



## FORMULATION AND EVALUATION OF HERBAL ORAL GEL BY USING EXTRACT OF *MANILKARA ZAPOTA* LEAVES TREATS MOUTH ULCER

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### ABSTRACT

The present study focuses on the formulation and evaluation of a herbal oral gel containing *Manilkara zapota* leaf extract for the treatment of mouth ulcers. Oral gels are semi-solid preparations that ensure prolonged retention at the application site and enhance therapeutic efficacy. *M. zapota* leaves are known to possess anti-inflammatory, antioxidant, analgesic, and wound-healing properties due to their rich phytoconstituents such as oleanolic acid, saponins, flavonoids, and phenolic compounds. In this study, the leaves were subjected to Soxhlet extraction, and the obtained extract was incorporated into a Carbopol-based gel formulation. The prepared gel was evaluated for colour, odour, consistency, pH, spreadability, viscosity, extrudability, and gel strength. The results indicated that the herbal gel exhibited smooth consistency, acceptable pH (5.6), good spreadability, high viscosity, and satisfactory extrudability, making it suitable for oral application. The formulation demonstrated good physical stability and favourable pharmaceutical properties. Overall, the study concludes that *Manilkara zapota* leaf extract can be effectively utilized in an oral gel formulation for managing mouth ulcers, offering a safe, economical, and natural alternative to conventional synthetic treatments.

**KEYWORDS:** *Manilkara zapota*, Herbal oral gel, Mouth ulcer, Oral mucosal treatment.

## 1. INTRODUCTION

Oral gel is a semi-solid, gel-based pharmaceutical formulation designed for application inside the mouth. It is commonly used to deliver medication directly to the oral cavity, targeting conditions such as mouth ulcers, gum infections, oral thrush, dental pain, or inflammation. Because of its gel consistency, it adheres well to the mucosal surfaces, allowing the active ingredient to stay in place longer and act more effectively.

Oral gels may contain antiseptic, analgesic, antifungal, antibacterial, anti-inflammatory, or anesthetic agents depending on their purpose. They are easy to apply, provide quick relief, and are preferred for localized treatment. Examples include gels for teething in children, gels for canker sores, and antifungal gels for treating oral candidiasis.

### 1.1 Types of Oral Gels

**Oral gels can be categorized based on their purpose or active ingredient:**

#### A. Therapeutic (Medicinal) Oral Gels

- **Analgesic gels** – for pain relief (e.g., benzocaine gel)
- **Anti-inflammatory gels** – for swelling and irritation
- **Antiseptic/antibacterial gels** – to prevent or treat infection
- **Antifungal gels** – for oral thrush (e.g., miconazole gel)
- **Corticosteroid gels** – for ulcers and inflammation
- **Astringent gels** – to shrink tissues and reduce discomfort

#### B. Dental/Oral Care Gels

- **Fluoride gels** – for cavity prevention
- **Desensitizing gels** – used for tooth sensitivity
- **Teething gels** – for infants (mild anesthetic gels)

#### C. Cosmetic/General Use Gels

- **Mouth freshening gels**
- **Whitening gels** (though more common as strips or trays)

### 1.2 Classification of Oral Gels

**Oral gels can also be classified based on their gel-forming base or mechanism:**

#### A. Based on Gel Base

##### 1. Synthetic polymer gels

- Carboxymethyl cellulose (CMC)
- Carbopol
- Polyvinyl alcohol

## **2. Natural polymer gels**

- Pectin
- Guar gum
- Xanthan gum
- Gelatin

## **B. Based on Drug Release Mechanism**

**1. Conventional gels** – immediate release

**2. Bioadhesive gels** – designed to stick longer to mucosa

**3. Sustained-release gels** – slow and controlled drug release

## **C. Based on Application Route (Within Oral Cavity)**

- Gingival gels
- Buccal gels
- Sublingual gels
- Dental gels

## **1.3 Advantages of Oral Gels**

- Easy application and comfortable on mucosal surfaces
- Good adhesion to the oral cavity, ensuring prolonged contact
- Localized action reduces systemic side effects
- Quick onset of relief, especially for pain or burning
- Pleasant taste can improve patient compliance
- Non-greasy and smooth consistency
- Suitable for pediatric and geriatric patients

## **1.4 Disadvantages of Oral Gels**

- May wash away with saliva, reducing contact time
- Bitter or unpleasant taste for some formulations
- Possible irritation or allergy to certain ingredients

- Short retention time compared to patches or films
- Difficult to apply accurately in certain oral areas
- Some active ingredients may be unstable in moist environments

## 1.5 Applications of Oral Gels

**Oral gels are used for**

### **A. Dental and Oral Conditions:**

- Mouth ulcers (aphthous stomatitis)
- Gingivitis and gum infections
- Oral candidiasis (thrush)
- Toothache and teething pain
- Denture-related soreness

### **B. Professional Dental Use**

- Fluoride treatment
- Desensitization procedures
- Local anesthesia before dental procedures

### **C. Symptomatic Relief**

- Burning mouth syndrome
- Inflammation and irritation
- Pain from braces or orthodontic appliances

## 2. PLANT PROFILE

Nature has blessed us with a wonderful flora and fauna, which has made our life beautiful. One of these wonders is a Sapodilla fruit. The Sapotaceae family includes about 500 species of evergreen trees and shrubs in around 65 genera Sapodilla, which is scientifically known as *Manilkara* /*apala* is one of the tropical plants belonging to this family. It is grown for many purposes such as for its fruits, timber and latex. The fruit sapodilla is commonly known as chickoo or sapota, which should not be confused with sapote that means soft and edible fruits. It possesses tremendous nutritional value. Sapodilla is regarded as natural energy booster as it contains fructose and sucrose. It has resemblance to pear because of this it was also called as *Manilkara* *Achras*, *Achras* *Capota* or *Nispero* *Achras*, (a derivative of the Greek word *Achras* for the Pear tree). Now it is cultivated throughout India, though it is native of Mexico

and Central America. The plant contains several phytochemical constituents like saponin, myricein-3-0-a-L-thammoside, ascorbic acid, - carotene, which have medicinal benefits. Moreover, various parts of the plant are used as home remedies to cure health problems.



**Fig. 1: Manilkara Zapota.**

**2.1 History:** Sapodilla is a tropical fruit. It is believed to be native to Yucatan and possibly other nearby parts of southern Mexico, as well as northern Belize and north-eastern Guatemala. It is believed that sapodilla was cultivated throughout tropical America, West Indies and southern part of Florida mainland, where it is a tall tree found in forests. Early in colonial times, it was carried to Philippines by the Spanish and later was adopted everywhere in the old world tropics. From the Philippines, it spread throughout Southeast Asia as a popular fruit tree, where it is not only consumed but also exported. It reached Sri Lanka in 1802. Sapodilla was introduced to India in 1895. Various species of sapodilla are now

cultivated in Africa, India, East Indies, Philippines, Malaysia, Thailand, the tropical and sub-tropical regions of America and in almost all tropical countries worldwide.

**2.2 Cultivation:** Sapodilla plant is usually grown in tropical areas, but can also be grown in semi-tropical areas in green-house. It can be grown up to 1200 m above sea level. Being a tropical fruit, it needs warm (10-38° C) and humid climate (70% relative humidity) for growth. Alluvial, sandy loam, red laterite and medium black soil having good drainage system, with acidic to neutral pH, provide best environment for sapodilla. For good yield, fertilizers containing 6-8% nitrogen, 2-4% phosphoric acid and 6-8% potash every 2-3 months and increasing gradually 10-250g per plant are used in the initial years. In the later years, 2 to 3 applications per year prove to be sufficient. Very little pruning is required for the plant. Plant should be protected from frost. Indian cultivars of sapodilla are summarized in Table 1.

**2.3 Propagation:** The sapodilla is most commonly propagated by seed and grafting. Seeds germinate readily but growth is slow and it takes 5 to 8 years. Seeds can remain viable for several years. Vegetative propagation should be used to obtain uniform planting material and avoid the initial slow growth of seedling trees.

**2.4 Effective Storage:** Mostly sapodillas are picked ripe. At normal room temperature and relative humidity (RH), the hard and immature sapodillas ripen within 9-10 days and rot in two weeks but extremely low temperature seriously retards the ripening of the fruit and damages its quality. Low relative humidity causes the fruit to wrinkle and shrivel up and extreme humidity causes the fruits to wrinkle and shrivel up and extreme humidity causes toughness. Sapodillas can be stored for 2 to 3 weeks at 12 to 16°C with 85 to 90% RH. The fruits can also be stored with 5% CO<sub>2</sub> for 18 days at normal temperature. Fully matured ripe fruits can be kept at a temperature of 1.67°C for as long as six weeks.

**2.5 Geographical Distribution:** Cultivation of sapodilla is done in the warm and humid areas of the world. It is indigenous to southern Mexico, Yucatan peninsula, central America and south America. It is very popular in Asian countries like Philippines, Sri Lanka, Thailand, Malaysia and India. In India sapodilla is grown in several states including Chennai, Andhra Pradesh, Maharashtra and Gujarat. Indian names of chickoo and international synonyms are depicted.

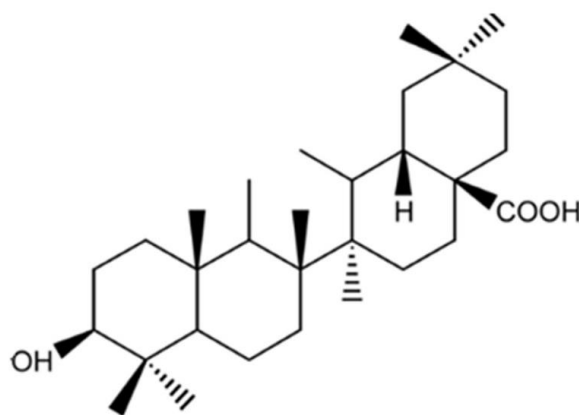
## 2.6 Botanical description

**Habit:** The sapodilla tree is an attractive upright, slow- growing, evergreen tree, which has extensive root system Tree may develop a dense and rounded crown with age. which can be sometimes open or irregular in shape, but at young stage it is distinctly pyramidal n shape Sapodilla tree is very rich in white, gunny latex called chickle. In the tropics, height of the trees can reach up to 100 feet, but it grafted cultivars are relatively shorter.

**Leaves:** The leaves are 3 to 4-1/2 inches long and I to 1- 1/2 inches wide. They are green, glossy, alter and spirally clustered at the lip of forked twigs. Stomata are more on upper participations and bell-like, approximately 3/8 inch in fit with these (trees) outer at these inner sepals. They enclose a pale green to white Tibila corolla and six Mand the stigma extends beyond the corella. They are bene slender stalks in the anil of the leaves. There are several luses of lowers throughout the year.

**Tris:** The sapodilla fruit is round or oval shaped, 2-4 inches in Diameter. The skin is lows and Scruffy. The flesh, which varies from yellow to shades of brown, has other or a galar restore. The raw fruit has a high latex content and a bit of latex remains even in the ripe fit. The raw fruit skin is rough and leathery and in becomes smooth on ripening. Unripe fruit has high weights of tannin, which can packer mouth. The favor of ripe fruit is deliciously feet and pleasant. It ranges from a pear flavour to crimetry brewing.

**2.7 Phytoconstituents Of Sapodilla:** The plant contains several physiochemical constituents belonging to categories such an alkaloids, carbohydrates, glycosides, (tannins, triterpenes and flavonoids etc., I also contain amino acids, proteins, ascorbic acid, phenols, carotenoids and naortals like iron, copper, zinc, calcium and potassium Vitamins are also present in substantial quantity, which make Chickoo useful cosmetic. The concentration of constituents varies in leaves, fruits, latex seeds and back. Major constituents isolated from fruits of M. sapota are polyphmals.



**Fig: 2 Structure Of Oleanolic acid.**

## 2.8 Pharmacological Uses

**Anti- Inflammatory:** Anti-inflammatory and antipyretic activity: Anti- inflammatory and anti-pyretic activity of *Manilkara zapota* leaves was found in albino wistar rats. Inflammation is associated with histamine or serotonin P release in first phase and formation and release of prostaglandin in the second phase. Anti-inflammatory activity of *Manilkara zapota* may be due to inhibition of release of histamine and serotonin. Inhibition of biosynthesis of prostaglandins by inhibiting cyclooxygenase pathway may also contribute for both anti-inflammatory and anti-pyretic activities. Anti- inflammatory and anti-pyretic activities of the leaves of the plant could be attributed to the active constituents like lupeol acetate, oleanolic acid; apigenin-7-O-a-L-thamnoside and myricetin-3-O-a-L-rhamnoside present in the *Manilkara zapota* leaves.

**Anti-Oxidant:** Anti-oxidants are compounds that inhibit oxidation, a chemical reaction that can produce free radicals. Auto-oxidation leads to degradation of Organic compounds, including living matter. Antioxidants are frequently added to industrial products, such as polymers, fuels, and lubricants, to extend their useable lifetimes.

## 3. MATERIAL AND METHOD

### 3.1 Pre-Extraction Preparation Of Plant Samples For Soxhlet

**Extraction:** The first step of studying medicinal plants is the creation of plant samples to preserve the phytoconstituents in the plants earlier to extraction. Plant materials like leaves, stem, barks, Toos, fruit and flowers are then used for the extraction. The following criteria are essential prior to the extraction. Selection and collection of plant materials.

The selection and the collection of plant material are important in making efficient phytoconstituent isolation. The disease free and healthy plants only selected for the plant extraction. This guideline explains the relevant collection time, collection techniques, processing and storage of plant material.

**Drying Of Plant Material:** The drying process is important for the extraction of plant materials, the fresh plant materials are having the active enzymes which is produces the active constituents intermediates and metabolic reactions in the plant materials, so that the drying is important for the pre-extraction preparation of plant materials, Many of the researchers are drying the plant in air dry process under the shade in the dark room because the overheat can losses the volatile substances from plant materials and some of the light sensitive constituents may loses in light condition And some of the dry methods like Microwave Drying.

### 3.2 Formulation Of Herbal Oral Gel

A sufficient quantity of Carbopol 934 was soaked in distilled water overnight, and then mixed with distilled water with non-stop stirring using a mechanical stirrer. Another solution containing varying quantity of EEA, EEO and EEZ and the required number of methyl paraben and propyl paraben were added with nonstop stirring. Propylene glycol was also added to the solution. This prepared solution was further mixed with Carbopol 934 solution carefully with continuous stirring, volume was made up to 30ml with water and the Ph was maintain by addition of triethanolamine to obtain gel of required consistency. Formulations of herbal gels were formulated by varying the herbal ingredients in each of the formulation.

**Table 1: Formulation Of Herbal Oral Gel.**

INGREDIENTS	QUANTITY
Extract	0.20gm
Carbopol	1gm
Propylene glycol	10ml
Liquid paraben	0.3ml
Glycerin	1.0ml
Triethanolamine	Q.s
Water	100ml

**Procedure:** Take 15ml of distilled water in a beaker and disperse specified amount of Carbopol 940 in it with continuous stirring. Kept the beaker aside to swell the Carbopol for half an hour. In another beaker take 5 ml of distilled water and add required quantity of liquid paraben to it by heating on water bath. Cool the solution, then add Propylene glycol 400. Further required quantity of extract was added to the above mixture and this solution was mixed properly to the Carbopol 940 gel with continuous stirring. Final volume made up to 30 ml by adding remaining distilled water and triethanolamine was added drop wise to the formulations or adjustment of required mouth skin pH (6.8.7) and to obtain the gel at required consistency. The same method was followed for preparation of control sample without adding any extract.

### 3.3 Evaluation Parameter

#### 3.3.1 Colour

##### Procedure

1. Place a small quantity of the gel on a clean white background (glass slide or ceramic tile).
2. Observe visually under normal daylight conditions.
3. Compare with standard colour characteristics expected for herbal gels (slightly green–brown for *M. zapota* extract).

#### 3.3.2 Odour

##### Procedure

1. Take a small amount of gel in a clean beaker or on a spatula.
2. Smell gently from a short distance without inhaling deeply.
3. Check for any characteristic/undesirable odours.

#### 3.3.3 Consistency

##### Procedure

1. Place a small amount of gel between the thumb and forefinger.
2. Spread gently and observe the texture (smooth, gritty, sticky, etc.).
3. Also evaluate flow behavior when the container is inverted.

#### 3.3.4 pH Measurement

##### Procedure

1. Dissolve 1 g of gel in 10 mL distilled water.
2. Stir well to form a uniform dispersion.

3. Measure pH using a calibrated digital pH meter.
4. Ideal pH for oral gels: 5.5 – 7.0

### **3.3.5 Spreadability**

#### **Procedure (Two-Slide Method)**

1. Take 1 g of gel and place it between two glass slides.
2. Apply a weight (about 1 kg) on the upper slide for 1 minute to allow uniform spreading.
3. Remove the weight; attach a hook to the upper slide and pull using a string with a known weight (e.g., 80 g).
4. Record the time taken (t sec) for the upper slide to move a set distance (usually 5–10 cm).

### **3.3.6 Viscosity**

#### **Procedure (Brookfield Viscometer)**

1. Place gel in a beaker and allow temperature to stabilize at 25°C.
2. Select appropriate spindle (usually Spindle No. 64 for gels).
3. Set rotational speed (e.g., 10, 20, 50 rpm).
4. Record viscosity at each speed and note shear-thinning or thickening behavior.

### **3.3.7 Extrudability**

#### **Procedure (Measures ease of gel extrusion from tube)**

1. Fill gel in a collapsible aluminium or laminated tube.
2. Press the tube to extrude a ribbon of gel through the nozzle.
3. Measure the weight required (g) to extrude a constant amount (0.5 cm ribbon).

### **3.3.8 Gel Strength**

#### **Procedure**

1. Place 50 g of gel in a 100 mL measuring cylinder.
2. Allow it to stand for 24 hours at room temperature to remove air bubbles.
3. Place a 5–10 g weight on the gel surface.
4. Record the time taken (in seconds) for the weight to penetrate 5 cm into the gel.

## 4. RESULTS AND DISCUSSION

### 4.1 EVALUATION OF HERBAL ORAL GEL

Table 2: Evaluation Of Herbal Oral Gel.

S.NO	TEST	RESULTS
1.	Color	Brown
2.	Odour	Odourless
3.	Consistency	Smooth
4.	pH	5.6
5.	Spread ability	23.5g.cm/s
6.	Viscosity	3815.97cps
7.	Extradurability	81% good
8.	Gel strength	5.0 in 30 sec
		10.5 in 60sec

### 4.2 DISCUSSION

The prepared gel formulation were evaluated for parameters such as physical appearance pH, homogeneity, spreadability, and viscosity. The observation reveals that the gels were having smooth texture and were elegant in appearance.

The gels showed good spread ability also from the above data it was observed the increase the concentration of plant extract increase the spread ability. All the prepared gels showed good homogeneity with absence of lumps. The developed preparation were much clear and transparent. The viscosity of all the developed gels was found to be excellent and within the range.

## 5. CONCLUSION

The main aim first to formulate herbal oral mouth ulcer gel that will cure mouth ulcer and reduce pain and irritation and side effects too. As seen from the results, it is possible to formulate herbal mouth ulcer gel by using sapota (*Manilkara Zapota*) leaves which is useful to treat the ulcer. From above study it is concluded that all preliminary test and stability studies suggested for utility of herbal mouth ulcer gel with economy and consumer compliance.

Nowadays there is a lot demand for herbal formulation in the market due to their cost effectively and absence of any side effects. From the above experimental data is clear that a gel formulation with herbal ingredients as sapota (*Manilkara Zapota*) leave has leave extract have good characteristics, viscosity and also possesses a good anti-inflammatory activity which is necessary in the management of mouth ulcer.

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