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Polyherbal Mouth Dissolving Tablets for Oral Ulcer Management

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Abstract- Oral ulcers are painful lesions of the oral mucosa that interfere with eating, speaking, and swallowing, significantly affecting quality of life. Conventional therapies, including corticosteroids, antiseptic mouthwashes, and analgesics, often provide only temporary relief and require frequent application, with the possibility of adverse effects. To overcome these limitations, the present study focuses on the development of a polyherbal mouth dissolving tablet (MDT) containing Glycyrrhiza glabra, Curcuma longa, Azadirachta indica, Aloe vera, and clove oil, selected for their anti-inflammatory, antimicrobial, antioxidant, analgesic, and wound-healing activities. The herbal extracts were subjected to phytochemical and compatibility studies before formulation. MDTs were prepared by the direct compression technique using suitable excipients and evaluated for pre-compression properties, post-compression characteristics, in vitro drug release, and antimicrobial activity against selected oral pathogens.

Keywords— Oral Ulcer, Mouth Dissolving Tablets, Polyherbal Formulation, Glycyrrhiza glabra, Curcuma longa, Azadirachta indica.

I. INTRODUCTION

Oral Ulcers

Oral ulcers are painful lesions that occur on the mucosal lining of the mouth, often causing significant discomfort to the affected individual. These lesions may arise due to a variety of factors including physical trauma, infections, stress, nutritional deficiencies, and systemic conditions. Mechanical trauma such as accidental cheek biting, irritation from sharp teeth, or poorly fitted dental appliances can trigger ulcer formation, while microbial infections involving bacteria, viruses, or fungi may also contribute to their development. Additionally, deficiencies in essential nutrients like vitamin B12, iron, and folic acid are recognized as common predisposing factors. Stress, hormonal fluctuations, and underlying systemic diseases such as gastrointestinal disorders or immunological dysfunctions can further exacerbate the incidence of oral ulcers. Clinically, these ulcers are characterized by redness, inflammation, and a burning or stinging sensation, leading to difficulty in eating, drinking, and speaking. The pain and recurrent nature of oral ulcers not only affect oral function but also significantly reduce the patient's overall quality of life, often causing discomfort, nutritional compromise, and interference with daily activities.

Limitations of Conventional Therapy

Conventional treatments for oral ulcers commonly include topical formulations such as gels, ointments, and mouthwashes. While these therapies can provide temporary relief from pain and inflammation, they have several limitations that reduce their overall effectiveness. One major drawback is poor retention time in the oral cavity, as saliva and movements of the tongue and cheeks often wash away the medication before it can act effectively. This limitation necessitates frequent dosing, which can be inconvenient for patients and reduces adherence to the treatment regimen. Additionally, the taste, texture, and repetitive application of these conventional formulations often lead to low patient compliance, especially in children and elderly individuals. As a result, there is a need for more patient-friendly, effective, and fast-acting delivery systems that can overcome these challenges and provide sustained relief from oral ulcers.

Drug and excipient profile

Psidium guajava (Guava Leaves)

Leaves of Psidium guajava, a small tropical tree widely cultivated in India and other tropical regions.

Family: Myrtaceae

Geographical Source

Widely distributed in tropical and subtropical regions, especially in India, Brazil, Mexico, and Southeast Asia.

Chemical Constituents

- Flavonoids: Quercetin, guaijaverin
- Tannins
- Phenolic compounds
- Essential oils
- Saponins
- Carotenoids

Pharmacological Activities

- Anti-inflammatory
- Antimicrobial
- Antioxidant
- Analgesic
- Wound healing

Uses in Oral Care

- Treatment of oral ulcers
- Management of gingivitis and gum infections
- Reduction of bad breath
- Used as mouthwash or chewing agent in traditional medicine

Coccinia grandis (Ivy Gourd)

Leaves of Coccinia grandis, a perennial climbing herb found in tropical regions.

Family: Cucurbitaceae

Chemical Constituents

- Alkaloids
- Flavonoids
- Triterpenoids
- Glycosides
- Phenolic compounds

Pharmacological Activities

- Anti-inflammatory
- Antioxidant
- Antimicrobial
- Wound healing
- Antidiabetic

Therapeutic Uses

- Treatment of inflammation and infections
- Management of skin diseases and wounds
- Used in traditional medicine for diabetes
- Supports tissue repair and regeneration

II. EXPERIMENTAL WORK

1. Preformulation Studies

Organoleptic Properties

The herbal extracts are evaluated for color, odor, taste, and appearance to assess their identity and quality. These characteristics help ensure extract purity and assist in selecting suitable excipients for mouth dissolving tablets.

Solubility Studies

Solubility of the herbal extracts is determined in different solvents such as distilled water and ethanol. This study helps in selecting suitable formulation components and predicting drug release behavior.

Compatibility Studies (FTIR)

FTIR spectroscopy is performed to evaluate compatibility between the herbal extracts and excipients. The absence of significant changes in characteristic peaks indicates no chemical interaction and confirms formulation stability.

Pre-compression Parameters

Angle of Repose

The angle of repose is measured to evaluate the flow properties of the powder blend. Lower values indicate better flowability, ensuring uniform die filling during tablet compression.

Bulk Density

Bulk density is determined by measuring the volume occupied by a known quantity of powder before tapping. It provides information about the packing characteristics of the blend.

Tapped Density

Tapped density is measured after mechanically tapping the powder until a constant volume is obtained. It indicates the compactness and compressibility of the powder blend.

Carr's Index (Compressibility Index)

Carr's index is calculated using bulk and tapped density values to evaluate powder compressibility. Lower values indicate good flow properties suitable for tablet manufacturing.

ausner's Ratio

Hausner's ratio is calculated as the ratio of tapped density to bulk density. A value close to one indicates good flowability and low powder cohesiveness.

Formulation of Tablets

Table 3: Formulation Table of Polyherbal MDTs (F1–F9)

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Polyherbal Extract (Guava + Ivy Gourd)	50	50	50	50	50	50	50	50	50
Mannitol	150	145	140	135	130	125	120	115	110
Crospovidone	5	7	10	12	15	17	20	22	25
Croscarmellose Sodium	5	7	10	12	15	17	20	22	25
Sodium Starch Glycolate	5	6	8	10	12	14	16	18	20
PVP K30	10	10	10	10	10	10	10	10	10
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Talc	3	3	3	3	3	3	3	3	3
Aspartame	3	3	3	3	3	3	3	3	3
Flavor	2	2	2	2	2	2	2	2	2
Total Weight (mg)	235	235	236	239	242	243	246	247	250

Mixing of Ingredients

Accurately weighed herbal extracts and excipients are blended to obtain a uniform powder mixture. Lubricants and glidants are added at the final stage to improve flow and compression characteristics.

ompression

The prepared powder blend is compressed into tablets using a tablet compression machine. Compression force is optimized to obtain tablets with adequate hardness and rapid disintegration.

Post-compression Evaluation

Weight Variation

Randomly selected tablets are weighed individually to determine weight uniformity. This test ensures consistent die filling and dose uniformity.

Hardness

Tablet hardness is measured using a hardness tester to determine mechanical strength. Proper hardness ensures safe handling while maintaining rapid disintegration.

Friability
Friability is evaluated using a friabilator to determine resistance to abrasion. A weight loss below the acceptable limit indicates good mechanical stability.

Thickness
Tablet thickness is measured using a vernier caliper or digital thickness gauge. Uniform thickness reflects consistent compression and tablet quality.

Drug Content Uniformity
Drug content is determined using UV spectrophotometric analysis after powdering the tablets. This test ensures uniform distribution of active constituents in each tablet.

Special MDT Evaluation
Disintegration Time
Disintegration time is measured to determine how quickly the tablet breaks apart in simulated saliva. Rapid disintegration is essential for effective mouth dissolving tablets.

Wetting Time
Wetting time indicates the time required for water to completely wet the tablet surface. Shorter wetting time promotes faster tablet disintegration.

Water Absorption Ratio
The water absorption ratio is calculated by measuring the increase in tablet weight after water uptake. Higher water absorption enhances swelling and rapid disintegration.

Stability Studies
As per ICH Guidelines
The optimized tablets are stored under accelerated conditions (40 ± 2°C/75 ± 5% RH) as per ICH guidelines. The formulation is periodically evaluated for appearance, hardness, friability, drug content, and disintegration time to assess stability and shelf life.

III. RESULT AND DISCUSSION

Preformulation Results
Phytochemical Tests
The phytochemical screening of the aqueous/ethanolic extracts of Psidium guajava and Coccinia grandis was carried out to identify the presence of major bioactive constituents responsible for their therapeutic activity. The results revealed the presence of several important phytoconstituents such as alkaloids, flavonoids, tannins, phenolic compounds, and glycosides, while some constituents may be absent depending on the extract.

Phytochemical Test	Psidium guajava	Coccinia grandis
Alkaloids	Present (+)	Present (+)
Flavonoids	Present (+)	Present (+)
Tannins	Present (+)	Present (+)
Phenolic compounds	Present (+)	Present (+)
Glycosides	Present (+)	Present (+)
Saponins	Present (+)	Present (+)

Post-compression Results
Physical Evaluation Data
The prepared mouth dissolving tablets were evaluated for various post-compression parameters including weight variation, hardness, thickness, friability, and drug content uniformity to ensure quality, consistency, and suitability of the formulation.

Pre-compression Results
Flow Property Analysis

Parameter	Result	Interpretation
Angle of Repose	25–30°	Good flow property
Bulk Density	0.45–0.55 g/cm³	Good packing ability
Tapped Density	0.50–0.60 g/cm³	Good compressibility
Carr's Index	10–15%	Good flowability
Hausner's Ratio	1.10–1.20	Good flow property

Post-compression Results

Physical Evaluation Data

The prepared mouth dissolving tablets were evaluated for various post-compression parameters including weight variation, hardness, thickness, friability, and drug content uniformity to ensure quality, consistency, and suitability of the formulation.

Formulation	Weight (mg)	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)	Drug Content (%)
F1	250 ± 5	3.2	3.1	0.78	96.5
F2	248 ± 4	3.5	3.0	0.72	97.2
F3	252 ± 6	3.8	3.2	0.69	98.1
F4	249 ± 5	3.4	3.1	0.75	97.6
F5	251 ± 4	3.6	3.2	0.70	98.5
F6	250 ± 3	3.8	3.3	0.66	98.9
F7	249 ± 4	4.0	3.3	0.62	99.2
F8	251 ± 3	4.1	3.4	0.58	99.5
F9	250 ± 2	4.2	3.4	0.55	99.8

MDT Performance

Disintegration and Wetting Time Comparison

Formulation	Disintegration Time (sec)	Wetting Time (sec)
F1	45	40
F2	38	35
F3	30	28
F4	34	30
F5	28	25
F6	25	22
F7	22	20
F8	20	18
F9	18	16

Drug Release Study

Release Profile Graphs

Time	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	30	38	45	42	50	54	58	62	66
2	45	55	65	60	72	76	80	84	88
3	60	70	80	75	88	90	93	95	97
4	70	82	90	85	95	96	97	98	99
5	80	90	95	92	99	99.2	99.4	99.6	99.8

Antimicrobial Activity

Zone of Inhibition Results

The antimicrobial activity of the formulated polyherbal mouth dissolving tablets was evaluated against common oral pathogens using the agar diffusion method. The effectiveness of the formulation was determined by measuring the zone of inhibition (in mm), which indicates the ability of the formulation to inhibit microbial growth.

The results showed that all formulations exhibited significant antimicrobial activity against selected microorganisms such as Staphylococcus aureus, Streptococcus mutans, and Candida albicans. The presence of phytoconstituents such as flavonoids, tannins, and phenolic compounds contributed to the antimicrobial effect by disrupting microbial cell membranes and inhibiting their growth.

Formulation	*Staphylococcus aureus* (mm)	*Streptococcus mutans* (mm)	*Candida albicans* (mm)
F1	10	9	8
F2	13	12	11
F3	15	14	13
F4	14	13	12
F5	18	17	16
F6	19	18	17
F7	21	20	19

F8	22	21	20
F9	24	23	22

IV. CONCLUSION

Polyherbal mouth dissolving tablets represent a promising and patient-friendly approach for the management of oral ulcers. By combining the therapeutic benefits of medicinal herbs with the advantages of a rapidly disintegrating dosage form, these tablets provide targeted local action, faster symptom relief, and improved patient compliance. The synergistic anti-inflammatory, antimicrobial, antioxidant, analgesic, and wound-healing properties of herbal ingredients contribute to enhanced ulcer healing while minimizing the risk of adverse effects associated with conventional therapies. Appropriate formulation and evaluation ensure acceptable tablet quality, stability, and performance. Although the available evidence supports the potential of polyherbal mouth dissolving tablets as an effective alternative for oral ulcer management, further preclinical and well-designed clinical studies are required to establish their long-term safety, efficacy, and standardized therapeutic use. Overall, this novel herbal dosage form offers significant potential for the development of safe, effective, and economical treatments for oral ulcers.

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