

FORMULATION AND EVALUATION OF POLYHERBAL MOUTH DISSOLVING FILM**Vrushabh Arun Chavan*¹, Prachi Vilasrao Alhade¹, Omkar Chandrakant Pawar¹, Miss. Jayashri S. Kasar²**¹Undergraduate Student, Mrs. Saraswati Wani College of Pharmacy, Ganegaon, Ahilyanagar, Maharashtra, India.²Project Guide, Mrs. Saraswati Wani College of Pharmacy, Maharashtra, India.***Corresponding Author: Vrushabh Arun Chavan**

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ABSTRACT

Oral ulcer is a painful inflammatory lesion affecting the oral mucosal membrane, causing discomfort during speaking, mastication, and swallowing. Conventional dosage forms such as gels, mouth paints, and topical ointments often suffer from poor retention, imprecise dosing, and reduced patient compliance. Mouth dissolving films have emerged as a promising drug delivery platform owing to their rapid disintegration, ease of administration, improved patient compliance, and localized therapeutic action. The present study aimed to formulate and evaluate a polyherbal mouth dissolving film containing extracts of *Punica granatum* leaves and curcumin for rapid treatment of oral ulcer. Polyherbal extracts were prepared by maceration and Soxhlet extraction methods. Mouth dissolving films were prepared by solvent casting technique using Hydroxypropyl Methylcellulose as film-forming polymer, glycerol as plasticizer, and crospovidone as superdisintegrant. Prepared formulations were evaluated for physical appearance, thickness, weight variation, surface pH, folding endurance, moisture uptake, drug content, disintegration time, in-vitro drug release, antimicrobial activity, and stability studies. Among all formulations, batch F5 demonstrated superior physicochemical properties with thickness of 0.21 ± 0.01 mm, folding endurance of 285 ± 4 , disintegration time of 21 ± 1 sec, and drug content of $98.6 \pm 0.8\%$. In-vitro release studies revealed 97.2% release within 15 minutes. Antimicrobial studies showed significant activity against *Staphylococcus aureus*, *Escherichia coli*, and *Candida albicans*. Stability studies demonstrated no significant changes over 90 days. The developed formulation may represent an effective herbal alternative for rapid management of oral ulcer.

KEYWORDS: Polyherbal film; Mouth dissolving film; Oral ulcer; Punica granatum; Curcumin; Solvent casting; Herbal drug delivery.**1. INTRODUCTION**

Oral ulceration is one of the most frequently encountered pathological conditions affecting the oral cavity. It is characterized by localized erosion of mucosal epithelium accompanied by pain, inflammation, redness, and difficulty in mastication. The incidence of oral ulceration is increasing due to stress, nutritional deficiencies, microbial infections, immunological disorders, and mechanical injuries.

Current treatment approaches include topical anesthetics, corticosteroids, antiseptic mouth paints, and anti-inflammatory gels. However, these systems exhibit several limitations such as poor retention at the site of

action, short residence time, inaccurate dosing, and poor patient compliance.

Mouth dissolving films represent a novel drug delivery platform that offers rapid hydration, immediate disintegration, improved mucosal contact, enhanced drug bioavailability, and superior patient convenience.

**Therapeutic significance of herbal actives
Punica granatum leaves**

Contain:

- Tannins
- Flavonoids
- Polyphenols

- Ellagic acid

Biological activities

- Antimicrobial
- Anti-inflammatory
- Wound healing
- Antioxidant



Chemical Constituents of Punica granatum leaves Major Phytochemical Constituents

Sr. No.	Constituent	Approximate Percentage (% w/w)
1	Total Polyphenols	18–25%
2	Tannins	10–18%
3	Flavonoids	5–12%
4	Gallic Acid	2–5%
5	Ellagic Acid	3–7%
6	Punicalagin	4–10%
7	Alkaloids	1–3%
8	Saponins	2–6%
9	Terpenoids	1–4%
10	Glycosides	2–5%

Major active constituents responsible for oral ulcer activity

- **Tannins (10–18%)** → astringent, wound healing
- **Flavonoids (5–12%)** → antioxidant, anti-inflammatory
- **Punicalagin (4–10%)** → antimicrobial
- **Ellagic acid (3–7%)** → tissue repair
- **Gallic acid (2–5%)** → antioxidant

Total active phenolic fraction

Approximately 30–45%

Curcumin

Biological activities:

- Anti-inflammatory
- Antioxidant
- Analgesic
- Mucosal repair
- Antimicrobial

The combination of these agents may produce synergistic therapeutic action in oral ulcer management.



Chemical Constituents of Curcumin

Curcumin is obtained from *Curcuma longa* Rhizomes. Curcuminoid composition

Sr. No.	Constituent	Approximate Percentage (% w/w)
1	Curcumin (I)	70–80%
2	Demethoxycurcumin	15–20%
3	Bisdemethoxycurcumin	3–8%
4	Essential Oils	2–7%
5	Turmerones	2–5%
6	Proteins & Carbohydrates	1–3%

Major active fraction

- Curcumin: 70–80% → anti-inflammatory
- Demethoxycurcumin: 15–20% → antioxidant
- Bisdemethoxycurcumin: 3–8% → antimicrobial

Total curcuminoids

Approximately 90–95%

Combined Therapeutic Justification

The combination of *Punica granatum* leaves extract and Curcumin provides:

Activity	Responsible Constituents
Antimicrobial	Punicalagin, tannins, curcuminoids
Anti-inflammatory	Flavonoids, curcumin
Antioxidant	Polyphenols, ellagic acid, curcumin
Wound healing	Tannins, gallic acid, curcumin

2. MATERIALS AND METHODS

Materials

Materials used in the study:

- Punica granatum leaves extract
- Curcumin extract
- Hydroxypropyl Methylcellulose
- Glycerol
- Crospovidone
- Citric acid
- Sodium benzoate
- Purified water

All chemicals used were of analytical grade.

2.2 Extraction of herbal materials

Extraction of *Punica granatum* leaves



Extraction of Curcumin

Curcumin was extracted by Soxhlet extraction using

ethanol as solvent. The obtained extract was concentrated and dried.



2.3 Preparation of mouth dissolving films

Films were prepared by **solvent casting technique**.

Required quantity of HPMC was dispersed in purified water with continuous stirring. Glycerol was added as plasticizer, crospovidone as superdisintegrant, citric acid as saliva stimulating agent, and sodium benzoate as

preservative. Polyherbal extracts were incorporated into the polymeric solution. The solution was poured into glass Petri plates and dried at 40°C in hot air oven for 24 hours. Dried films were peeled and cut into uniform dimensions.



Ingredient	Function
HPMC	Film-forming polymer
Glycerol	Plasticizer
Crospovidone	Superdisintegrant
Citric acid	Saliva stimulating agent
Sodium benzoate	Preservative
Punica granatum extract	Active constituent
Curcumin extract	Active constituent
Purified water	Solvent

2.1 Formulation design

Batch	HPMC (mg)	Glycerol (mL)	Crospovidone (mg)	Herbal extract (mg)
F1	300	0.30	20	50
F2	350	0.35	25	50
F3	400	0.40	30	50
F4	450	0.45	35	50
F5	500	0.50	40	50

3. Evaluation Tests

3.1 Thickness

Film thickness was measured using micrometer screw gauge at different points.

3.2 Weight variation

Individual films were weighed using digital balance.

3.3 Surface pH

Film was moistened with distilled water and pH was measured using pH meter.

3.4 Folding endurance

The film was repeatedly folded at the same place until breaking.

3.5 Disintegration time

Film was placed in phosphate buffer pH 6.8 and time required for complete disintegration was recorded.

3.6 Drug content

Drug content was determined by UV spectrophotometric analysis.

3.7 Moisture uptake

Films were exposed to controlled humidity and percentage moisture uptake was calculated.

3.8 In-vitro drug release

Drug release was studied using dissolution apparatus in phosphate buffer pH 6.8.

3.9 Antimicrobial study

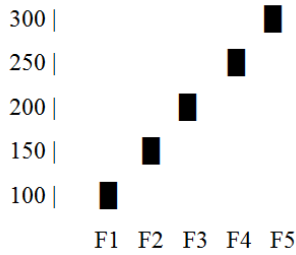
Antimicrobial activity was determined by agar diffusion method against:

- Staphylococcus aureus
- Escherichia coli
- Candida albicans

3.10 Stability study

Optimized formulation was stored at 25°C ±2°C / 60% RH for 90 days.

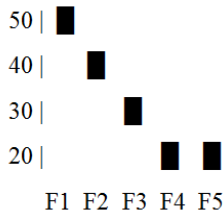
Parameter	F1	F2	F3	F4	F5
Thickness (mm)	0.14	0.16	0.18	0.19	0.21
Weight (mg)	112	118	121	126	131
Surface pH	6.2	6.4	6.6	6.7	6.8
Folding endurance	145	178	210	242	285
Disintegration (sec)	48	42	35	29	21
Drug content (%)	91.4	94.2	96.1	97.3	98.6
Moisture uptake (%)	5.2	4.8	4.3	4.1	3.8



Graph 1: Folding endurance.

Discussion

Increase in polymer concentration increased film flexibility and mechanical strength due to improved polymeric chain entanglement.



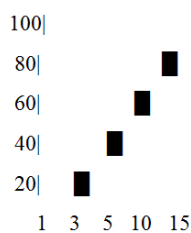
Graph 2: Disintegration time.

Discussion

Increase in crospovidone concentration significantly reduced disintegration time due to enhanced capillary action and water uptake.

4. In-vitro Drug Release

Time (min)	Release (%)
1	28
3	52
5	71
10	89
15	97



Graph 3: Drug release profile.

Discussion

Rapid release was observed due to:

- Hydrophilic nature of HPMC
- Fast swelling behavior
- Enhanced wetting by crospovidone

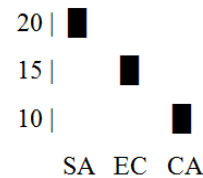
5. Antimicrobial study

Test organisms:

- Staphylococcus aureus
- Escherichia coli
- Candida albicans

Table 5: Zone of inhibition.

Organism	Zone (mm)
S. aureus	19
E. coli	16
C. albicans	14



Graph 4: Antimicrobial activity.

Discussion

Strong antimicrobial activity confirms synergistic action of pomegranate tannins and curcumin phenolics.

6. Stability study

Storage condition:

25°C ±2°C / 60% RH

Day	Drug content (%)	Disintegration (sec)
0	98.6	21
30	98.1	22
60	97.5	23
90	96.9	24



Graph 5: Stability profile

Discussion

No significant degradation was observed during storage.

Statistical analysis

Data expressed as:

Mean \pm SD (n=3)

One-way ANOVA showed significant differences among formulations ($p < 0.05$).

7. RESULTS AND DISCUSSION

The prepared formulations exhibited smooth surface, uniform thickness, flexibility, and acceptable organoleptic properties. Increasing polymer concentration improved folding endurance while crospovidone reduced disintegration time. The optimized formulation F5 demonstrated superior physicochemical performance and rapid release characteristics.

The antimicrobial activity confirmed effectiveness against common oral pathogens, supporting its application in oral ulcer treatment.

8. CONCLUSION

The study successfully developed a polyherbal mouth dissolving film containing *Punica granatum* leaves extract and curcumin extract for rapid management of oral ulcer. The optimized formulation exhibited excellent mechanical strength, rapid disintegration, high drug content, effective antimicrobial activity, and satisfactory stability. This formulation may serve as a promising herbal alternative in localized oral drug delivery.

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