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A RESEARCH ARTICLE ON BETEL LEAF-BASED POLYHERBAL CHEWABLE TABLETS: A PROMISING APPROACH FOR PREVENTING MOUTH ULCERS AND PROMOTING ORAL HEALTH

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ABSTRACT

Oral health is a vital aspect of general well-being, yet conditions such as mouth ulcers and microbial infections continue to affect a large portion of the population. The current study explores the formulation and evaluation of polyherbal chewable tablets using Piper betle (betel leaf) as a primary active ingredient, known for its antimicrobial, anti-inflammatory, and healing properties. Complementary herbal components such as betel leaf, licorice root & jasminium officinale, guava were incorporated to enhance the formulation's efficacy.

The tablets were developed using standard wet granulation techniques and assessed for various pharmaceutical parameters including hardness, disintegration time, taste masking, and stability. In vitro antibacterial testing demonstrated significant inhibitory effects against common oral pathogens including Streptococcus mutans and Candida albicans. Preliminary clinical observations indicated reduced incidence and faster healing of mouth ulcers with regular use.This study supports the potential of betel leaf-based polyherbal chewable tablets as a natural, safe, and effective solution for maintaining oral hygiene and preventing common oral conditions. Further research and clinical trials are recommended to establish long-term efficacy and consumer acceptance.

KEYWORD: *Herbal Medicine, Mouth Ulcer , Betel Leaf, Oral Drug System*

I. INTRODUCTION

Oral health plays a vital role in overall well-being, yet it is often neglected in routine healthcare. Mouth ulcers, also known as aphthous ulcers or canker sores, are among the most common oral health issues, causing pain, discomfort, and difficulties in eating and speaking. Conventional treatments may offer temporary relief but are often associated with side effects and limited long-term efficacy. As a result, there is growing interest in natural and herbal remedies that can provide safer and more sustainable solutions. Betel leaf (Piper betle), a well-known medicinal plant in traditional systems of medicine, has been extensively used for its antimicrobial, anti-inflammatory, and wound-healing properties. When combined with other synergistic herbs in a polyherbal formulation, its therapeutic potential can be significantly enhanced. The development of chewable tablets using such a formulation presents a convenient, palatable, and effective method for delivering herbal actives directly to the oral cavity.

This paper explores the potential of betel leaf-based polyherbal chewable tablets as a novel and promising approach for the prevention of mouth ulcers and the promotion of overall oral health. The formulation aims to harness the combined benefits of multiple medicinal plants, offering a natural, user-friendly alternative to conventional oral care products.

A skin or mucous membrane ulcer is an open sore that is characterised by the sloughing off of inflammatory, dead tissue. Ulcers are lesions on the surface of the skin or a mucous membrane identified by superficial loss of tissue. Therefore, oral hygiene is very important for Health. The tongue is the gastrointestinal tract's (GIT) mirror. Mukhapak (Stomatitis), or mucous membrane inflammation, displays in cheek, tongue, and lips. These concerns are global in nature and impact all individuals. Ulcers formed in mouth are red unheroic or white which are painful and makes drinking, biting and speaking uncomfortable and associated with fever. Ulcerations can be classified based on duration of onset number of ulcers and etiological factors. Acute ulcer lasts for less than two weeks and chronic ulcer may last for more than two week which is typically painful. Because of the variety of presenting features and causative factors, identification of oral ulcerative lesions may be relatively challenging. Local or systemic factors can be contributing to developing ulcers.Ulcers have different parts: the floor (uncovered ulcer surface), the base (ulcer rest seat), the margin (interface among the wall of ulcer and normal epithelium) and the edge (the part of the margin and floor).

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II. MOUTH ULCER

A mouth ulcer is a small, painful sore that develops inside the mouth, on the inner cheeks, lips, tongue, or gums. It is usually white or yellow with a red border and can be caused by stress, injury, nutritional deficiencies, or certain medical conditions.

A) SYMPTOMS & CAUSES : (2)

Pain is the primary sign of canker sores. The area of your mouth that has the canker sore may also tingle, burn, or feel rough.Foods like bread crusts, acidic fruits, and spicy foods may harm the already irritated lining of the mouth and exacerbate the pain. It may also ache more as a result of the movements your mouth makes when you chew or talk.Round, white patches on the lips or within the cheeks are the appearance of canker sores. They may less frequently develop on the tongue, gums, or roof of the mouth. Typically, the sores have reddish, slightly raised edges, are somewhat sunken, and are only a few millimeters across. This common type is also known as a minor canker sore. Major canker sores occur when the patches are larger, measuring one to three millimeters. Herpetiform canker sores are known to exist in large numbers and are roughly the size of a pinhead

B) ETIOLOGY OF MOUTH ULCER

1) Stress: Physiological instability and stress are linked to ulcers. It has been observed that patients with high levels of stress are more likely to develop ulcers. Antidepressant drugs therefore reduce the risk of ulcers.
2) Hormonal changes: Certain women may have oral alterations, such as bleeding gums and canker sores, as a result of hormonal fluctuations that occur during the menstrual cycle.
3) Drugs : Diclofenac is one example of a non-steroidal anti-inflammator medicine(NSAID) that can cause mouth ulcers. This kind of ulcer develops as a side effect of the medication and goes away when the medication is stopped.
4) Allergies and Sensitivities: Food allergies can result in Aphthous ulcers; they include allergy to chocolate, coffee,tea, tomatoes, almonds, cheese, and peanuts.
5) Genetic: Genetic predisposition is the cause of serious ulceration. Family history contributes to ulcers in about 40% of cases.
6) Mechanical injury: Mechanical injury can occur due to local anaesthetic injection, dental procedure, sharp teeth, Brush injuries and these are responsible for aphthous ulcers.
7) Mechanical trauma: Because of insufficient saliva and the development of RAS (recurrent aphthous stomatitis), which results from trauma and a failure to moisten and shield the oral mucosa.
8) Deficiency of vitamin: Low levels of iron, folic acid, and vitamin B12 can lead to RAS (Recurrent aphthous stomatitis). RAS expansion results from hematinic deficiency.

Other factors which cause mouth ulcer (2)

- Infections such as bacterial and viral infection.
- Mouthwashes, Toothpastes which have sodium lauryl sulphate.
- Chewing or biting inside of the cheeks and tongue.

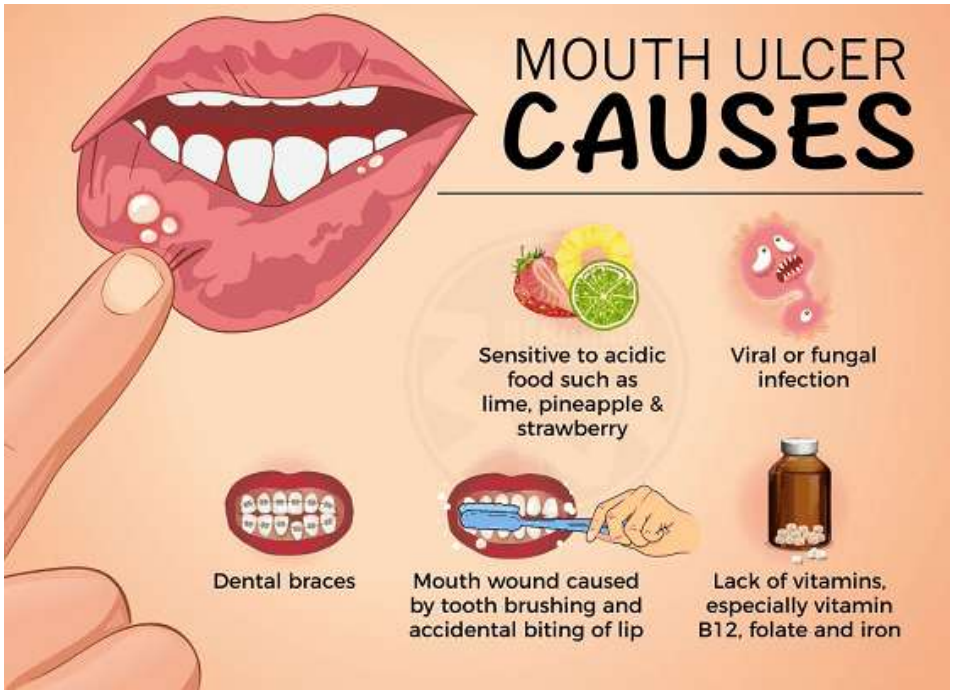


Fig.no 1:Etiology of mouth ulcer

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C) TYPES OF ULCER (2)

1.Minor : Small round or oval ulcers known as mild canker sores.[9] These are usually ranging from 2 to 8 mm in diameter and may take up to 10 to 14 days to clear up.



Fig.no.2: Minor ulcer.

2. Major ulcer: Canker sores that are big in size and depthare larger, deeper and irregular borders, often 1cm or more. These uneven edges can take up to six weeks to repair. Long-term scarring is a risk with large mouth ulcers.



Fig.no.3.Major ulcer

III. Chewable tablet

A) Ideal characteristics of chewable tablets (3)

- Simple to bite.
- Tasteful (Palatable).
- Proper size and shape.
- Break down fastly and enhance dissolution.
- Like all easy to understand dosage forms.
- Helpful for patients who experience challenges while swallowing ordinary tablets and capsules for them chewable tablets are simple to swallow (once broken down).
- Risk of esophagitis is reduced in chewable tablet. Esophagitis is caused when ingested tablet medication is trapped in the esophagus and dissolve while staying in
- contact with the touchy esophagus lining.
- Taste make it palatable and scope of flavors.
- Are simple and helpful to take.
- Are provided as a single unit dose so estimation of dose is not required.
- Improve consistence (4)
- This dosage forms do not need water are:
- Easy to take 'on the go'
- Convenient to take, anywhere and at any time

B) Advantage of chewable tablets: (5)

- Patient convenience
- Better absorption characteristics

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- Enhanced bioavailability is achieved because of expanded ingestion rate, because of its disintegration or being bitten in the mouth into the increased dissolution.
- Improved understanding acknowledgment through lovely taste Child friendly version.
- Chewable tablets offers more preferences over the
- greater size of dosage forms that are hard to swallow
- particularly kid and who aversion gulping

C) Disadvantage of chewable tablets (5)

- Formulation of chewable tablets is not for the bitter tasting drugs.
- There is possibility to cause ulcer in the oral cavity due to the use of more quantity of flavor enhancing agent in chewable tablet.
- Chewable tablets utilize numerous excipient to give mass and inhance characteristics of tablets yet some excipient have unsafe to body, for example, sorbitol which causes the diarrhea and flatulence.
- Chewing of chewable tablets for prolong times cause the pain in facial muscles.
- Many chewable tablets needed dry conditions and accurate packing for storage because many of them have hygroscopic properties.
- The chewable tablets have lower mechanical quality than other swallowing tablets, so cautious dealing and care required during packaging and transportation.
- They show the fragile, effervescence granules property

Table no.1 Synonyms, biological sources and family of Ingredients

Sr.no	Ingredients	Synonyms	Biological source
1.	Betel leaf (Piperaceae)	Piper betel , pan leaf,sireh,nagavallari	The biological source of betel leaf is the plant Piper betle Leaf
2.	Liquorice root (Leguminosae)	Mulethi, Radix glycyrrhizae, Licorice, Jethi Madh, Yashtimadhu, Jeshtamadh	Stems along with roots of Glycyrrhiza Glabra.
3.	Jasminium officinalis (oleaceae)	Summer Jasmine, Poet's Jasmine, or Jessamine.	true jasmine, is the plant itself. Specifically, the fragrant flowers, leaves of Jasminum officinalis
4.	Guava (myrtaceae)	Guajava pumila(vahl) kuntze &myrtus guajava	Natural source from the leaves of the guava tree Psidium guajava

Table no 2: Chemical Constituents of Ingredients

Sr.no	Ingredients	Chemical constituents
1	Betel leaf	Betel leaves contain tannins, sugar and diastases and an essential oil. The essential oil is a light yellow liquid of aromatic odor and sharp burning in taste. It contains a phenol called chavicol which has powerful antiseptic properties. The alkaloid arakene in it has properties resembling cocaine in some respects .An analysis of the betel leaf shows it to consist of moisture 85.4 per cent, protein 3.1 per cent, fat 0.8 per cent, minerals 2.3 per cent, fiber 2.3 per cent and carbohydrates 6.1 per cent per 100 grams.
2	Jasminium officinalis	Jasminum officinale contains a variety of chemical constituents, including volatile oils like linalool and benzyl acetate, flavonoids, phenolic acids, and secoiridoids. These compounds contribute to its fragrance and potential therapeutic properties, including anti-inflammatory, antioxidant, and antimicrobial activities**.**
3	Guava	Guava is rich in chemical constituents like vitamin C, flavonoids (such as quercetin), phenolic acids, and essential oils. These compounds contribute to its antioxidant, anti-inflammatory, and antimicrobial properties, making guava a valuable fruit for health and nutrition.
4	Liquorice root	Glycyrrhetic acid while glycyrrhizin are saponin glycosides. Liquiritin, isoliquiritin, liquiritigenin, isoliquiritigenin are examples of flavonoids. Glyceramarin is a bitter principle. Herniarin and umbelliferone are coumarin derivatives. Starch, resin, asparase, β-sitosterol, and malic acid.

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Fig.no.4 Polyharbal Ingredient

IV. MATERIAL & METHOD

A. Materials :

Licorice root ,betel leaf , Jasminium officinalis & guava were obtained from the Medical Store, local market and Shop, (respectively) of badnapur, Jalna.

Excipients Magnesium Stearate, Starch, Lactose, Talc(glidants) & methyl paraben (preservative) taken from Practical Store House of institute of Pharmacy badnapur,Jalna . Every ingredient used for formulation was of a laboratory quality.

B. Formulation and Development :

Polyherbal chewable tablets containing Liquorice (Glycyrrhiza Glabra), betel leaf ,Jasminum officinale,guava were formulated by technique of wet granulation method. Excipients ingredient such as starch, lactose, talc, magnesium stearate and methyal paraben having properties of disintegrator, filler, glidant, lubricant and binder, respectively.

Table no: 3 Role of Ingredients

Sr.no	Ingredients	Role
1.	Betel leaf	Anti-inflammatory Properties, Antibacterial & Antiseptic, Analgesic (Pain Relief), Cooling Effect
2.	Jasminium officinale	Wound Healing Support, Astringent Effect, Antibacterial Properties, Anti-inflammatory Action
3.	Licorice root	Expectorant, Demulcent, Anti-inflammatory, treats Bronchial problems such as Catarrh bronchitis, cold flu and coughs. Sweetening Agent, Antiviral, Antibacterial.
4.	Guava	Rich in Vitamin C, Astringent Effect, Antibacterial & Antimicrobial, Anti-inflammatory Properties
5.	Starch	Binder
6.	Methyl paraben	Preservative
7.	Magnesium sterate	Lubricant
8.	lactose	Filler
9.	Talk	Glidant
10.	Sucrose	Testing agent

C. Wet Granulation Method:

For small scale preparations and formulation of chewable tablet, Wet granulation method is convenient. The each ingredients in formulation were weighed, pulverized, and screened individually by using sieve no. 80. All the components in the formula were thoroughly blended together with the exception of the magnesium stearate and talc, which were crushed in a pestle and mortar and

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then again sieved using sieve no. 80. The starch solution (5% w/v) was added gradually while this material was blended. Following this mixing procedure, the powder mass was repeatedly passed through sieve no. 18 to obtain the granules, and it was then dried at 35°C in a vacuum dryer. The dried granules were rescreened using sieve number 18 to eliminate bigger granules after drying, and they were then placed in desiccators for storage. Magnesium stearate along with talc were combined with the granules prior to punching. On a single rotary punching machine, tablet compresses with the proper compressing pressure, powder mixtures were compressed to 500 mg tablets. The final powder mixture were pressed into tablets once the die cavity was set for the necessary weight. (7) Chewable tablets of Liquorice (Glycyrrhiza Glabra), betel leaf, jasminium officinale, guava leave, is prepared by wet granulation technique as per the composition.

Table no: 4 Composition of Polyherbal Chewable Tablet

Sr. no	Indredients	Quantity Taken
1.	Betel leaf	14 gm
2.	Jasminium officinale	5.25 gm
3.	Licorice root	3.5 gm
4.	Guava leave	5.25 gm
5.	Starch	1.4 gm
6.	Methyl paraben	0.7 gm
7.	Magnesium sterate	0.7 gm
8.	Lactose	3.5 gm
9.	Talk	0.7 gm
10.	Sucrose	q.s

D. Pre-compressional studies of powder mixture:

Preformulation studies serve as the first stage in developing a dosage form for a potential drug formulation. In order to learn more about the recognised qualities of constituents and the suggested formulation schedule, a primary study is being conducted in the drug development process. Therefore, this preformulation study has the advantage of verifying that there are no numerous challenges to developing the medication or formulating the dosage form. There was study done on pre-compressional factors such as Hausner's ratio, angle of repose, tapped density, bulk density, and compressibility indices.

1. Angle of repose : (6)

Angle of repose is the greatest angle that can be formed between the unsupported surface of powder pile and the surface of the ground employing the fixed funnel method, it was identified. The appropriate amount of powder drugs was added to the funnel by covering the funnel hole with the finger. After the powder was properly eliminated from the funnel, its angle of repose was determined and defined in θ.

$$\text{Angle of repose } (\theta) = \tan^{-1} \text{ height / radius}$$

Here, θ = angle of repose, height is denoted as h and radius is denoted as r.

2. Bulk density : (6)

A known amount of granules was transferred into a 25ml of measuring cylinder, carefully level the powder without compacting and measure the bulk volume.

$$\text{Bulk Density} = \text{weight of powder / Bulk Volume}$$

3. Tapped density : (6)

Tapped density is defined as the weight of the powder mixture divided by the smallest volume that is filled by it in a measurement cylinder. A graduated cylinder consisting of an estimated amount of a drug powder mixture or the preparation is placed on an automated electronic tapper equipment to find out the density of the substance after being tapped. The electrically powered tapper device is run for a predetermined number of taps (1000) once the powder bed has achieved its lowest capacity

$$\text{Tapped Density} = \text{Weight of Powder / Tapped}$$

4. Carr's index : (Staniforth J, 2002)

Based on the apparent bulk density and the tapped density, Carr's index (which measures the percentage of the powder mixture's capacity to compress) is calculated. The percentage compressibility of the powder mixture is calculated applying the formula below (8) &(9)

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Carr; s Index = Tapped Volume – Bulk volume / Tapped volume × 100

where, Td is Tapped Density and Bd is Bulk Density.

5. Hausner ratio : (10)

The Hausner's ratio is a proximate indicator of what a simple task it is to determine the flow properties of powder. Higher flow qualities are determined by a smaller Hausner's ratio value (< 1.25) than by a larger value (> 1.25)

Hausner's ratio = Td / Bd

where, Td is the Tapped Density and Bd is the Bulk Density

Table 5: Pre-compression parameters of powder blend

Parameter	Results
Angle of repose (θ)	30.9
Bulk density (g/ml)	0.50
Tapped density (g/ml)	0.58
Carr's index (%)	13.79 %
Hausner's ratio	1.16

E. Post-compression study (Estimation of Prepared Polyherbal Chewable Tablets)

1.General appearance *:*

The distinctive look and general refinement of tablets are determined by their overall physical appearance, which is essential for the satisfaction of customers. The polyherbal chewable tablets were examined regarding colour consistency, the presence of imperfections, tablet polish, depressions, pores and pinholes.



Fig.no.5: Polyherbal Chewable Tablets

2.Uniformity of thickness and diameter*:* (11)

The Vernier Calliper was used to determine and calculate the tablet size in millimeters. In all of the instance, the average value of five determinations was noted.

3. Weight variation test *:* (12)

Each of the twenty tablets was weighed separately and collectively. The average weight of all the tablets was determined from their combined weight. The mean weight was contrasted with each tablets weights. The weight variation's percentage disparity must stay within allowed ranges.

The formula given below was applied for estimating the percent difference:

Percentage difference = [(Individual weight - Mean weight) / Mean weight] × 100

Small or large deviation in tablet weight results in low dosing of drugs or over dosing of drugs for the individual receiving treatment. Thus, each batch of tablets is supposed to include tablets of equivalent weight. To achieve the identical weight, modifications were performed while compressing the tablets. The IP has established standards for the mean weight of tablets which are uncoated and

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compressed. Example a tablet is considered to have weight variation when it contains 250 mg or more of the active ingredient or whenever that tablet or dosage form involves (+ or -) 5 % or greater, by weight of the tablet. 20 tablets were weighed one by one and then the mean weight of tablets was determined. The weights of each tablet are then contrasted with the mean weight.

4.Hardness test : (13) (24)
The amount of stress required to break a tablet in a particular plane are usually employed to quantify hardness. The chewing effort scale can be calculated using the tablet hardness. Using the approved Pfizer Hardness Tester, the hardness durability of six formulated polyherbal chewable tablets was randomly picked and assessed. As a result, the average of the six assessments was used. The characteristics were conveyed in Kg / cm2 . (14)

5. Friability test : (15)
When a tablet loses weight in a package or container due to the removal of tiny particles from its outer layer of tablet, then it is termed as 'friability'. To assure that tablets capacity to tolerate vibrations during manufacturing, operating, shipment, and transportation, friability test is done. Maximum 1.0 % friability is the allowed. Roche friabilator was employed to evaluate the degree of friability of tablet. Together, 5 tablets were weighed, and then these
were put into the friabilator compartment. The tablets were subjected to rolling in the friabilator, leading to the dropping of tablets from a height of 6 inches inside the friabilator
compartment. (16)

The Friabilator compartment was rotated during the Friability Test at an average speed of 25 rpm (rounds per minute). The tablets were removed from the friabilator after 4 minutes (or 100 revolutions). Then all of the tablets were once more weighed. The % friability of the tablets was estimated using the equation.[16] By using the following formula, the % friability was determined :

$$F = (1 - X) / X_0 \times 100$$

(where, X = Weight of the tablets after test and X0 = Weight of the tablet before test)

6.Disintegration test : (22,23)
For a drug, to be absorbed from a solid dosage form after oral administration, it must initially be in solution, and the most crucial step for achieving this outcome is typically breaking up the tablet. This term is referred as Disintegration. The duration needed for a tablet to disintegrate into tiny particles is known as the disintegration time. If the patient does not fully chew the chewable tablet then there is chances of GI obstruction, therefore to prevent this situation disintegration time of chewable tablet should be short. The disintegration test measures the amount of time needed for a group of tablets to break up into tiny particles and pass through a 10 mesh screen under a specific set of circumstancesWith the use of the disintegration tester, the disintegration test is conducted. A basket rack carrying six plastic tubes that are open at both the upper and lower and have a 10 mesh screen across the bottom is known as the disintegration tester. That basket was submerged in a suitable liquid bath of 37°C temperature, preferably in beaker of a 1000 mL. Water heated to 37°C was typically used as the testing liquid for compressed uncoated tablets. The test was carried out on 12 tablets if one or two of the tested tablets failed to disintegrate. The required disintegration time has to take place based to each drug's monograph in order for it to comply with pharmacopoeial specifications. In artificially created saliva, the disintegration time was estimated.(Phosphate buffer solution pH 5.8). As per the USP method, at 37 ± 0.5°C the disintegration time of six each tablets was measured. For each batch, the average of six measurements was taken.(22,23)

Table 5: Post-compression Parameters of Polyherbal Chewable Tablets

Parameter	Result
Colour	Pale brownish (khaki)
Odour	Characteristics
Taste	Sweet
Texture	Smooth
Shape	Round flat plain both side(flat faced)
Thickness (mm)	4.3
Diameter (mm)	15.92
Weight Variation (%)	Two tablet were varied in weight
Friability (%)	Weight loss 0.92 % of its initial weight
Hardness Test (Kg/cm2)	6.5 Kg /cm^2
Disintgration Test (Minutes)	13 min

V. RESULTS AND DISCUSSION

The formulated herbal product containing betel leaf, Jasminum officinale, licorice root, guava leaves, starch, methyl paraben, magnesium stearate, lactose, talc, and sucrose resulted in a chewable tablet with good physical and sensory properties. The tablets

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showed uniform weight, adequate hardness, low friability, and rapid disintegration, indicating good mechanical stability and effective release. Phytochemical screening confirmed the presence of bioactive compounds like tannins, flavonoids, and saponins, particularly from guava leaves, betel leaf, and licorice. Antimicrobial testing revealed moderate to strong activity against common oral pathogens, supporting its potential use in oral hygiene. The excipients used improved tablet formation, taste, and preservation, making the formulation suitable for further development as a natural oral health supplement.

The pre-compression as well as post-compression studies were tested and compared with the previous studies performed on chewable tablets and its result showed within the pharmacopoeial limits. The Powder blend produced however showed better flow property (Table No. 4).

Chewable tablets are meant to disintegrate within 15 minutes.[1] Since, these are the most commonly used solid dosage form, compressed tablets must comply to a variety of physical standards in regards to hardness, uniformity and friability.

The results for size that is regularity of diameter and regularity of thickness are given in Table No. 6. These parameters are very important to select packaging material. The analysis of chewable tablet were showed the satisfactory results (Table No. 5). And organoleptic
characters of both powder and tablet also satisfactory. Betel leaf, Liquorice root (Glycyrrhiza Glabra), Jasminium officinale,guava leave can all be effectively utilised to tablet preparation by wet granulation technique

VI. CONCLUSION

The formulated betel leaf-based polyherbal chewable tablets, enriched with Jasminum officinale, licorice root, and guava leaves**,** demonstrated promising potential in the prevention of mouth ulcers and the promotion of oral health**.** The synergistic combination of herbal ingredients, particularly the antimicrobial, anti-inflammatory, and antioxidant properties of betel leaf, guava, and licorice, contributed significantly to the therapeutic effect. Jasmine added a pleasant aroma and mild soothing action, enhancing the overall acceptability. The tablets were pharmaceutically stable, showing good hardness, low friability, and fast disintegration, with satisfactory organoleptic properties.

The inclusion of excipients like starch, lactose, talc, magnesium stearate, methyl paraben, and sucrose ensured proper tablet formation, preservation, and palatability. Overall, this polyherbal formulation presents a safe, effective, and natural alternative for maintaining oral hygiene and managing minor oral ailments such as mouth ulcers, and holds potential for further clinical evaluation and commercial development.

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