



**INTERNATIONAL JOURNAL OF
PHARMACEUTICAL SCIENCES**
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: <https://www.ijpsjournal.com>



Research Paper

Formulation, Characterization, And Evaluation of Betel Leaf Jelly for Oral Administration

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ARTICLE INFO

Published: 25 Jan. 2025

Keywords:

Betel leaf, Evaluation, Extract, Jelly, Oral dosage form, Research, Evaluation.

DOI:

10.5281/zenodo.14738038

ABSTRACT

Traditional medicine has long acknowledged about therapeutic benefits of Piper betel, or betel leaf, because of its strong antibacterial, antioxidant, anti-inflammatory, and antifungal qualities. In order to provide a tasty and efficient way to administer its medicinal effects, this study intends to create and evaluate a novel oral formulation betel leaf herbal jelly. To increase patient compliance, the formulation was made with a betel leaf extract, added to a jelly base that contained gelatine as a gelling agent, and sweetened. The prepared jelly was evaluated for physicochemical properties such as texture, stickiness, grittiness, viscosity, pH, weight variation, spreadability, In-vitro dissolution study. As results, the jelly provides a stable and palatable oral delivery system for betel leaf phytochemicals, making it a viable substitute for herbal medicine, especially when it comes to treating inflammatory and oral infections. Further studies are warranted to investigate clinical applications and optimize dosage forms.

INTRODUCTION

Jelly is a semisolid, non-greasy, transparent or translucent preparation that can be applied both internally and externally or jellies are water-soluble bases prepared from natural substances such as Gelatin, tragacanth, pectin and synthetic source such as cellulose derivative ⁽¹⁾. Oral medicated jellies are the palatable Solid dosage form administered in the oral cavity, meant to dissolve in mouth or pharynx for its local or

systemic effect ⁽²⁾. The scientific name of betel vine is Piper betel L. belongs to the family Piperaceae; Plant leaves are used for the preparation of traditional medicine to treat various diseases. Betel leaf is commonly known as betel vine. It is widely used for chewing practices in most countries, like India, for avoiding bad breath, strengthening the gums and stimulating the digestive fire ⁽³⁾. In India, betel leaves, which are heart-shaped and dark green, are also referred to as

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



paan. There are 100 different species of betel leaf discovered worldwide, 40 of which are only found in India, and the remaining 30 are found in Bangladesh and West Bengal ⁽⁴⁾. In research carried out in (2017), betel leaf contains phytocomponents which show antioxidant, anti-inflammatory, anti-platelet, antithrombotic, antibacterial and antifungal properties.

Types of Jellies

a) **Medicated Jelly:** These are mainly used over mucous membrane and skin & they possess spermicidal, local anesthetics, and antiseptic properties. These jellies hold adequate amount water which after evaporation gives a local cooling effect and residual film provides protection Example: Ephedrine sulphate jelly is used to seize the bleeding of nose since it is vasoconstrictor.

b) **Lubricating Jelly:** These jellies are intended for lubrication of equipment's used in diagnosis like surgical gloves, catheters.

c) **Miscellaneous Jelly:** These are intended for diverse applications like electrocardiography & patch testing ⁽⁵⁾⁽⁶⁾.

❖ Ideal Characteristics of Oral Jelly

1. After being administered in the mouth, it should to dissolve or disintegrate in a matter of seconds.
2. After administration, there must be no residue left in the mouth.
3. It should be compatible and have a pleasant feel in the mouth.
4. It need to be suitable with disguising flavour.
5. It should not be fragile or broken on transportation.
6. It should be stable in altered environmental conditions such as changes in humidity and temperature.
7. Production and packaging costs should be economical.
8. It need to be stable while kept in storage condition.

9. The excipients used should be inert, safe and compatible with other constituents ⁽⁷⁾⁽⁸⁾.

❖ Advantages of oral medicated jelly

1. It can be administer easily i.e., anywhere, anytime as it is easy to handle & doesn't require water
2. Moreover the drugs that are liberated & swallowed from medicated jelly, will reach the gastrointestinal tract either in dissolved or suspended form in saliva and hence it will be easily available ⁽⁹⁾.
3. No risk of choking or suffocation, thus improving safety
4. Rapid drug delivery and rapid onset of action.
5. Manufacturing time is less compared to other conventional dosage forms.
6. Orals jellies have good chemical stability ⁽⁷⁾.

❖ Disadvantages of oral medicated jelly

1. Since it is an aqueous formulation, proper packaging is necessary to preserve the medications' stability in a variety of environments.
2. If not properly prepared, it could result in an unpleasant flavour ⁽¹⁰⁾.

MATERIAL METHOD

❖ Material :

- **Betel Leaf (*Piper betel*)**
- **Gelatin**

Betel Leaf (*Piper betel*)



❖ **Synonym:** Piper betel, Paan, Betel leaf, betel vine and piper leaf.

❖ **Biological source :** The biological source of betel leaf is the plant *Piper betel*.

❖ **Family:** Piperaceae.

❖ **Taxonomy :**

- Kingdom : Plantae
- Division : Magnoliophyta
- Class : Magnolipsida
- Order : Piperales
- Family : Piperaceae
- Genus : Piper
- Species : Betel ⁽¹¹⁾

❖ **Chemical Constituents:** Constituent of the leaves is the volatile oil, Betel oil, Contains two phenols, betelphenol (chavibetol) and chavicol. Leaves reported to yield an alkaloid: arakene, with properties similar to cocaine. Volatile oil, 0.8 - 1.8% - chavicol, betelphenol, eugenol, allyl pyrocatechin.

❖ **Pharmacological uses**

Betel leaf contains phytocomponents which show antioxidant, anti-inflammatory, anti-platelet, antithrombotic, antibacterial and antifungal properties ⁽¹²⁾.

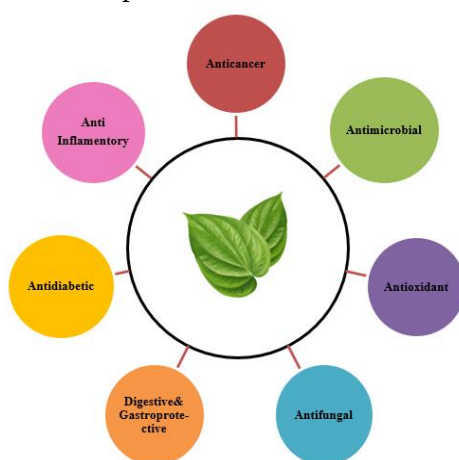
1. Anti-cancer activity : Laboratory and clinical studies have confirmed that chronic inflammation initiated many human diseases, including cancer and tumor. The betel leaf was used as a common household remedy for inflammation in oral cavity ⁽¹³⁾.
2. Anti-allergic activity : Piper betle on production of allergic mediators by bone marrow-derived cells and lung epithelial cells. The results suggested that Piper betel may offer a new therapeutic approach for the control of allergic diseases through inhibition of production of allergic mediators ⁽¹³⁾.
3. Anti-inflammatory effects: The betel leaf is used as a common household remedy for inflammation in the oral cavity , has shown that the ethanolic extract of betel leaf has been reported to possess anti-inflammatory activities at non-toxic concentrations in the complete Freund's adjuvant-induced model of arthritis in rats. Eugenol, one of the principal

constituent of betel leaf has also been shown to possess anti-inflammatory effects in various animal models of studies with various inflamogens ⁽¹⁴⁾.

4. Antimicrobial activity : The betel shows the antimicrobial activity against Streptococcus pyrogenes, Staphylococcus aureus, Proteus vulgaris, Escherichia coli, Pseudomonas aeruginosa etc. Beside this the leaf extract also possess the bactericidal activity against the urinary tract pathogenic bacteria such as Enterocococcus faecalis, C.koseri, C.fruendi, Klebsiella pneumonia ^{(15) (16) (17)}.
5. Digestive& Gastroprotective : The gastroprotective effect of Piper betel was not mediated via inhibition of acid secretion in the gastric mucosa but by increasing its mucus content. The extensive research has been proven that anti-oxidants might be effective mechanism not only in protecting against gastric mucosal injury, but also inhibiting progression of gastric ulceration ⁽¹⁵⁾.
6. Anti anxiety activity : Anxiety is defined as an uncomfortable emotional state with no apparent cause or feeling out of control. It causes a number of symptoms that are not medically explained, reduces functioning, causes insomnia, and decreases efficiency ⁽¹⁸⁾. The antianxiety activity of P. betel leaves was evaluated in Swiss albino mice using a hydro alcoholic extract. In the light/dark exploration test, there was a progressive improvement that was dose-dependent, and in the antianxiety model, there was a rise in plus when compared to the control group that was given diazepam as usual ⁽¹⁹⁾.
7. Anti-hypertensive activity : One of the risk factors for heart disease and stroke is high cholesterol. Research has indicated that betel leaf reduces low-density lipoprotein, triglycerides, and total cholesterol. (LDL) cholesterol as well as elevated VLDL

cholesterol (very low-density lipoprotein). Additionally, it aids in increasing HDL cholesterol levels. Eugenol, a naturally occurring antioxidant that combats free radicals, is the cause of betel leaf's lipid-lowering action. Eugenol decreases intestinal fat absorption and prevents the liver from producing cholesterol. This raises the pace at

which "bad" LDL cholesterol is catabolized even more. High plasma concentrations of triglycerides and cholesterol are transported to the liver where they are subsequently eliminated as bile acids. Thus, betel leaves use a variety of methods to assist lower elevated lipid levels ⁽²⁰⁾.



Sr. No.	Oral Benefits Of Betel Leaf
1	Chewing also makes the gums strong and thereby helps to conserve the teeth
2	Use betel leaves for cure of oral candidiasis
3	Betel leaves are used for cure of inflammations inside the oral cavity in traditional system of medicine
4	Betel leaf extract possesses broad spectrum antibacterial, antifungal and antiprotozoal activity in oral cavity
5	Betel leaves are used for the control of dental caries and for the cure of other periodontal disorder
6	Helps to maintain wellbeing of the mouth

Gelatin:



Synonym: Gelfoam, puragel, gelatinum.

Biological Source: Gelatin is a protein derivative obtained by evaporating an aqueous extract made

from bones, skins, and tendons of various domestic animals. Some important sources are: Ox, *Bos taurus*, and Sheep, *Ovisaries*.

Family: Bovidae.

Chemical constituents: Gelatin is made up of 18 varieties of complex amino acids, 57% of glycine, proline and hydroxyproline are the major compounds, while the remaining 43% are other distinguished amino acids families such as glutamic acid, alanine, arginine and aspartic acid ⁽²¹⁾

❖ METHOD



1. Material procurement



The betel leaves are obtained from Nandurbar, Maharashtra. Other ingredients like Citric acid, Gelatin, Sugar are issued from the central store of our college (JES's college of pharmacy).

2. Preparation of extract: Purchased betel leaves were first washed thoroughly and it was cut into small pieces and it was grinded by using electric blender and the juice was strained.

3. Preparation of jelly :

• Prepare Betel Leaf Mixture

Sr. No	Ingredient	Quantity	Uses
1	Betel leaf extract	5	Mouth Freshener
2	Gelatin	4.5	Binding agent
3	Sugar	20	Sweetening
4	Citric Acid	0.5	Preservative
5	Water	70	Vehicle

Evaluation Parameter

- **Physical Appearance :** The prepared jellies were examined visually for color, taste, texture, clarity and consistency. These tests are important regarding patients' compliance and acceptance ^{(22) (23)}.
- **Stickiness and grittiness :** Texture of the medicated jelly in terms of stickiness and grittiness can specifically be determined by mildly rubbing the jelly between fingers ^{(1) (24)}.
- **Texture analysis :** It was physically investigated for how the jelly surface felt to the touch.

Mix betel leaf extract with a portion of the water to create a homogenous mixture.

• Dissolve Gelatin

Heat water until boiling. Gradually add gelatin to the boiling water, stirring continuously until fully dissolved.

• Add Sugar and Citric Acid

Add sugar and citric acid to the dissolved in gelatin solution. Stir until the sugar and citric acid are completely dissolved.

• Incorporate Betel Leaf solution

Add the betel leaf mixture to the of above gelatin and sugar mixture, stirring thoroughly to ensure an even distribution.

• Cool and Set

Pour the mixture into molds or containers. The jelly is left to cool down in room temperature (23-30°C) for an hour before transferring to the refrigerator (4-5°C) and left for 24 hours.

- **pH:** Determining the pH of oral jelly is important for several reasons Stability and Shelf Life, Taste and Palatability , Bioavailability ,Safety and Irritation ,Quality Control. The pH of the jelly can be determined using digital pH meter 0.5 g of jelly was dissolved in 50 mL of distilled water to form a 1% solution ^{(25) (26)}.
- **Spreadability:** The spreadability of jelly is determined by a combination of its physical properties, chemical composition, and the conditions in which it is used. Here are the main factors that influence its Viscosity, Yield Stress, Temperature, Composition, Air

Incorporation Thinning, Time and Storage Conditions. For the determination of spreadability sample of jelly was applied between two glass slides compressed to uniform thickness by placing 1000gm weight. The time required to separate the two slide moves over the slide was taken measured of spreadability^{(27) (28)}.

$$S = m \cdot L / T$$

Where,

m= weight tide to slide

L= length moved on glass slide

T= time taken

- **Weight Variation Test:** The goal is to keep the fill weight of jellies within a specific range. The main goal of this test is to assure proper dosage delivery. Mass uniformity was implemented to guarantee that each jelly had the appropriate amount of medication. : ten Medicated jelly were selected and weighed individually. Average weight was calculated and the individual weights were compared with the average weight^{(29) (30)}.

Following steps were conducted for performing weight uniformity:

Select 10 jellies.

Weighing each of 10 jellies separately with an analytical balance.

Then calculating the average weight of jellies.

Calculate standard deviation

- **Viscosity :** Viscosity is the one important parameter which provides vital information during the optimization of the soft gel⁽³¹⁾. Viscosity was measured by Brookfield viscometer using spindle no. 64 at 3 RPM at room temperature⁽³²⁾. Procedure: Put the jelly sample in a dry, clean container big enough to submerge the spindle all the way to the bottom without touching it. Avoid overfilling the container; just enough should be added to keep the spindle submerged. After turning it on, adjust the Brookfield viscometer's speed

(RPM). If necessary, gradually raise from a modest starting speed. When the reading becomes steady, give the viscometer a few seconds to stabilize. Take note of the viscosity reading that the viscometer is showing. If the sample starts to settle, repeat the measurement two or three times, making careful to mix it in between.

- **In-vitro dissolution study:** 37 C $\pm$ 0.50C and 50 rpm were maintained in the USP paddle-type apparatus used for the in-vitro dissolution investigation utilizing the dissolving media (900ml). 5 ml of the sample should be removed, diluted up to 10 ml in a volumetric flask with the same, and removed 10, 20, 30, 40, 50, 60, 90, and 120 minutes later. The sink condition should be maintained by replacing the removed 5 ml of sample with new media. By employing an appropriate analytical method or a UV spectrophotometer, the sample's drug content was determined. After measuring absorbance, the percentage of drug release was estimated⁽³³⁾.

RESULT



Physical Appearance: The physical appearance of jelly was found as follows,

- Colour : Green
- Taste : Betel leaf like taste
- Clarity : Transparent

Stickiness and grittiness: Texture of the medicated jelly in terms of stickiness and grittiness can specifically be determined by mildly rubbing

the jelly between fingers. The prepared jelly is non sticky and non-Gritty.

Texture analysis: It was physically investigated for how the jelly surface felt to the touch and the texture of jelly is smooth.

pH: The pH of the jelly was found to be 4.52 by using digital pH meter.



Spreadability: For the determination of spreadability sample of jelly was applied between

two glass slides compressed to uniform thickness by placing 1000gm weight.

$$S = m \cdot L / T$$

$$S = 1000 \cdot 7.4 / 300$$

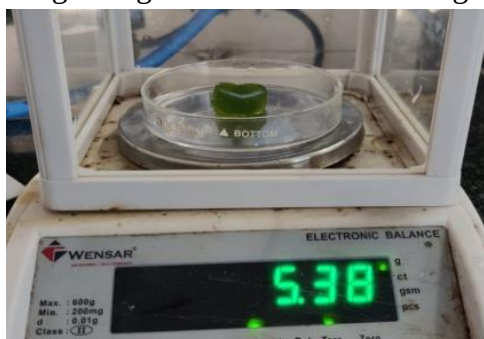
$$S = 24.66 \text{ gm.cm/sec}$$



Weight Variation Test: Ten Medicated jelly were selected and weighed individually. Average weight was calculated and the individual weights were compared with the average weight.

Sr. No.	Weight of the jelly(gm.)	Sr. No.	Weight of the jelly(gm.)
1.	5.3	6	5.3
2	5.2	7	5.2
3	5.3	8	5.3
4	5.3	9	5.3
5	5.4	10	5.3

The average weight was found to be 5.3 gm.



Viscosity: Viscosity was measured by Brookfield viscometer at room temperature. The viscosity of jelly was found to be 8640cp.

In-vitro dissolution study: 37 C ± 0.50C and 50 rpm were maintained in the USP paddle-type apparatus used for the in-vitro dissolution investigation utilizing the dissolving media (900ml). The 89% of jelly is get dissolved after the 120 min of time interval.

Sr. No.	Parameters	Result
1.	Color	Green
2.	Taste	Betel leaf like taste
3.	Clarity	Transparent
5.	Stickiness and grittiness	No sticky, No gritty
6.	Texture analysis	Smooth
7.	pH	4.52

8.	Spredablity	24.66 (gm.cm/sec)
9.	Weight Variation	Average weight is 5.3
10.	Viscosity	8640 cp
11.	In-vitro dissolution study	89%

CONCLUSION

The formulation and evaluation of oral betel leaf jelly demonstrate its promising potential as a functional and therapeutic product. Known for its therapeutic qualities, betel leaf extract is added to the jelly to improve its effectiveness and give it a distinct flavor. To sum up, oral betel leaf jelly improves patient compliance in addition to acting as oral delivery route for the bioactive ingredients of betel leaf. Potential applications in preventive healthcare, further clinical assessments, and long-term stability may be the main topics of future research.

ACKNOWLEDGEMENT

I want to sincerely thank everyone who helped make this study on the "Formulation, Characterization, and Evaluation of Betel Leaf Jelly for Oral Administration" possible by giving their time, knowledge, and assistance. First and foremost, I want to express my gratitude to Mr. Kishor Rathi Sir my research supervisor, for all of their beneficial guidance, unwavering support, and perceptive suggestions during this project. This effort has been greatly influenced by their knowledge. I am really appreciative of J.E.S'S College of Pharmacy, Nandurbar for offering the tools, lab space, and assistance that were required to complete this study.

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HOW TO CITE: Prachi Pote*, Aakanksha Bhoi, Hemangi Shinde, Priyanka Marathe, Kishor Rathi, Ravindra Patil, Formulation, Characterization, And Evaluation of Betel Leaf Jelly for Oral Administration, *Int. J. of Pharm. Sci.*, 2025, Vol 3, Issue 1, 2135-2144. <https://doi.org/10.5281/zenodo.14738038>

