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FORMULATION AND EVALUATE A MUCOADHESIVE BUCCAL PATCH OF *PSIDIUM GUAJAVA* LEAF EXTRACT FOR EFFECTIVE LOCAL DRUGS

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ABSTRACT

The present study aimed to formulate and evaluate a mucoadhesive buccal patch containing *Psidium guajava* (guava) leaf extract for effective local drug delivery. Buccal patches were prepared by the solvent casting method using HPMC K15 and Carbopol 940 as polymers. Three formulations (F1, F2, and F3) were developed and evaluated for thickness, weight variation, folding endurance, surface pH, swelling index, drug content, mucoadhesive strength, drug release, and stability. All formulations showed satisfactory physicochemical properties and good mucoadhesion. Formulation F3 exhibited the highest drug content (98.1%), mucoadhesive strength (29 g), and sustained drug release profile. The results indicate that guava leaf extract can be successfully incorporated into a mucoadhesive buccal patch and may serve as a promising herbal drug delivery system for the treatment of oral infections, inflammation, and ulcers.

KEYWORDS: Psidium guajava, Buccal Patch, Mucoadhesive Drug Delivery, HPMC K15, Carbopol 940, Guava Leaf Extract, Herbal Formulation, Oral Drug Delivery.

INTRODUCTION

The oral route is arguably the most favored among the several drug delivery methods for both patients and clinicians. Many medications cannot be effectively administered through the

traditional oral route due to extensive pre-systemic clearance following administration, which frequently results in a lack of significant correlation between membrane permeability, absorption, and bioavailability. This is based on our current understanding of the biochemical and physiological aspects of absorption and metabolism.[1] Mucosal layers (nasal, rectal, vaginal, ocular, and oral cavity) are frequently regarded as possible locations for drug administration and have clear advantages for systemic drug delivery, in contrast to the oral route. These benefits include the potential for a liver bypass effect and the prevention of pre-systemic clearance in the GI tract, which improves absorption and, consequently, bioavailability.[2] The nasal cavity has been studied as a site for systemic drug delivery; however, drug absorption from this site may be greatly impacted by the large intra- and inter-subject variability in mucus secretion in the nasal mucosa, as well as the potential irritation and irreversible damage to the ciliary action of the nasal cavity from chronic application of nasal dosage. Rectal, vaginal, and ocular mucosae all have certain benefits, but because of their low patient tolerability, these sites are only used for local applications rather than systemic medication delivery.[3,4,5] The buccal route is particularly appealing for both local and systemic drug bioavailability because it can keep a delivery system in one place for a long time. In addition to providing quick medication transfer to the systemic circulation and avoiding breakdown by gastrointestinal enzymes and first-pass hepatic metabolism, the buccal mucosa is comparatively permeable and has a high blood supply, making absorption from this location effective.[6]

The following categories apply to drug distribution through the oral cavity's membranes Sublingual distribution is systemic delivery of medicine through the mucosal membranes lining the floor of the mouth Drug administration via the mucosal membranes lining the cheeks is known as buccal delivery. Drug distribution into the mouth cavity is referred to as local delivery.[7] The pharmacological actions and the medicinal uses of aqueous extracts of guava leaves in folk medicine include the treatment of various types of gastrointestinal disturbances such as vomiting, diarrhea, inhibition of the peristaltic reflex, gastroenteritis, spasmolytic activity, dysentery, abdominal distention, flatulence and gastric pain.[8] These extracts have also been indicated to cause disturbances of the central nervous system: insomnia, convulsions and epilepsy.[9] Bronchitis, asthma attacks, cough, pulmonary diseases could be also treated with guava teas[10] and could also be useful as anti-inflammatory and hemostatic agent. Moreover, aqueous extracts of guava leaves were described to be effective against a number of microbial and strains[11] anti-rotavirus activity.[12]

Table 1: Pharmacological Activities of *Psidium guajava*.[13,14,15,16,17,18,19,20,21,22,23]

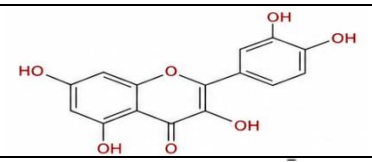
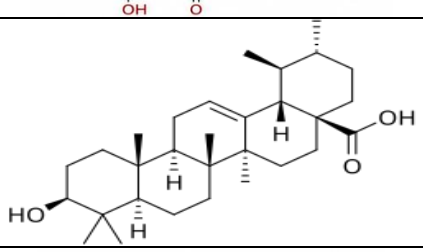
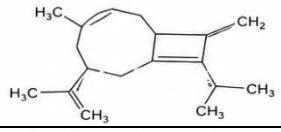
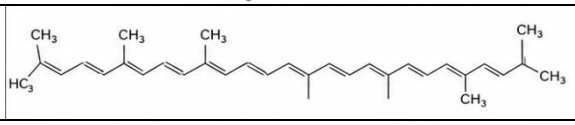
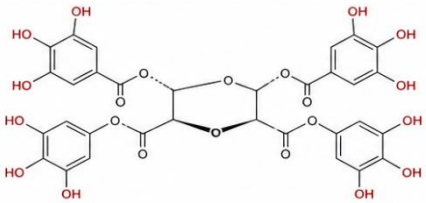
Pharmacological Activity	Plant Part/Extract Used	Major Finding
Antioxidant activity	Distilled water, 65% ethanol & 95% ethanol leaf extracts	Showed strong free radical scavenging and lipid peroxidation inhibitory activity
Antidiabetic activity	Ethanolic stem bark & aqueous leaf extract	Produced significant hypoglycemic effect in diabetic rats
Antimicrobial activity	Aqueous bark & methanolic leaf extract	Exhibited antibacterial activity against various microorganisms
Antidiarrhoeal activity	Leaf aqueous extract	Reduced diarrhea, intestinal motility and enteropooling
Antiplaque activity	Guaijaverin isolated from leaves	Inhibited growth of Streptococcus mutans
Analgesic activity	Aqueous, hexane, ethyl acetate & methanol leaf extracts	Demonstrated pain relieving and anti-inflammatory effects
Oral care activity	Twigs and leaves	Used as chewing sticks for maintaining oral hygiene and preventing dental plaque
CNS activity	Leaf decoction	Traditionally used for spasms and cerebral disorders

Many civilisations have long utilised guava leaves (from the *Psidium guajava* plant) for their therapeutic qualities, which may include anti-inflammatory effects. The therapeutic effects of these leaves are attributed to their abundance of bioactive substances such flavonoids, tannins, and essential oils. Guava leaves are a viable natural treatment for illnesses connected to inflammation because of their anti-inflammatory, antioxidant, and antibacterial qualities, according to scientific studies.[24,25] It is believed that the active ingredients in guava leaves function by neutralising free radicals, lowering the generation of pro-inflammatory cytokines, and modifying the immune system. Guava leaves are so frequently used to treat inflammatory ailments like arthritis, digestive issues, and skin disorders. The leaves can be eaten as a herbal tea, or their extracts can be applied topically to reduce inflammation, among other uses.[26] Although further research is required to completely comprehend the mechanisms and effectiveness of guava leaves in the treatment of inflammation, their promise as a natural anti-inflammatory medication is supported by their historical use and the existence of bioactive chemicals.[27,28]

Psidium guajava contains a wide variety of bioactive phytochemicals distributed in different parts of the plant. The leaves are rich in essential oils, flavonoids, tannins, polyphenols, and

pentacyclic triterpenoids such as ursolic acid and oleanolic acid. Major volatile constituents reported include caryophyllene, copaene, and eucalyptol. Flavonoids like quercetin, guaijaverin, hyperin, quercitrin, and morin glycosides were also identified in leaf extracts. Seeds contain phenolic compounds, flavonoids, lycopene, β-carotene, and acylated flavonol glycosides. The flesh and fruits are abundant in carotenoids, especially lycopene, lutein, and β-carotene, along with benzophenone glycosides, aldehydes, esters, sesquiterpenes, and water-soluble polysaccharides. The whole plant additionally contains tannins, polyphenolic compounds, flavonoids, and other triterpenoids responsible for its diverse pharmacological activities such as antioxidant, antimicrobial, antidiabetic, anti-inflammatory, and antidiarrhoeal effects.[29,30]

Table 2: Main Chemical Constituents of *Psidium guajava*.

Compound	Chemical Structure	Chemical Class	Plant Part
Quercetin		Flavonoid	Leaves
Ursolic acid		Triterpenoid	Leaves
Caryophyllene		Sesquiterpene	Leaves
Lycopene		Carotenoid	Fruits
Tannins		Polyphenolic compound	Whole plant

METHODOLOGY

1. Collection of Plant Material

Fresh guava leaves (Psidium guajava) were collected from a local area and washed thoroughly with distilled water to remove dust and impurities. The leaves were shade dried at room temperature for several days and then powdered using a grinder. The powdered leaves

were stored in an airtight container for further use.[31,34]

2. Extraction of Guava Leaf Extract

The dried powder of guava leaves was extracted using hydroalcoholic solvent by maceration and sonication method. Ethanol and water were mixed in the ratio of 85:15. The powdered leaves were soaked in the solvent mixture and sonicated for 1–2 hours at 40–60°C. The extract was filtered using Whatman filter paper and the filtrate was dried at room temperature to obtain concentrated extract.[31,36,37]

3. Materials Used

Materials used in the formulation included guava leaf extract, HPMC K15, Carbopol 940, glycerine, Tween 80, ethanol, and distilled water.[31]

4. Preparation of Buccal Patch by Solvent Casting Method

Required quantity of HPMC K15 and Carbopol 940 were dissolved separately in ethanol. Both polymeric solutions were mixed together with continuous stirring. Guava leaf extract was added into the polymeric mixture followed by addition of glycerine as plasticizer and Tween 80 as surfactant. The final solution was poured into a Petri plate and allowed to dry at room temperature for 72 hours. After complete drying, the formed patches were cut into suitable size and packed in aluminium foil for further evaluation,[32,35]

Fig. 4: Carbopol & HPMC base gel preparation.

Table No. 3: Formulation Table.[38,39,40,41,42,43]

S.no	Ingredient	F1	F2	F3	Role
1	Guava leaf extract	1mg	1mg	1mg	Active ingredient
2	HPMC K15 (mg)	150	200	250	Film forming polymer
3	Carbopol 940 (mg)	50	75	100	Mucoadhesive polymer

4	Glycerine (mg)	0.02	0.03	0.04	Plasticizer
5	Tween 80(mg)	0.03	0.05	0.07	Surfactant
6	Ethanol(ml)	6	7	8	Solvent
7	Distilled water(ml)	1	1	1	Solvent

EVALUATION OF BUCCAL PATCH *PSIDIUM GUAJAVA*

1. Collection of Plant Material

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Evaluation of buccal patch

1. Thickness and Weight Variation

Thickness of patches was measured using a micrometer screw gauge at different positions and average value was calculated. Weight variation was determined by weighing individual patches and calculating the mean weight.[52,53,55]

2. Folding Endurance

Folding endurance was determined by repeatedly folding the patch at the same place until it broke. The number of folds required to break the patch indicated folding endurance.[52,54,58]

3. Surface pH

The patch was allowed to swell on agar plate prepared with isotonic phosphate buffer for 2 hours. Surface pH was measured using pH paper to ensure compatibility with buccal mucosa.[52,53,58]

4. Swelling Index

The initial weight of patch was recorded and patches were allowed to swell on agar surface. Swollen patches were weighed at specific time intervals. Swelling index was calculated using the formula: SI (%) = [(Wt − W0)[51,52,53]

5. Stability Study

Prepared patches were subjected to stability testing under different conditions of temperature, humidity, and light for three months to determine physical stability.[56,57]

Fig. 5: Preparation of buccal patch.

Table No. 4: Result Discussion.

Evaluation parameters	F1	F2	F3
Thickness(mm)	0.21	0.26	0.31
Weight variation(mg)	118	125	132
Folding Endurance	185	228	265
Surface PH	6.4	6.7	6.8
Swelling index (%)	52	68	79
Drug content (%)	91.2	96.5	98.1
Mucoadhesive strength(g)	18	24	29

Drug Release (%)	92.4	87.3	80.1
Stability	Stable	Stable	Stable

RESULT

The mucoadhesive buccal patches containing *Psidium guajava* leaf extract were successfully prepared by the solvent casting method using HPMC K15 and Carbopol 940 polymers. All the formulations (F1, F2, and F3) showed smooth appearance, good flexibility, and satisfactory mucoadhesive properties. The evaluation results demonstrated that the concentration of polymers significantly affected the physicochemical and drug release characteristics of the prepared patches.

The thickness of the prepared patches increased from 0.21 mm in F1 to 0.31 mm in F3 due to the higher concentration of polymers. Similarly, weight variation also increased from 118 mg to 132 mg, indicating uniform distribution of ingredients within the formulations. Folding endurance values ranged from 185 to 265, showing that all patches possessed good mechanical strength and flexibility suitable for buccal application.

The surface pH of all formulations was found between 6.4 and 6.8, which is close to the normal salivary pH and indicates that the patches would not cause irritation to the buccal mucosa. The swelling index increased from 52% in F1 to 79% in F3, showing that higher polymer concentration enhanced water absorption and swelling behavior of the patches.

Drug content analysis showed satisfactory drug uniformity in all formulations, ranging from 91.2% to 98.1%. The highest drug content was observed in formulation F3, indicating efficient incorporation of guava leaf extract into the polymeric matrix. Mucoadhesive strength also increased from 18 g in F1 to 29 g in F3 due to the increased amount of Carbopol 940, which enhanced adhesion of the patch to the buccal mucosa.

In vitro drug release studies revealed that formulation F1 showed the highest drug release (92.4%), while F3 showed slower and sustained release (80.1%) because of the higher polymer content and thicker matrix formation. Stability studies indicated that all formulations remained stable without significant physical changes during the study period.

Overall, formulation F3 was considered the optimized formulation because it exhibited excellent mucoadhesive strength, high drug content, better swelling behavior, and sustained drug release profile. The study concluded that *Psidium guajava* leaf extract can be effectively incorporated into a mucoadhesive buccal patch for local drug delivery and may be useful in

the treatment of oral inflammatory and microbial conditions.

DISCUSSION

The present study was carried out to formulate and evaluate a mucoadhesive buccal patch containing *Psidium guajava* leaf extract for effective local drug delivery. The buccal route was selected because it provides direct drug absorption through the buccal mucosa, avoids first-pass metabolism, and improves local therapeutic action in oral conditions. The prepared formulations demonstrated satisfactory physicochemical and mechanical properties, indicating the suitability of guava leaf extract for buccal patch formulation.

The buccal patches were successfully prepared by the solvent casting method using HPMC K15 and Carbopol 940 as polymers. HPMC acted as a film-forming polymer, while Carbopol provided strong mucoadhesive properties. The prepared patches were smooth, flexible, and showed uniform appearance without cracks or air bubbles. The increase in polymer concentration from F1 to F3 resulted in increased thickness and weight of the patches, which may be due to the formation of a denser polymeric matrix.

Folding endurance values indicated good flexibility and mechanical strength of the patches. Formulation F3 showed the highest folding endurance value, suggesting improved elasticity because of higher polymer concentration and proper plasticizing effect of glycerine. Surface pH of all formulations remained near neutral, which is considered suitable for buccal application and minimizes the risk of irritation to the oral mucosa.

The swelling index increased with increasing concentration of polymers, especially Carbopol 940, due to its high water absorption capacity. Adequate swelling is important because it promotes intimate contact between the patch and buccal mucosa, thereby improving mucoadhesion and drug diffusion. The mucoadhesive strength of the formulations also increased from F1 to F3, confirming that higher Carbopol concentration enhances adhesion of the patch to the mucosal surface.

Drug content studies revealed uniform distribution of guava leaf extract within the patches, indicating efficient mixing of ingredients during formulation. The drug release study showed that formulation F1 released the drug rapidly, while F3 exhibited a more controlled and sustained drug release pattern due to the thicker and denser polymeric network. Sustained drug release is beneficial for maintaining prolonged therapeutic activity at the site of application.

The stability study confirmed that all formulations remained physically stable under different storage conditions without major changes in appearance or performance. Among all formulations, F3 was considered the optimized formulation because it showed better mucoadhesive strength, higher drug content, greater swelling index, and sustained drug release profile.

The results of the present study support the traditional medicinal use of *Psidium guajava* leaves for oral inflammatory and microbial conditions. Due to the presence of flavonoids, tannins, terpenoids, and other bioactive compounds, guava leaf extract exhibited promising potential for incorporation into buccal drug delivery systems. Therefore, the developed mucoadhesive buccal patch may serve as an effective herbal formulation for local treatment of oral infections, inflammation, and ulcers.

CONCLUSION

The present study successfully formulated and evaluated a mucoadhesive buccal patch containing *Psidium guajava* leaf extract for effective local drug delivery. The buccal patches were prepared by the solvent casting method using HPMC K15 and Carbopol 940 polymers, and all formulations showed satisfactory physicochemical and mechanical properties.

The evaluation studies demonstrated that the prepared patches possessed acceptable thickness, uniform weight variation, good folding endurance, suitable surface pH, satisfactory swelling behavior, and adequate mucoadhesive strength. Drug content analysis confirmed uniform distribution of guava leaf extract in the polymeric matrix. In vitro drug release studies indicated sustained drug release behavior, especially in formulation F3, which showed better mucoadhesion and controlled release characteristics compared to other formulations.

The presence of flavonoids, tannins, terpenoids, and other bioactive constituents in *Psidium guajava* leaves may contribute to the antimicrobial, anti-inflammatory, and antioxidant activities of the formulation, making it useful for the treatment of oral infections, ulcers, and inflammatory conditions. Stability studies also confirmed that the prepared patches remained stable under different storage conditions.

Among all the formulations, F3 was found to be the optimized formulation because of its superior mucoadhesive strength, higher drug content, improved swelling index, and sustained drug release profile. Therefore, it can be concluded that *Psidium guajava* leaf extract can be

effectively incorporated into a mucoadhesive buccal patch and may serve as a promising herbal drug delivery system for local oral therapy.

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