hours.

#### 3.6.2. Method of preparation of Emulgel

Emulgel are prepared by incorporating gel and emulsion the emulsion & gel prepared separately and mixed.

Firstly, Prepare the aqueous phase then prepare an oily phase, both are mix and prepare the emulsion after preparing the emulsion then prepare a gel phase and gel is incorporated in emulsion and finally emulgel are prepare.

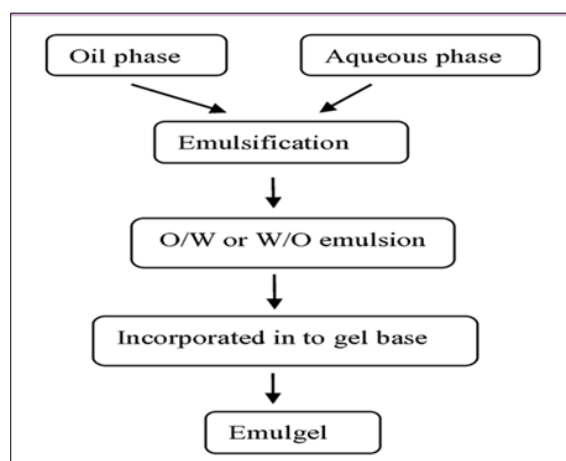
Aqueous phase: - Dissolve Tween 60 in purified water then methyl and propyl paraben dissolved in propylene glycol whereas extract of *Vitex negundo* or dissolve in water prepare the aqueous phase.

Oily phase: - The oily phase of the emulsion was prepared by dissolving span 20 in liquid paraffin and added the castor oil and menthe oil & prepare the oily phase.

Gel phase: - The gel phase information was prepared by using Carbopol 940 in purified water with constant stirring. Both oily & aqueous phase are heated separately at 70 °C– 80°C firstly prepare emulsion, aqueous phase is dispersed into oil phase and make emulsion.

After making the emulsion then added the gel phase with constant starring and emulsion as prepare & transfer into the container with direction external used only. (7)

#### 3.6.3. Formulation of Emulgel



**Figure 1** Formulation of Emulgel

**Table 1** Formulation table of Emulgel Preparation

SR.NO	Name of Ingredient	F1	F2	F3
1	<i>Vitex negundo</i> extract	01 mg	01 mg	01 mg
2	Carbopol 940	0.8 mg	01 mg	0.8 mg
3	Liquid Paraffin	4.2ml	4.2ml	4.2ml
4	Tween 20	0.5 mg	0.5 mg	0.5 mg
5	Span 20	0.5 mg	0.5 mg	0.5 mg
6	Propylene Glycol	0.5 mg	0.5 mg	0.5 mg
7	Methyl Paraben	0.1mg	0.1mg	0.1mg
8	Ethyl Paraben	0.5 mg	0.5 mg	0.5 mg
9	Peppermint oil	0.8 ml	1.5 ml	01ml
10	Eucalyptus oil	0.8ml	1.5 ml	01ml
11	Menthol	0.5 mg	0.5 mg	0.5 mg
12	Water	q.s	q.s	q.s

### 3.7. Evaluation of Emulgel

#### 3.7.1. Physical Evaluation

##### Measurement of pH determination

pH of the emulgel was measured by using pH meter. 1g of each formulation dispersed in 10ml of purified water separately all the dispersion were shaken properly and determine the pH using a digital pH meter.

##### Color

The color of the formulation checked against white background green color was observed.

##### Odor

The odor of the gel was checked by mixing the gel in water and smelling it. Odorless gel was found.

##### Consistency

The Consistency was checked by applying the gel on skin. The best Consistency gel was found.

##### Greasiness

The greasiness was checked by applying the gel on skin. The non- oily was found.

##### Homogeneity

The homogeneity was tested by visual inspection after allowing them to get in a container homogenizes mater was found.

##### Spread ability

Spread ability is checked by two slides put an emulgel on first slide and cover this by second slide and these are easily spread.

##### Stability study

The formulation gel was filled in the collapsible tube and store at the different temperature and humidity condition then checked appearance, pH and spread ability.

Skin irritancy test

Mark the location on the dorsal surface of the hand applies the gel to the designated area and check the irritancy

### 3.8. Type of emulsion

Little amount of water is mixed with emulsion. If water distributes uniformly, it is O/W type of emulsion and if water separates out as a layer than it is W/O type of emulsion.

The emulsion was determined by using a dilution method

**Table 2** Emulsion Type

Emulsion	Emulsion Type
F1	O/W
F2	O/W
F3	O/W

### 3.9. Solubility of *Vitex negundo* Extract

**Table 3** Solubility of *Vitex negundo* in various solvents

Sr. No	Vehicle	Solubility
1	Alcohol	Soluble
2	Water	Soluble
3	Propylene glycol	Soluble
4	Acetone	Soluble

## 4. Results and discussion

The herbal gel was prepared and subjected to evaluation of the various parameter. The herbal gel was dark greenish in color and had a cool smooth feeling after application. The pH of gel was 6-7. The gel was found non-oil, non-irritant, and easily removable after application through a water and cotton gauze.

The herbal gel was dark greenish color and translucent in appearance and had a cool smooth feeling on application. PH also maintains constant through the study which was found 6-7. Spread ability were also measure and found to be less variant than the initially prepare gel after performing stability study.

The gel is non-greasy, non-sticky and nontoxic. These are easily removed after application through water and cotton gauze.

Stability study: - All the prepare emulgel formulation were found to be stable upon storage for 3 week at room temperature no change was observed in their physical appearance, pH Spread ability, viscosity, phase separation are not observe.

**Table 4** Evaluation Parametrs

Formulation	pH	Spread ability	Skin irritation
F1	6.3	14.17	Nil
F2	6.2	18.40	Nil
F3	6.2	16.30	Nil

**Table 5** Physical Properties of Formulation

Sr no.	Color	Phase separation	Grittiness	Homogeneity	Consistency
1	Green	None	-	Excellent	Excellent
2	Pale Green	None	-	Good	Good
3	Green	None	-	Excellent	Excellent

## 5. Conclusion

we can concluded hereby that it is a most effective drug delivery system. The herbal formulation having demand in the market. Because having best therapeutic effect and without having any adverse effect. This formulated gel is having anti-inflammatory properties with therapeutic effect.

In the experiment we can conclude and proven to be one of the most effective, better, and convenient drug delivery system. Emulgel is non- greasy, non-sticky and easily applicable. Herbal formulation has grooving demand in the market. Establish the herbal gel containing *Vitex negundo* leaves extract. Emulgel can be considered as an emerging novel drug delivery system with enhanced characteristics and advantages.

## Compliance with ethical standards

### Acknowledgments

We are very thankful to the principal, SMBT Institute of Diploma Pharmacy, and SMBT Trust Dhamangaon for giving Opportunity and permission to performed research activity in laboratories.

### Disclosure of conflict of interest

There is no conflict of interest to be disclosed.

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