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DEVELOPMENT AND EVALUATION OF MUCOADHESIVE BUCCAL FILM USING MUSA PARADISIACA PEEL EXTRACT FOR TREATMENT OF ORAL ULCER

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ABSTRACT

The current investigation concentrated on the development and assessment of *Musa paradisiaca* peel extract mucoadhesive buccal film for oral ulcer treatment. Oral ulcers are painful lesions of the oral mucosa that may become severe due to secondary fungal infection caused by Candida albicans. The presence of Candida albicans increases inflammation, delays healing and causes discomfort during eating and speaking. Banana peel includes bioactive substances such phenolic compounds, tannins and flavonoids and alkaloids with wound-healing, antioxidant and antifungal qualities. Soxhlet extraction was used to prepare the extract, which was then added to buccal films using the solvent casting technique. The produced films were assessed for thickness, folding durability, surface pH and physical attractiveness and antifungal activity against Candida albicans. The formulated buccal film showed good flexibility, acceptable physicochemical properties.

Keywords: Oral ulcer, Musa paradisiaca, Mucoadhesive Buccal Film, Candida albicans, Antifungal Activity.

1 INTRODUCTION

The oral route is arguably the most satisfying for both patients and doctors among the many diverse ways that drugs can be delivered. Mucoadhesive polymers have been used for buccal medication delivery since the early 1980s and continue to this day. Recently, there has been a growing interest in oral controlled release medication delivery to improve therapeutic outcomes, such as patient compliance, administration convenience. and flexibility in formulation. Furthermore, oral transmucosal drug administration circumvents the first pass hepatic metabolism by skipping pre-systemic clearance in the GI tract and providing direct access to the systemic circulation via the jugular vein.[1] High bioavailability is the outcome of this. This results in high bioavailability with a smaller dosage, less frequent

administration and reduced toxicity. After local injury, the membranes lining the mouth cavity show quick cellular regeneration and are easily accessible. This kind of technology provides the general public as well as certain demographic groups including children, the elderly, bedridden patients and mentally people with an easy way to take their medications. 5,6 In order to improve patient convenience and compliance, the mucoadhesive buccal films containing Musa Paradisiaca peel Extract were created in the current study to treat mouth ulcers by combining the medication in an appropriate polymer system.[2] Candida albicans can also make ulcerated lesions more uncomfortable and take longer to heal. Oral ulcers may therefore benefit from formulations that have antifungal activity against Candida albicans.[3]

1.1 Banana Peel Composition

A wide range of bioactive chemicals, nutrients and fibers make up banana peel, which increases its potential applications in a number of industries, including food, agriculture and medicines. Notably, 40–50% of banana peels' total content is made up of nutritional fibers.[13]

The cellulose, hemicelluloses and lignin that make up these fibers vary significantly depending on the type of banana and how ripe it is.[17] The high fiber content helps lower cholesterol and support digestive health. With a starch content of about 22.6%, green banana peels are especially high in resistant starch. Enzymatic enzymes transform this starch into sugars as the banana ages.[14] Banana peels have been found to contain more than 40 distinct phenolic chemicals, including tannins and flavonoids. These substances are known for their strong antibacterial, antiviral, antifungal and antioxidant qualities, which are linked to a number of health advantages.[4]

1.2 Advantages of oral film

- Compared to other traditional dosage forms, oral film dissolves more quickly and is more stable and lasting.
- Compared to liquid formulations, oral film allows for better dosage precision because each strip is made with a precise amount of medication.
- Compared to liquid formulations, oral film allows for better dosage precision because each strip is made with a precise amount of medication.
- Oral film guarantees more precise drug administration.

1.3 Disadvantages Of Oral Film

- Uniformity in dosage is a problem.
- It absorbs moisture from the atmosphere.
- For the product's stability and safety needed, appropriate packaging.[5]

1.4 Antifungal activity

Banana peel extract possesses significant antifungal activity due to The existence of different phytoconstituents, including phenolic chemicals, alkaloids, glycosides, flavonoids and tannins.[12] These bioactive substances work against Candida albicans by damaging the fungal cell membrane, inhibit in gergosterol synthes is and altering cell permeability, which ultimately leads to fungal cell death. The antifungal activity of banana peel extract is commonly evaluated by agar well diffusion method using Sabouraud Dextrose Agar (SDA).[6]

2 MATERIAL AND METHODOLOGY

2.1 MATERIAL

2.1.1 Chemicals

Table 1: List of chemicals

Sr. No.	Name of Chemicals	Quantity
1.	Ethanol	700 ml
2.	Carbopole	500 mg
3.	Glycerine	5 ml
4.	Citric acid	0.5 gm
5.	Saccharin sodium	1 gm

6.	Hydroxy propyl methyl cellulose	3 gm
7.	Sodium benzoate	1 gm
8.	Propylene glycol	0.4 ml
9.	Distilled water	2 lit

2.2 METHODOLOGY

2.2.1 Collection of banana fruits:

Fruits of Musa paradisiaca is collected from local market.

2.2.2 Drying of peels:[10]

After being spread out on a tray that had been previously weighed, the banana peel pieces were subjected to a tray dryer.

2.2.3 Conversion of peels into powder

The fruits of Musa paradisiaca were collected from the local market. The collected fruits were thoroughly washed with water to remove dust and other impurities. After washing, the banana peels were carefully separated from the fruits. The collected banana peels were spread uniformly on a previously weighed tray and subjected to drying in a tray dryer at 60°C until completely dried. The dried banana peels were then ground into a fine powder using a suitable grinding machine. The prepared powder was subjected to preformulation studies to evaluate its physicochemical properties. Finally, the prepared banana peel powder was stored at room temperature for further experimental studies.

2.2.4 Grinding and preparation of powder:

Standard sieves were chosen, starting with Sieve No.44, where the coarses particles remained on top and the finest ones settled at the bottom. [7]

The sample, which had a weight of approximately 150g was placed onto the coarsest sieve, No. 44, after being weighed.

The sieve shaker was secured in position, and the sieves were shaken for a duration of 20 minutes.

The material retained on each sieve was transferred on to separate sheets of paper and weighed accordingly.[8]

2.3 Extraction with Soxhlet Method:

2.3.1 Procedure of Soxhlet Extraction:[15]

The dried and powdered banana peels of Musa paradisiaca (50–100 g) were weighed and placed into a Soxhlet thimble. Ethanol was used as the extraction solvent in the Soxhlet apparatus. The extraction was carried out under appropriate laboratory conditions under the supervision of trained personnel. During the extraction process, the solvent repeatedly passed through the powdered peel material, facilitating the extraction of phytoconstituents. After completion of the extraction cycles, the ethanolic extract was collected and filtered to remove any suspended particles and impurities. The obtained ethanolic extract was then used for the preparation of mucoadhesive buccal films. Finally, the prepared buccal films were subjected to further evaluation for their potential application in oral ulcer treatment.

2.3.2 Determination of λmax:

A100 millilitre volumetric flask was filled with one millilitre of the extract, which was then diluted with ethanol.

One millilitre of the extract was extracted using this solution, transferred to a 100 millilitre volumetric flask and diluted with ethanol. Determine the maximum using a UV-visible spectrophotometer.[9]

2.3.3 Construction of calibration curve:

In various concentration of the extract like prepared.1µg/ml, 2µg/ml, 3µg/ml, 4µg/ml, 5 µg/ml was prepared and further drug content was determined by the measuring absorbance at the 278nm using to the UV-Visible spectrophotometer.[16]

2.4 Formulation of Oral film:

2.4.1 Solvent Casting Method:[15]

The peel extract of Musa paradisiaca was collected and used for the preparation of mucoadhesive buccal films. Initially, 3 g of Hydroxypropyl Methylcellulose (HPMC) was accurately weighed and dissolved in 20–30 mL of distilled water with continuous stirring until a clear and uniform polymer solution was obtained. Then, 500 mg of Carbopol was added to the polymer solution as a mucoadhesive polymer. Separately, 1 g of Musa paradisiaca peel extract was dissolved in 2–3 mL of ethanol to prepare the extract solution. The prepared extract solution was then added to the polymer blend and mixed thoroughly. After that, 1 mL of glycerin was added as a plasticizer, followed by the addition of 0.36 mL of propylene glycol as a flexibility enhancer. Furthermore, 200 mg of citric acid was added as a saliva stimulant and pH stabilizer, and 100 mg of saccharin sodium was incorporated as a sweetening agent. The entire mixture was stirred thoroughly to obtain a uniform casting solution. The prepared solution was then poured into a Petri plate and allowed to dry in a hot air oven or at room temperature. After complete drying, the film was carefully peeled off from the Petri plate and cut into the required size. Finally, the prepared mucoadhesive buccal films were stored in an airtight container until further evaluation and assessment.

3 RESULT AND DISCUSION

3.1 Pre formulation studies

3.1.1 Organoleptic parameter

Table 2: Organoleptic parameter

Sr. No.	Parameter	Result
1.	Color	Dark Brown
2.	Odour	Characteristic
3.	Taste	Bitter
4.	Texture	Rough

3.1.2 Solubility study

Table 3: Solubility parameter

Sr. No.	Solvent	Solubility Result
1.	Distlled Water	Slightly Soluble
2.	Ethanol	Soluble
3.	Methanol	Freely Soluble

3.1.3 Melting point

Table 4: Melting point determination

Sr. No.	Parameter	Result
1.	Melting Point	120-122°C

3.1.4 pH determination

Table 5: pH determination

Sr. No	Parameter	Result
1.	pH	6.2

3.1.5 Evaluation of flow properties

Table 6: Evaluation of flow properties

Sr.no.	Parameter	Result	Interpretation
1.	Bulk density	0.4 g/ml	Indicates initial packing Property of power
2.	Tapped density	0.5 g/ml	Indicates packing after tapping
3.	Carr's compressibility index	20 %	Good flow property
4.	Housner ratio	1.25	Fair to good flow property
5.	Angle of repose	33°	Good flow property of powder

3.1.6 Evaluation of physicochemical properties

Table 7: Evaluation of physicochemical properties

Sr.no	Parameter	Result	Interpretation
1.	Total Ash value	40 %w/w	Inorganic content present
2.	Water-soluble ash	12 %w/w	Indicates presence of water-soluble inorganic salts
3.	Acid-soluble ash	4 %w/w	Small amount of silica contamination

3.1.7 Phytochemical Test Of Musa Paradisiaca

Table 8: Phytochemical Test of Musa Paradisiaca:

Sr.no.	Test	Inference	Result
1.	Test for Tannins		
	Ferric chloride test	Dark blue-green appearance	Present
2.	Test for Alkaloids		
	Dragendorff's test	Orange reddish precipitate	Present
3.	Test for Flavonoids		
	Shinoda test	Pink color developed	present
4.	Test for saponins		
	Foam test	Persistent foam formed	Present
5.	Test for Phenolic compound		
	Ferric chloride test	Bluish black coloration	present

3.2 Characterisation of film

3.2.1 Physical appearance

Table 9: Physical appearance

Parameter	Result
Color	Light brown
Texture	Smooth
Flexibility	Flexible
Appearance	Uniform

3.2.2 Determination of λ max

The wavelength of *Musa Paradisiaca* peel extract muco-adhesive buccal film was found to be 201 nm and absorption range of various concentrations, 1µg/ml to 5µg/ml absorption range was found to be 1.09 & 2.17.

Table 10: Determination of λ max & absorbance

Sr .No.	Concentration	Absorbance
1	1 µg/ml	1.09
2	2 µg/ml	1.35
3	3 µg/ml	1.67
4	4 µg/ml	2.00
5	5 µg/ml	2.17

3.2.3 Concentration calibration curve

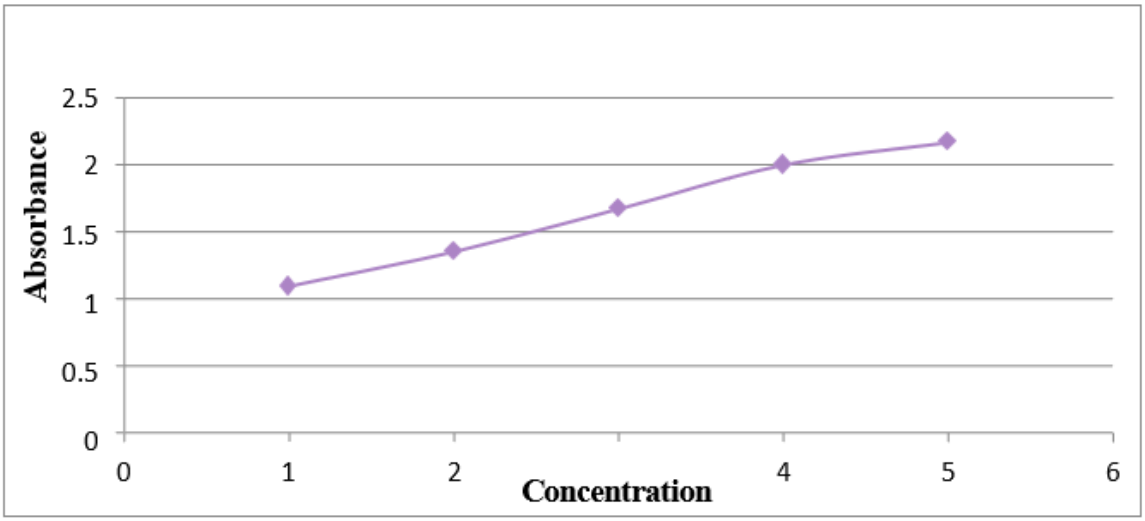

Figure 1: Concentration of Calibration Curve.

3.2.4 Antifungal Activity

The findings demonstrated that the Banana Peel Extract Mucoadhesive Buccal Film produced a 10 mm zone of inhibition against Candida albicans, in contrast to the conventional Miconazoles how edazone of inhibition of 19mm.These findings indicate that the banana peel extractin corporated into the mucoadhesive buccal film possesses antifungal properties. These substances have been shown to damage fungal cell membranes, prevent fungal development and obstruct the production of bio films.

When compared to the common antifungal medication miconazole, the study found that Banana Peel Extract Mucoadhesive Buccal Film demonstrated strong antifungal effectiveness against Candida albicans.

Table 11: Antifungal Activity of test samples against C. albicans

SR. NO	SAMPLES	ZONE OF INHIBITION (mm)
1	Control	00
2	Standard (Miconazole)	19
3	Banana Peel extract mucoadhesive Buccal film	10

4 CONCLUSION

The present study successfully developed and evaluated mucoadhesive buccal films containing *Musa paradisiaca* peel extract for the treatment of oral ulcers. The antifungal evaluation demonstrated that the banana peel extract buccal film exhibited inhibitory activity against Candida albicans with a zone of inhibition of 10 mm, indicating its potential antifungal effectiveness. Candida albicans is considered a secondary causative agent in oral ulcer. In conditions, fungal colonization by Candida albicans can delay healing, increase inflammation, irritation and discomfort. Therefore, incorporation of banana peel extract with antifungal activity into a mucoadhesive buccal film may help in reducing secondary fungal infection, promoting faster healing and improving overall oral ulcer management.

STATEMENTS ON COMPLIANCE WITH ETHICAL STANDARDS

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Disclosure of conflict of interest

The authors declare that there are no conflicts of interest regarding the publication of this manuscript. All authors have contributed to the research work and approved the final version of the manuscript

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