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Formulation And Evaluation of Polyherbal Mouth Ulcer Gel Containing Bombax Ceiba Thorn Extract and Psidium Guajava Leaf Extract

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Superficial, antibacterial, antifungal, penetration, antiulcer, glycosides

Abstract
Studies show that the most typical symptom we experience is a mouth ulcer or canker sore. Clinically, the lesion is characterised by a single or numerous deep and superficial seals that are accompanied by microbial invasions. In order to cure mouth ulcers, the current study set out to make and evaluate a herbal gel employing Psidium guajava leaf and Bombax ceiba thorn extracts. Shamimin, an antibacterial compound found in Bombax ceiba Linn., suppresses fungal, viral, and bacterial infection of mouth ulcers. Both quercetin and myrcetin, which are both contained in Psidium guajava Linn., exhibit strong antiulcer activity. Phenolic acids, flavonoids, terpenoids, glycosides, and saponins are all present in the leaf extract of Psidium guajava, which has antibacterial and antiulcer properties. In order to effectively treat mouth ulcers, the present study of Bombax ceiba thorn extract and Psidium guajava leaf extract may boost drug penetration from the affected area, which may result in the treatment exhibiting both antifungal and antibacterial activity. In comparison to synthetic formulations, the developed herbal formulation was more stable, safe, and successful at treating mouth ulcers.

1. Introduction

Bombax ceiba

The family Bombaceae includes the silk cotton tree, Bombax ceiba (Malvaceae). The antibacterial effect is due to shamimin, which is a component of Bombax ceiba plant extract. By encouraging protein precipitation, gallic acid, which is included in the extract, prevents the growth of mouth ulcers. Phenolic compounds, flavone, saponin, triterpenoids, polysaccharides, tannins, and sterols are among the other chemicals found in Bombax ceiba extracts. By causing protein to precipitate, the hydro-alcholic Bombax ceiba thorn extract is responsible for preventing mouth ulcers. In cases of heavy menstruation bleeding, bombax ceibaroots are used because they have antioxidant properties[1][2] and [3] B. ceiba has properties that accelerate the heart [4], has hypotensive and hypoglycemia effects, analgesic properties, and performs as a typical anti-inflammatory medication. The dried delicate fruits of B. ceiba are beneficial for wound healing, promoting breast milk production, and treating conditions like calculus problems, chronic inflammation, kidney ulceration, other types of dysuria[5], pimples, acne, and boils. It is steeped and used as a tonic, the bark of B. ceiba[7]. Tannins in the aqueous extract of Bombax ceiba bark are used to treat pathogenic bacterial strains because of their anti-bacterial activity.

Psidium guajava :

Psidium guajava, also known as guava, is a plant in the Myrtaceae family. The essential oil of guava leaves contained sesquiterpenes including trans-caryophyllene, humulene, and caryophyllene oxide as well as monoterpenes such 1,8-cineole and limonene, which had antibacterial, insecticidal, and fungicidal properties. Psidium guajava leaf extract contains a flavonoid with antiulcer properties. The

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quercetin found in Psidium guajava exhibits antioxidant, anti-inflammatory, spasmolytic, antiviral, and anticancer action. High amounts of both organic and inorganic chemicals, including secondary metabolites such polyphenols, antioxidants, antiviral, and anti-inflammatory substances, can be found in guava. More vitamins and minerals are present. Flavonoids and other phenolic compounds are important inside guava. Flavonoids and lycopene are significant antioxidants. They assist in the treatment of malignant cells and slow down accelerated ageing of the skin [8]. Myocardial inotropsia may be affected by guava[9]. Guava skin extract can lower blood sugar levels when used for 21 days [10]. Guava has potent antimicrobial qualities.

Topical drug delivery system :

The topical route offers numerous advantages, particularly when compared to other drug delivery techniques, including continuous medicine delivery, less side effects, and improved patient compliance. To be applied externally, topical pharmaceutical products are designed. They are made to work on the surface of one or more layers of the skin, locally (for example, sunburn, keratolytic agents, local anaesthetics, antiseptics, and anti-inflammatory drugs).

Advantages of topical drug delivery system:

In order to provide the most effective cutaneous and percutaneous medication delivery, topical drug administration has recently grown in popularity due to a variety of advantages:

i. To prevent drug interactions with food and beverages, as well as problems with gastrointestinal drug absorption brought on by medicines, enzymatic activity, and gut pH.

ii. To avoid the first pass effect, which occurs when a pharmacological substance enters the systemic and portal circulation for the first time after being absorbed through the gastrointestinal tract and may stop the drug from being deactivated by digestive and liver enzymes.

iii. Non-intrusive, with the patient's permission.

Disadvantages of topical drug delivery system :

i. Due to the wide range of solubility in the vehicle component and the great variety of cutaneous fluxes, the entire drug is inappropriate for this delivery method.

ii. Due to the skin's barrier properties and dose size, this route can only deliver a limited number of medications.

iii. Age and general health are two skin-related characteristics that can affect the system's reliability in dispensing medication.

Oral mouth ulcer :

An inflamed, painful depression with red borders and a yellowish or white colour on the mucus lining of the oral cavity is known as a mouth ulcer[11].Canker sores, also known as mouth ulcers, are often tiny, painful lesions that appear in the mouth or at the gum line. A mouth ulcer can make it unpleasant to talk and eat.

According to their clinical condition, mouth ulcers are categorised into three groups:

1. **Minor mouth ulcer -**

Minor ulcers have a diameter of less than a centimetre and heal in one to two weeks.

Figure 1: Minor mouth ulcer

2.Major mouth ulcer –

Major ulcers have a diameter of two to three centimetres, are deeper, and take longer to heal.

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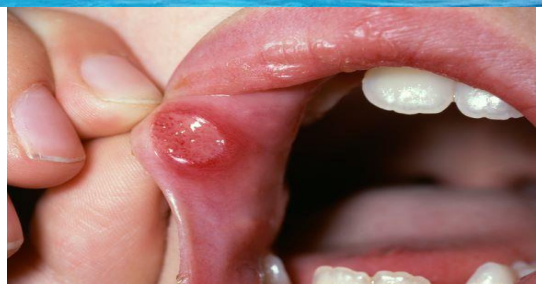

Figure 2: Major mouth ulcer

Common cause of mouth ulcer -

Although there is no recognised aetiology or pathophysiology for mouth ulcers, some factors are thought to be significant, such as iron and vitamin deficiencies, particularly B12 and C, poor dental hygiene, infections, stress, indigestion, mechanical injury, skin disease, etc. [12]

1) Hereditary factors: About 30%–40% of patients with aphthous ulcers have a family history [13], indicating that there is a genetic component to this condition. In certain cases, a family history of recurrent aphthous ulcers is evident. Young age of onset and symptoms of greater severity are two common connections.

2) Physical or psychological stress: Aphthous ulcer incidence are strongly correlated with stressful living circumstances [14]. Psychological stress may act as a trigger or a moderating element in the development of recurrent aphthous stomatitis. Stress has not been conclusively shown to be the cause of or a contributing factor in investigations to recurrent apthous stomatitis [15].

3)Nutritional deficiencies, including those affecting iron, folic acid, vitamin B12, B1, and B2 and B6, have been linked to a subset of aphthous ulcer patients. Depending on diet and dietary supplementation, different regions' contributions of nutritional deficits to aphthous ulcers are likely to differ [16].

4) Trauma: Stress and localised trauma are the most common causes of aphthous ulcers. Accidental self-biting, dental work, sharp-edged foods (like potato chips), anaesthetic injections, and tooth brush bristles can all cause damage to the oral mucosa. In addition to this, stress from the surroundings and your emotions might cause an aphthous ulcer [17].

5) Food sensitivities: Numerous foods have the potential to trigger allergies. Patients with recurrent apthous stomatitis exhibit anti-cow milk and anti-wheat protein antibodies (celiac illness). As a result, several typically allergenic foods (such as strawberries, tomatoes, and nuts) haven't been directly linked to recurrent apthous stomatitis [18].

6) Immunological diseases: Apthous ulcers are more prevalent and more severe in people with immune disorders, such as cyclic neutropenia, inflammatory bowel disease, Behçet's illness, and HIV disease. [19]

The most common topical treatments for mouth ulcers in Western medicine include corticosteroids, antibiotics, and analgesics. But when used for a longer time and more frequently, they all run the risk of having negative side effects[20]. Gels are mainly semi-solids that have a liquid phase that has been thickened with additional chemicals. Topical gels are applied to specific mucosal surfaces or to the skin as a topical or percutaneous medicine[21].

Materials and their roles

2. Materials And Method

Sr.No	Materials	Role of materials
1	*Bombax ceiba*thorn extract	Antioxidant, analgesic effects, anti-inflammatory, antibacterial, hepatoprotective.
2	*Psidium guajava* leaf extract	Antioxidants, antiviral, anti-inflammatory, antibacterial, anti-mutagenic, antiulcer.
3	Carbapol 934	In addition to bioadhesive, emulsifying, release-modifying, and suspending agents
4	Propylene glycol	disinfection, humectant, plasticizer, antimicrobial preservative, and disinfectant

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5	Triethanolamine	Alkalizing agent; emulsifying agent
6	Methyl paraben	Antimicrobial preservative
7	Propyl paraben	Antimicrobial preservative

Table 1: Materials and their roles

Materials and suppliers

Sr.No	Materials	Suppliers
1	*Bombax ceiba*thorn extract	Farm of Jambulpada, Vasai
2	*Psidium guajava* leaf extract	Thanjai Naturals, Kolathur, Chennai
3	Carbapol 934	Research lab Fine Chem. Mumbai
4	Propylene glycol	Research lab Fine Chem. Mumbai
5	Triethanolamine	Research lab Fine Chem. Mumbai
6	Methyl paraben	Mumbai's Fine Chem Research Lab
7	Propyl paraben	Fine Chem Research Lab in Mumbai

Table 2: Materials and suppliers

Formulation of poly-herbal mouth ulcer gel:

The gel was made with enough carbapol 934, methyl paraben, propyl paraben, triethanolamine, and propylene glycol as well as distilled water to make 50 g of herbal gel in accordance with table number. The method for formulation was,

1. 0.5 gm of Carbapol 934 was dispersed in 50 ml of distilled water while being continuously stirred, and methyl and propyl paraben were added to another beaker of hot distilled water over a water bath.
2. After heating, allow the solution to cool before adding the appropriate quantity of propylene glycol 400 and adding the extracts of Bombax ceiba thorn and Psidium guajava leaf.
3. Then, while stirring continuously, add the combined ingredients to the Carbapol 934 gel. Add triethanolamine dropwise to correct the pH with the appropriate label on the gel container [22][23][24][25][26][27][28][29].

Figure 3: All 9 batches of Polyherbal mouth ulcer gel

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
***Bombax ceiba*thorn extract (gm)**	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
***Psidium guajava* leaf extract (gm)**	1	1	1	1	1	1	1	1	1
Carbapol 934 (gm)	0.5	0.78	0.3	0.3	**0.7**	0.21	0.5	0.7	0.5
Propylene glycol (ml)	2.5	2.5	3.5	1.5	3.5	2.5	1.08	1.5	3.9

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Methyl paraben (gm)	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Propyl paraben (gm)	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Triethanolamine	2 Drops	2 Drops	2 Drops	2 Drops	2 Drops	2 Drops	2 Drops	2 Drops	2 Drops
Distilled water	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

Table 3: Formulation of poly-herbal mouth ulcer gel

Evaluation of polyherbal mouth herbal gel

- **Measurement of pH**

  The gel's pH was measured using a digital pH metre (EQUI-TRONICS MODEL-614). In 100 ml of purified water, 1 g of gel was dissolved, and the mixture was left unattended for 2 hours. Each formulation's pH was determined in triplicate, and average results were computed. [30] (Table no:4)

- **Spreadability**

  A glass plate with a circle that was already marked with a 1 cm diameter was coated with 0.5 g of gel to test the spreadability. 500 g of weight was placed on the top glass plate and left there for five minutes. [32]

  Results are shown in Table 5.

  - The formula was used to calculate it is,
  - S =M×L/T
  - L = length of the glass slides
  - T = time required to separate the slides
  - M = weight fastened to upper slide

- **Viscosity**

  The viscosity of several gel formulations including Bombax ceiba thorn and Psidium guajava leaf extracts was investigated at 25°C. With the aid of a Brookfield viscometer, the gel's viscosity was determined (Model LMDV 60). In a glass beaker with a capacity of 50 ml, 50 g of accurately weighed gel was transferred. The gel is submerged in spindle no. 6, which has been chosen. As soon as the reading stabilised, the viscometer was run at 10 revolutions per minute, and the reading was recorded in pascals .[32] (Table no:5)

- **Moisture absorption studies**

  In this test, a desiccator is filled with 1 gm of gel. In the same desiccator, a beaker filled with distilled water is set next to the gel. After 24 hours, measure the weight of the gel. The weight of a gel composition would increase if it absorbed any moisture.

- **Drug content**

  20 ml of phosphate buffer solution with a pH of 7.4 was used to dissolve 1 gramme of gel, and the resulting liquid was then filtered through paper. Then, an absorbance measurement was made using a Shimadzu UV 1700 (Japan) UV spectrometer at 255 nm.

  $$\text{Drug content} = \frac{\text{Theoretical concentration} - \text{practical concentration}}{\text{Theoretical concentration}} \times 100$$

- **Centrifugation test**

  All 9 batches of gel were put into centrifuged equipment (a Remi centrifuge) for centrifugation testing. The centrifuge was turned on for an hour at 1000 rpm to evaluate the separation of the two phases. (See Table 8).

- **Freeze thaw test**

  In a freeze-thaw test, herbal gels were exposed to -10 0C freezing for 24 hours, followed by 24 hours of thawing at normal temperature. Five cycles of this cycle were completed, and visual observation was used to track changes.

- **Gel strength**

  The amount of time needed for the weight to pierce the gel was used to gauge the gel's strength. Five grammes of sample material were taken from each of the successful batches. On top of the gel, a 3.5gm weight was placed. the length of time needed for the weight to successfully pierce 0.5 cm of gel.(Table 9)

- **Extrudability**

  In standard capped collapsible aluminium tubes, the gel compositions were packaged and sealed. To assess extrudability, the thumb pressure was

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applied. Excellent +++, Good ++, and Satisfactory + were the grades given[33]. (Table 10).

- **Stability Study**

Stability testing on closed and open containers were performed. In this instance, gel was kept at room temperature for three months[34].(Table 11)

- **In-vitro Studies on Drug Release**

Franz diffusion cells, which had a cell volume of 16.5 mL and an effective diffusion area of 3.14 cm 2, were used for the drug release tests. Gel was evenly applied to the surface of the cellophane membrane (1 g). The donor and receptor chambers of the diffusion cell were clamped with a cellophane membrane. Phosphate buffer solution that had just been produced was placed into the receptor chamber (pH 6.8). The receptor chamber was stirred using a magnetic stirrer. The appropriate sampling intervals were met. Samples were tested for drug content after the appropriate dilutions using a UV visible spectrophotometer at maximum (nm). The total amount of drug released was computed as a function of time at each appropriate time interval, and the drug was then completely replaced with new buffer. [35].

- **Antifungal activity**

Using the Cup-plate method, the antifungal activity of all batches of formulations developed as well as formulations without drug-containing gel (blank formulation) was evaluated in comparison to formulations that are readily accessible on the market. The bacteria cultures employed were Aspergillus aureus and Candida albicans. The antifungal test involved agar well diffusion. The prepared food was brought in, placed in sterile petri dishes, and allowed to dry and cool. A micron wire loop was then used to disperse every bacterial culture. A 6 mm diameter sterile cork borer was used to drill holes that were 4 mm deep. In the holes, add 0.5 gramme of gel from each batch next. Plates were then kept at 27 degrees Celsius for 48 hours. After that, the diameter in mm of the zone of inhibition that each chemical produced with each fungal strength was measured[36].

3. Result and Discussion

pH of poly-herbal mouth ulcer gel:

Readings of pH are in triplicates in following table no 4.All pH are suitable to oral cavity.

Formulations	pH
F1	6.85
F2	6.73
F3	6.80
F4	6.64
F5	6.52
F6	6.45
F7	6.47
F8	6.62
F9	6.74

Table 4: pH of poly-herbal mouth ulcer gel

Viscosity and Spreadability

Sr. No.	Carbapol 934 (%)	Propylene glycol (%)	Viscosity (Pa.S)	Spreadability (gm.Cm/sec)
F1	0.5	2.5	3.420	5.29
F2	0.78	2.5	3.998	4.98
F3	0.3	3.5	3.274	5.54
F4	0.3	1.5	3.189	5.62
F5	0.7	3.5	3.085	5.84
F6	0.21	2.5	3.280	5.42

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F7	0.5	1.08	3.334	5.38
F8	0.7	1.5	3.156	5.78
F9	0.5	3.9	2.778	6.50

Table 5: Viscosity and spreadability of polyherbal gel

Moisture absorption studies:

Batches F1, F2, F3, F4, F5, F6, F7, F8 of the formulation pass the test as there is no changes in their weight after the gel placed beside water containing beaker in desiccator. These formulations are stable throughout the time. But formulation batch F9 shows slightly increase in weight may because of amount of propylene glycol in this formulation is more as compare to other formulations. This factor affects stability.

% Drug content of *Bombax ceiba* thorn extract and *Psidium guajava* leaf extract

% Drug content per gram of *Bombax ceiba* thorn extractgel is given in following table no. 6 and in figure 4.

Formulation	% Drug content
F1	87.02%
F2	90.4%
F3	86.9%
F4	92.5%
F5	96.9%
F6	88.5%
F7	91.5%
F8	94.7%
F9	93.7%

Table 6: % Drug content of *Bombax ceiba*

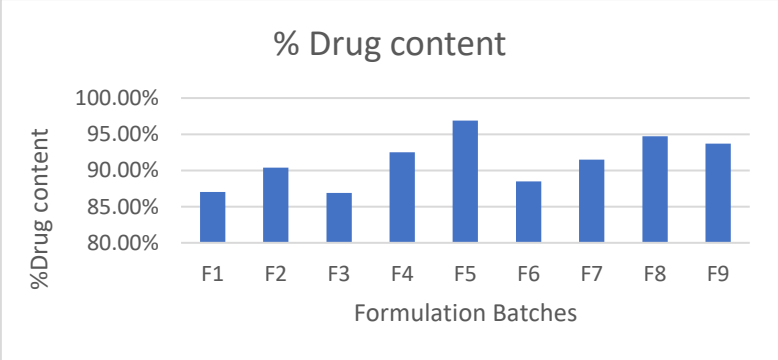

Figure 4: Bombax ceiba thorn extract % drug content

% Drug content per gram of *Psidium guajava leaf* extract gel is given in following table 6 and in figure 5.

Formulation	% Drug content
F1	88.50%
F2	91.56%
F3	86.90%
F4	93.75%
F5	97.05%
F6	89.36%
F7	92.20%
F8	95.45%
F9	94.89%

Table 7: % Drug content of *Psidium guajava* leaf extract

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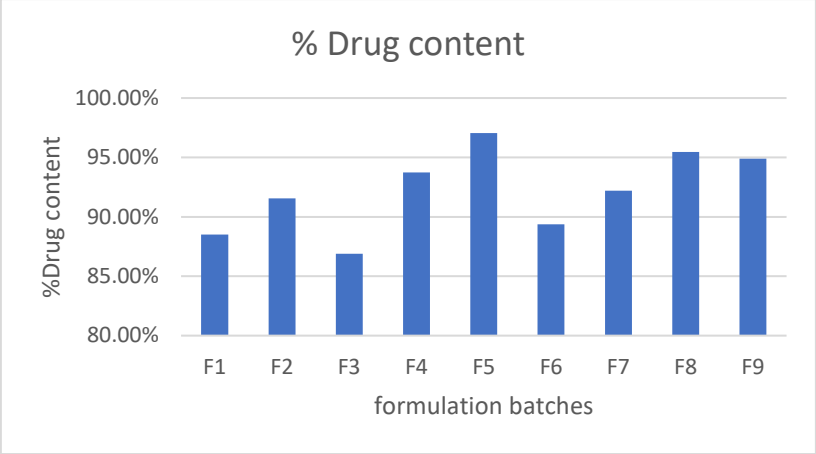

Figure 5: % Drug content of *Psidium guajava* leaf extract

Centrifugation test:

When the gels placed for centrifugation, the results are shown in Table 8.

Formulation	Observation
F1	There is no phase separation
F2	There is no phase separation
F3	There is no phase separation
F4	There is no phase separation
F5	There is no phase separation
F6	There is no phase separation
F7	There is no phase separation
F8	There is no phase separation
F9	Phase separation

Table 8: Centrifugation test

Freeze thaw testing:

All the gels were placed in freezer and at room temperature. All gels are stable and there is no change in their appearance or colour or texture or there is no observation of phase separation. Hence all gels pass the freeze thaw test.

Gel strength:

Formulation	Gel strength (Seconds)
F1	16
F2	20
F3	18
F4	35
F5	39
F6	30
F7	25
F8	32
F9	27

Table 9: Gel strength

Extrudability:

Formulation	Extrudability
F1	++
F2	+++
F3	++
F4	+
F5	+++

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F6	++
F7	++
F8	++
F9	+

Table10: Extrudability test

Stability Study

Medication discovery includes the stability testing of drug formulation. Stability studies that followed ICH recommendations were carried out to estimate the formulation's stability. Two months were spent storing the polyherbal mouth ulcer gel in a container in a humidity chamber set at 30 2°C/65 5% and 40 2°C/75 5% RH. The sample's spreadability, medication release, viscosity, and physical characteristics were assessed. Table No. shows the outcomes. Stability tests were done on the optimised batch, and since there is little to no sign of instability, it is safe to assume that the batch that is the most stable will be the final product. (Table 11)

Temperature and humidity	**Parameter**	**Observation (in months)**	
		Stability data for 1 month	Stability data for 2 month
	pH	6.54	6.56
	Colour	Reddish Brown	Reddish Brown
30 ± 2°C /65 ± 5% RH	Texture	Smooth	Smooth
	Viscosity (Pa.s)	3.090	3.099
	Spreadability (gm.cm/sec)		
	pH	6.89	6.95
	Colour	Reddish Brown	Reddish Brown
40 ± 2°C /75 ± 5% RH	Texture	Smooth	Smooth
	Viscosity (Pa.s)	3.509	3.690
	Spreadability (gm.cm/sec)	4.76	4.30

Table 11: Stability study of Poly-herbal mouth ulcer gel

% Drug release

% Drug release of *Bombax ceiba* thorn extract

% Drug release of *Bombax ceiba* thorn extract gel is given in below table 12 and figure 6.

Time (min)	**F1(%)**	**F2(%)**	**F3(%)**	**F4(%)**	**F5(%)**	**F6(%)**	**F7(%)**	**F8(%)**	**F9(%)**
0	0	0	0	0	0	0	0	0	0
0.5	17.27	12.72	12.72	14.09	10.9	13.18	8.63	9.54	14.09
1	22.27	17.27	24.09	20.9	15.9	25.45	15	14.54	24.09
2	29.54	22.27	34.09	28.18	19.18	32.72	25.9	23.63	35.45
3	40.45	33.63	40	35.9	29.54	42.72	34.63	35.9	43.63
4	49.54	40	47.27	43.63	39.09	51.81	41.81	42.27	51.81
5	53.18	47.27	53.63	52.4	53.72	56.95	54.09	52.27	57.27
6	55.9	57.72	55.45	58.63	64.77	67.27	64.54	57.72	61.36
7	59.54	62.27	66.36	78.63	88.18	82.4	80.9	69.09	73.63
8	63.18	65.45	66.36	78.63	88.18	82.4	80.9	69.09	73.63

Table 12: % Drug release of *Bombax ceiba* thorn extract gel

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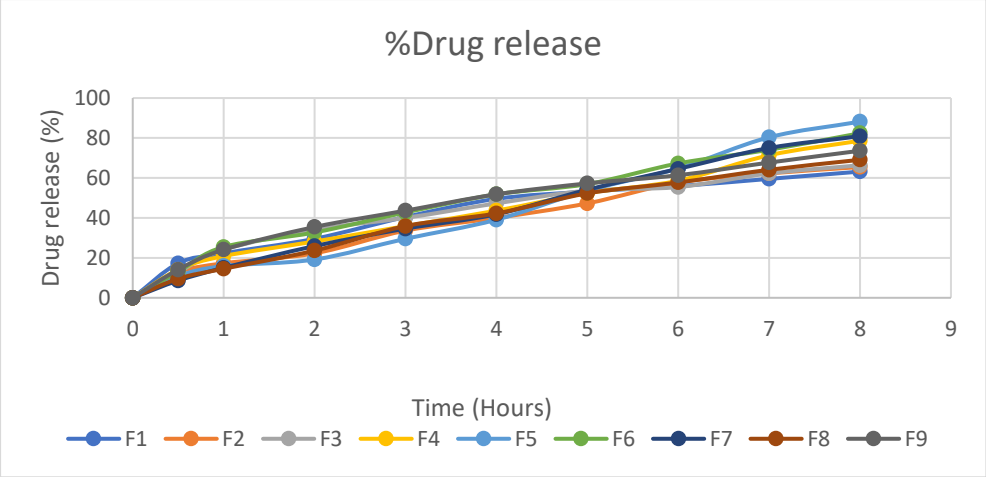

Figure 6: % Drug release of *Bombax ceiba* thorn extract gel

% Drug release of *Psidium guajava leaf* extract

% Drug release of *Psidium guajava leaf*extract gel is given in below Table 13 and figure 7.

Time (min)	F1(%)	F2(%)	F3(%)	F4(%)	F5(%)	F6(%)	F7(%)	F8(%)	F9(%)
0	0	0	0	0	0	0	0	0	0
0.5	18.36	14.67	14.56	15.67	11.75	15.69	10.56	11.96	16.5
1	22.27	17.27	24.09	20.9	15.9	25.45	15	14.54	24.09
2	29.54	22.27	34.09	28.18	19.18	32.72	25.9	23.63	35.45
3	40.45	33.63	41.78	35.9	29.54	42.72	34.63	35.9	43.63
4	49.54	42.5	47.27	43.63	39.09	51.81	41.81	42.27	51.81
5	53.18	47.27	53.63	52.4	53.72	56.95	54.09	52.27	57.27
6	55.9	57.72	55.45	58.63	64.77	67.27	64.54	57.72	61.36
7	59.54	62.27	62.27	71.36	80.36	74.09	75	64.09	67.7
8	65.36	6.8	67.5	80.46	90.5	84.2	82.75	71.56	75.89

Table 13: % Drug release of *Psidium guajava leaf* extract

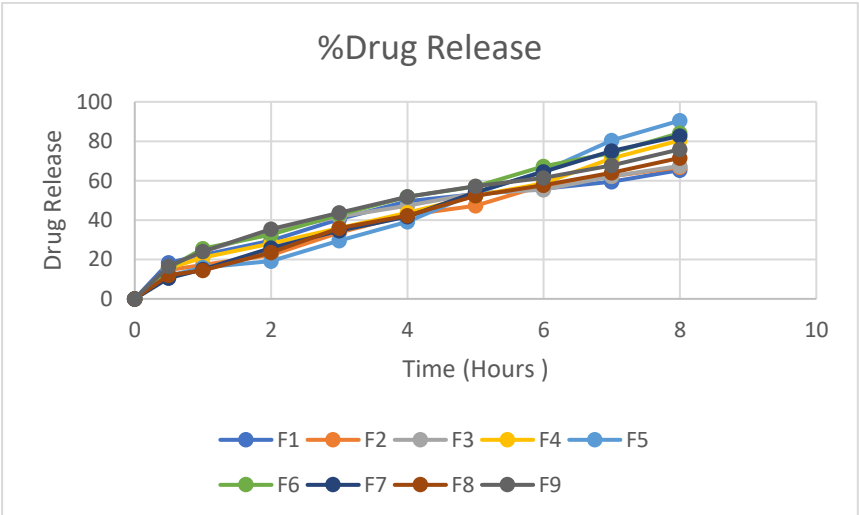

Figure 7: Psidium guajava leaf extract % drug release

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HPTLC of *Bombax ceiba* Linn.thorn and *Psidium guajava* Linn.leaf extract

HPTLC of Psidium guajava and Bombax ceiba Linn. Mobile phase experiments were conducted with Linn leaf extract: Ethyl acetate: Toluene. 9:1 v/v/. Figure 8

Track Assignment

Track	Vial ID	Description	Volume	Position	Type
1	SA-2223057-01	Psidium guajava leaf extract	5.0 µl	E3	Sample
2	SA-2223057-01	Psidium guajava leaf extract	10.0 µl	E3	Sample
3	SA-2223057-01	Psidium guajava leaf extract	15.0 µl	E3	Sample
4	SB-2223057-01	Bombax Ceiba Thorn extract	5.0 µl	E4	Sample
5	SB-2223057-01	Bombax Ceiba Thorn extract	10.0 µl	E4	Sample
6	SB-2223057-01	Bombax Ceiba Thorn extract	15.0 µl	E4	Sample

Track Assignment notes

Development 1 - Chamber:	
Tank	TTC 10x10
Mobile phase	Toluene : ethyl acetate (9:1)
Saturation time	20 min
Use saturation pad	true
Use smartALERT	false
Volume front through	5 ml
Volume rear through	5 ml
Drying time	5 min
Drying temperature	Room temperature
Notes	

Conclusion of HPTLC of extract :

1) Fingerprinting analysis was performed for the givensample.
2) After the development the Photo documentation was carried out in R white,R254nm and R 366nm.
3) After development bands were observed only in R 366nm, no bands obeserved in R White and R254nm.
4) After derivatisation of plate is done with Anisaldehyde Sulphuric acid reagent and heating at 110°C for 3minutes.
5) After the Derivatisation the photo documentation and scanning is done.

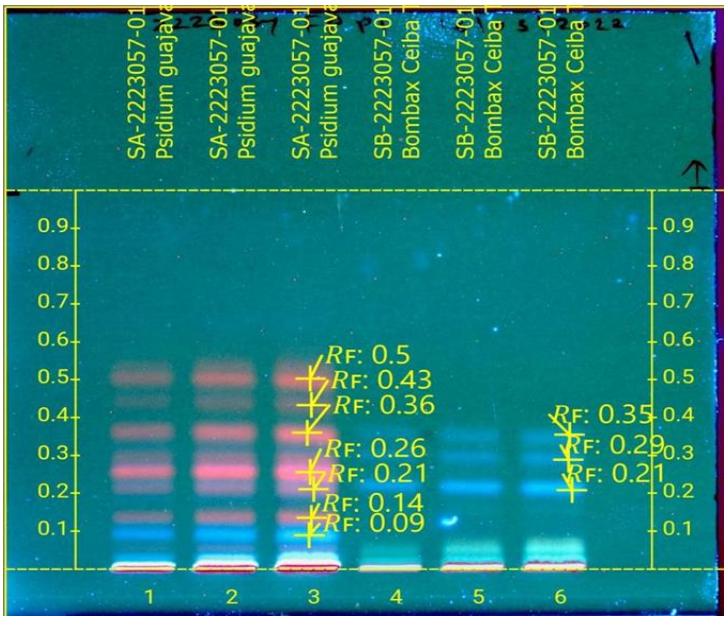

Figure 8 : HPTLCfingerprint of *Bombax ceiba* (SB-2223057-01) thorn extract and *Psidium guajava* leaf extract (SB- 2223057-01) at R 366 nm.

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4. Conclusion

Shamimin, found in Bombax ceiba Linn., has antibacterial properties and prevents fungal, viral, and bacterial infection in mouth ulcers. Essential oils and flavonoids are found in Psidium guajava Linn. Myrcetin, found in Psidium guajava Linn., has antiulcer activity, and Quercetin has antioxidant properties. The presented study of Bombax ceiba thorn extract and Psidium guajava leaf extract for the effective management of mouth ulcers may boost drug penetration from the affected area, indicating antifungal and antibacterial action. The presence of propylene glycol may boost the gel's stability. Bombax ceiba thorn extract has antiulcer properties. It also possesses antioxidant properties, which aid in the protection of the mouth's surface from oxidative damage. The leaf extract of Psidium guajava contains phenolic acids, flavonoids, terpenoids, glycosides, and saponins, which have antibacterial and antiulcer activity. As a result, a polyherbal combination of Bombax ceiba thorn extract and Psidium guajava leaf extract has been added into the gel used to treat mouth ulcers. Stat Ease® Design-Expert v13.0.2.0 optimally computed parameters for gel preparation using the Central composite approach. According to design expert software, the optimised batch comprising carbapol 934 0.7% and propylene glycol 3.5% achieves the greatest results in terms of viscosity, spreadability, and drug release. As a result, the batch holding the above requirements is the optimum batch among these 9 batches. According to in vitro studies, polyherbal gel made of Bombax ceiba thorn extract and Psidium guajava leaf extract is useful to heal mouth ulcers. And the optimised batch remained stable for three months with the greatest drug dispersion.

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