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## Formulation and Evaluation of Herbal Gel Tooth Herbal Gel



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### ABSTRACT

The main purpose of this work is the formulation and evaluation of tooth herbal gel of clove oil for the treatment of dental diseases. Dental disease is a major health problem throughout the world. The active ingredient of this tooth herbal gel is clove oil. The clove oil was evaluated for physical parameters like acid value, saponification value, and ester value. The gel was prepared using Carbopol, Propylene glycol, and clove oil as a permeation enhancer. Three gel formulations were prepared with various concentrations of Carbopol. The prepared tooth herbal gel was evaluated for various properties such as pH, spreadability, homogeneity, odor, appearance.



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## INTRODUCTION

At current time dental diseases are one of the rising health problems in the world. Either dental problems are acute or chronic. For the treatment of various dental problems use of effective anti-bacterial agents and sufficient drug concentration are required at site of action without any adverse drug effects(1). Dentifrice is used to maintain oral health and dental health having property to clean and polish the teeth. Dentifrices are mainly of two types one is simple dentifrices and another is therapeutic dentifrices (2). Dentifrices are available in market in the form of paste, gel and powder. These preparations contain few flavouring agent, detergent, fluoride, binders and various most important ingredients like humectants, desensitizers and several medications either they are herbal based or chemical based. They help to prevention from dental caries, dental plaque and many other oral diseases. In now days use of herbal-based dentifrices are popular due to their less side effects(3).

**Herbal gels:** Herbal gels are defined as semi-inflexible systems in which movements of a dispersing medium is confined using an interlacing three-dimensional network of particles from different herbs or solvated macromolecules of the dispersed phase. Herbal gels have better ability as a vehicle to manage drug topically in comparison to ointment, they are non-sticky and require less energy during formulation and have aesthetic value. Herbal gels have several benefits over traditional gels, including a reduction in side effects and an increase in therapeutic effectiveness.

To target local diseases at the mucosal surface and decrease total dose required and potential adverse effects from adhesive components, mucoadhesive dosage forms have been used. The binding elements in these formulations were polymers. When used in formulations these polymers are frequently water soluble, and attract water from the mucosal surface, making powerful contact. When these polymers are saturated with water and increases the retention time on mucous surface and promotes adhesive contact (4).

Formulated gel was evaluated for spread-ability, pH, homogeneity, odour and appearance. Surface pH values that were neutral or mildly acidic suggested that this formulation could be used without causing any oral cavity irritation. The polymer formulation spreadability was found to be within acceptable ranges.

## MATERIAL AND METHODS

Table No. 1. Material used

S.NO.	MATERIALS	FUNCTION
1.	Clove oil	Active pharmaceutical ingredients
2.	Carbopol940	Gelling agent
3.	Polyethylene glycol	Cosolvent
4.	Glycerine	Drug solubilizer
5.	Methyl paraben	Preservative
6.	Propyl paraben	Preservative
7.	Saccharin	Sweetening agent
8.	Distilled water	Vehicle



Figure No. 1. Material used

### 1. Clove oil:

- Clove is the oil distilled from the dried flower buds of *Syzygium aromaticum*(Linn.) Merrill and Perry [*Eugenia caryophyllus*].

### Description:

- Clove oil is a clear, colorless or pale-yellow liquid when freshly distilled, becoming darker and thicker by aging or exposure to air; odour as of clove.
- Clove oil contains not less than 85.0 percent w/w and not more than 95.0 percent w/w of phenolic substances mainly eugenol, C<sub>10</sub>H<sub>12</sub>O<sub>2</sub>.
- It acts as active pharmaceutical agent (5).

## 2. Carbopol:

- These are also known as carbomers. Carbomers are high molecular mass polymers of acrylic acid cross-linked with polyalkenyl ethers of sugars or polyalcohols.
- Carbomers contain not less than 56.0 percent and not more than 68.0 percent of carboxylic acid (-COOH) groups, calculated on a dried basis.

### Description:

- It is a white, fluffy powder.
- It is hygroscopic.
- It is used as a gelling agent (6).

## 3. Polyethylene glycol:

Polyethylene glycol is a synthetic resin made by polymerizing ethylene glycol, in particular series of water-soluble oligomers.

### Description:

- It is a clear, colourless or viscous liquid.
- Works as a cosolvent (7).

## 4. Glycerine: Glycerol

**Molecular formula:**  $C_3H_8O_3$ .

Glycerine is propane-1,2,3-triol.

Glycerine contains not less than 98.0 percent and not more than 101.0 percent of  $C_3H_8O_3$ , calculated on an anhydrous basis.

### Description:

- Glycerine is a clear, colourless, syrupy liquid.
- It is very hygroscopic in nature.
- It is used as a drug solubilizer(8).

## 5. Methylparaben:

Methyl hydroxybenzoate

**Molecular formula:**  $C_8H_8O_3$ .

Methylparaben is methyl 4-hydroxybenzoate.

Methylparaben contains not less than 99.0 percent and not more than 101.0 percent of  $C_8H_8O_3$ .

### Description:

- It is colourless or white crystalline powder.
- It is used as a preservative (9).

## 6. Propyl paraben:

Propyl Hydroxybenzoate

**Molecular formula:**  $C_{10}H_{12}O_3$ .

Propylparaben is propyl 4-hydroxybenzoate.

Propylparaben contains not less than 99.0 percent and not less than 101.0 percent of  $C_{10}H_{12}O_3$ , calculates on a dried basis.

### Description:

- It is a white, odourless, crystalline powder.
- It is used as a preservative (10).

## 7. Saccharin:

**Molecular formula:**  $C_7H_5NO_3S$ .

Saccharin is 1,2-benzisothiazol-3(2H)-one 1,1-dioxide.

Saccharin contains not less than 98.0 percent and not more than 101.0 percent of  $C_7H_5NO_3S$ , calculated on dried basis.

**Description:**

- These are white crystals or white crystalline powder, which is odourless or with a faint, aromatic odour.
- It is used as a sweetening agent (11).

**1.1. Procedure for preparation of gel:**

1. Carbopol 940 was soaked in water for 24 hours.
2. A weighed amount of methyl paraben and propyl paraben were added and thoroughly mixed.
3. Required quantity of polyethylene glycol were added and stirred continuously.
4. Required quantity of glycerine were added.
5. A weighed amount of Carbopol gel was added.
6. Clove oil was added to the prepared gel.
7. Stirring is done until a homogenous product is formed.

**1.2. Composition of gel formulations**

**Table No. 2. Composition of gel**

INGREDIENTS	F1	F2	F3
Clove oil (ml)	0.75	0.75	0.75
Carbopol (g)	0.4	0.6	0.9
Polyethylene glycol (ml)	15	15	15
Glycerine (ml)	5	5	5
Methyl paraben (g)	0.2	0.2	0.2
Propyl paraben (g)	0.02	0.02	0.02
Saccharin (g)	0.4	0.4	0.4
Distilled water	q. s	q. s	q. s

**1.3. Physicochemical characteristics of clove oil:**

The clove oil was analyzed for physicochemical characteristics like acid value, ester value, solubility, saponification value, colour, odour.

### 1. Acid value:

The acid value is the number that expresses in milligrams the amount of potassium hydroxide necessary to neutralize the free fatty acids present in 1 g of the substance(12).

$$\text{Acid value} = \frac{\text{potassium hydroxide consumed}}{\text{weight (g) of the sample}} \times 5.611$$

### 2. Saponification value:

The saponification value is the number of milligrams of potassium hydroxide necessary to neutralize the free fatty acids and to saponify the esters present in 1g of the substance (13).

Saponification value = mg of potassium hydroxide consumed by 1g clove oil.

### 3. Ester value:

The ester value is the number of milligrams of potassium hydroxide required to saponify the esters present in 1g of the substance (14).

$$\text{Ester value} = \text{Saponification value} - \text{Acid value.}$$

### 4. Solubility:

Solubility is the ability of a substance, the solute, to form a solution with another substance, the solvent.

- Clove oil is freely soluble in ethanol.

### 5. Colour:

- The colour of the formulation was checked out against a white background.

### 6. Odour:

- The odour of the gels was checked by mixing the gel in water and taking the smell.

## 6. Evaluation of gel formulation

### 1. Physical appearance:

- **Consistency**

The consistency was checked by applying on skin.

- **Greasiness**

The greasiness was assisted by application on the skin.

- **Appearance**

All the formulations of clove oil gel were pale yellow in colour.

- **Odour**

The odour of gel was checked by mixing the gel in water and taking the smell.

## **2. Determination of pH:**

The pH of gel was determined using digital pH meter by dipping the glass electrode completely into gel system (15).

## **3. Determination of spreadability:**

Spreadability was determined by glass slide apparatus. 2gm of gel was placed on the slide and another slide is placed on the slide, the gel was then sandwiched between the slides. Slides were pulled in opposite directions. Measure the spreading of gel after some time. Note the values of at least three readings.

Spreadability was calculated using the following formula:

$$S = M \times L/T$$

S = spreadability

M = mass of upper slide

L = length of moved glass slide

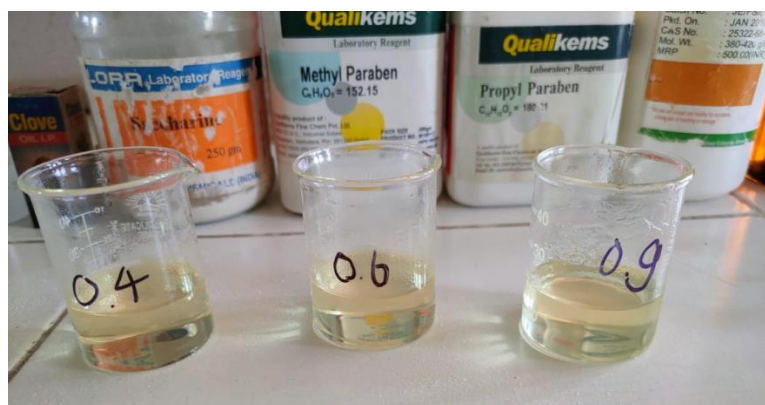
T = time in seconds.

## **4. Determination of homogeneity:**

All the developed gels were tested for homogeneity by visual inspection after the gel have been set in the container(16-17). They were tested for their appearance and the presence of any aggregates.



**RESULT AND DISCUSSION:**



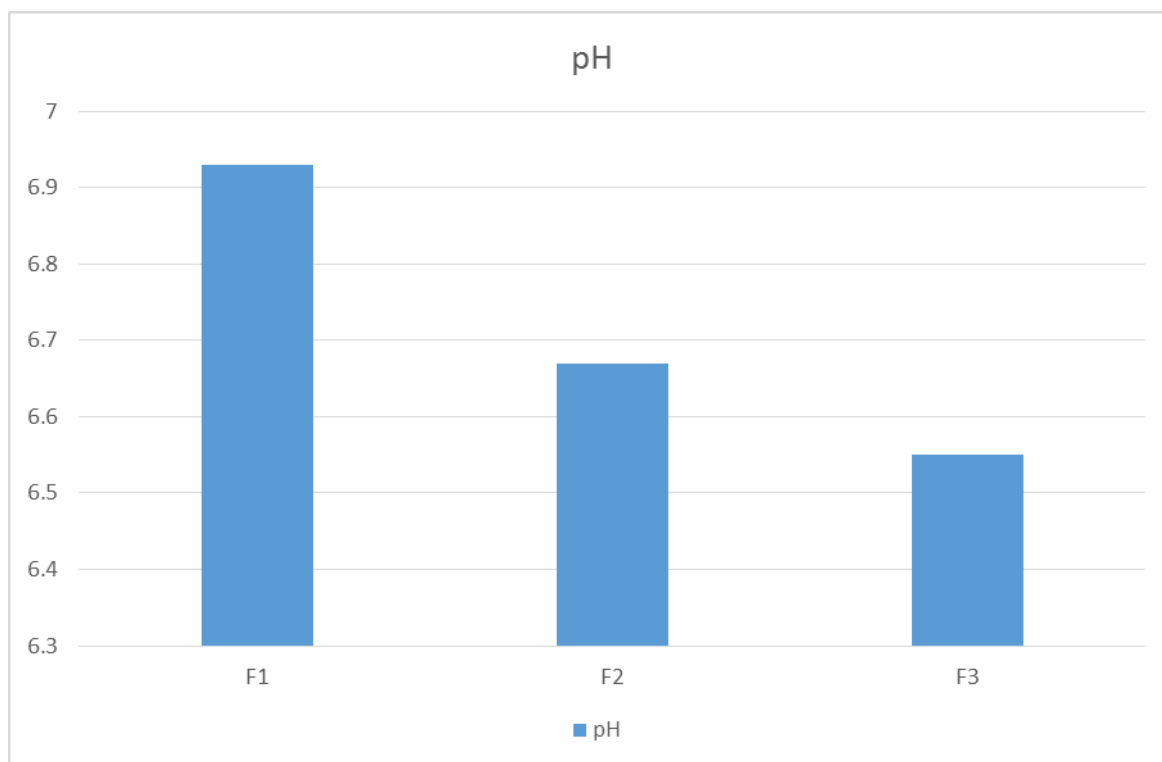
**Figure no. 2. Prepared sample of tooth herbal gel**

**Table No. 3. Physicochemical characteristics of clove oil**

S.no.	Parameters	Clove oil procured	Clove oil standard
1.	Colour	Pale yellow	Pale yellow
2.	Odour	Aromatic	Aromatic
3.	Acid value	3.36	3.84
4.	Saponification value	40.1	42.07
5.	Ester value	36.74	38.22
6.	Solubility	Freely soluble	Freely soluble

**Table No. 4. Evaluation of gel formulation**

Formulation	Appearance	pH	Homogeneity	Odour	Spreadability(gcm/sec)
F1	Pale yellow	6.93	Good	Aromatic	18.45
F2	Pale yellow	6.67	Very good	Aromatic	17.38
F3	Pale yellow	6.55	Good	Aromatic	14.04



**Figure no. 3. pH of formulated tooth herbal gel samples**

#### **DISCUSSION:**

The procured clove oil was characterized for the following parameters:

Acid value: 3.36

Ester value: 36.74

Solubility: Freely soluble on ethanol

The formulation was developed by using clove oil of same concentration and Carbopol 940 at different concentrations. The formulation composition is given in Table no. 2.

All the three formulations were evaluated for physical properties. All the formulations were pale yellow in colour and had a characteristic odour of clove oil as shown in Table no. 4.

The pH of all formulations was ranged from 6.5 to 6.9 as shown in Table no. 4, which was well within the normal pH range of buccal cavity 6-7, which substantiates that the prepared gels will be irritation free.

The homogeneity of all formulations was shown in Table no. 4. All the formulations were homogeneous and free from aggregates.

The spread ability of the gels was found to be in the range of 14.04 to 18.45 gm-cm/sec, confirming that gels may spread smoothly and uniformly. The formulations were translucent.

## CONCLUSION

The formulation developed from clove oil showed significant results. After the study it can be concluded that, the above-formulated gel is totally capable of cleaning the teeth, maintaining the oral hygiene and also prevent the growth of microorganisms inside the oral cavity.

The tooth herbal gel may also possess anti-plaque, anti-toothache and also prevents gum related problems.

The tooth herbal gel has high penetration power as compared to other ointments or mouthwashes etc. It absorbs fast in gums and reduce inflammations and other dental problems.

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