

Formulation Development of Mouth Dissolving Films Of *Solanum Trilobatum*

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ABSTRACT

This study focuses on the formulation and evaluation of mouth dissolving films (MDFs) containing ethanolic extracts of *Solanum trilobatum* Linn., a medicinal plant known for its therapeutic effects on respiratory and throat infections. The extract was prepared using the maceration method and incorporated into MDFs using the solvent casting technique with HPMC 15 cPs as the film-forming polymer, along with sucralose, glycerin, and ginger flavour. The antibacterial activity of the extract was tested against *Staphylococcus aureus* and *Klebsiella pneumoniae*, showing significant zones of inhibition, confirming its antimicrobial potential. The formulated films were evaluated for weight uniformity, thickness, surface pH, folding endurance, drug content, disintegration time, dispersion time, and in vitro dissolution. The results indicated that all formulations met USP requirements, exhibiting rapid disintegration (7 - 20 seconds), neutral surface pH, satisfactory drug content (98 - 101%), and efficient dissolution within 30 seconds. Both F1 and F2 formulations demonstrated good film characteristics and enhanced drug release. Overall, *Solanum trilobatum* MDFs show promise as a patient-friendly dosage form for treating throat infections, with potential for future clinical application and commercialization following stability studies.

Keywords: Mouth dissolving films, *Solanum trilobatum*, Throat infections, Climbing Brinjal

INTRODUCTION

Mouth Dissolving Films (MDFs) are innovative oral drug delivery systems that dissolve quickly when placed on the tongue, offering a convenient alternative to tablets and capsules. Initially introduced as breath fresheners, they have evolved into effective carriers for therapeutic agents. MDFs are especially beneficial for pediatric, geriatric, and dysphagic patients due to ease of administration, no need for water, and reduced choking risk. With advantages such as improved patient compliance, faster onset of action, and bypassing of first-pass metabolism, MDFs are gaining attention across the pharmaceutical industry as a modern, patient-friendly dosage form.

Throat infections are common illnesses typically caused by viral or bacterial agents, affecting areas such as the pharynx, tonsils, or larynx. These conditions are often referred to as pharyngitis, tonsillitis, or laryngitis, depending on the specific site of inflammation. Pharyngitis, in particular, is

characterized by scratchiness, pain, and difficulty swallowing, while tonsillitis involves swelling and redness of the tonsils. Sore throat symptoms vary but commonly include irritation, tenderness, hoarseness, and systemic signs like fever and swollen glands.

Bacterial infections can also cause sore throats. The most common one is strep throat, an infection of the throat and tonsils caused by Group A *Streptococcus* bacterium (GAS), *Staphylococcus aureus* and *Klebsiella pneumoniae*. *Staphylococcus aureus* is a gram-positive, round-shaped bacterium that is a member of the firmicutes, and it is a usual member of the microbiota of the body, frequently found in the upper respiratory tract and on the skin. *Klebsiella pneumoniae* is a gram-negative, non-motile, encapsulated, lactose-fermenting, rod-shaped bacterium. It causes different types of healthcare-associated infections, including bloodstream infections, wound or surgical site infections, and meningitis.

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

***Solanum trilobatum* Linn** (Solanaceae), the nightshade (order Solanales), with 102 genera and nearly 2,500 species. It is a prickly, diffuse, bright green perennial herb, woody at the base, 2-3 m height, found throughout India, mostly in dry places as a weed along roadsides and waste lands. The plant has many branched, spiny, scandent shrubs. Leaves are deltoid or triangular, irregularly lobed. Flowers are purplish-blue, in cymes. Berries are globose, red or scarlet.

Botanical name : *Solanum trilobatum* Linn.

Family : Solanaceae

Genus : *Solanum*.

Species : *Trilobatum*.

Order : *Solanales*.

Common name: Climbing Brinjal, Purple-fruited pea Eggplant.



Figure 1: Photographic presentation of *Solanum trilobatum*

AIM

The aim of this research work is to prepare an ethanolic extract of leaves and stem of *Solanum trilobatum* Linn and formulate that as a mouth dissolving film using solvent casting method. It is aiming to enhance local action against throat infections, improve patient compliance, and increase oral bioavailability. And also, to evaluate the physicochemical characteristics of the formulated film.

MATERIALS & METHODS

Materials

Solanum trilobatum plant is collected from rural parts of Madurai. Hypromellose (Hydroxypropyl methyl cellulose, 15 cPs) USP was bought from SD Fine Chemicals Ltd, India. Sucralose USP NF was procured from the NutraSweet company, US. Ginger flavour was bought from Modern Scientific Lab, India. Glycerin was procured from Paxmy Speciality Chemicals, India.

1.Preparation of extracts by Maceration method

S.trilobatum were washed with running tap water, dried the leaves under the shade for a week, and grind the leaves to a coarse powder using a mortar and pestle and stored in an air-tight container until further use. Ethanol solvent extract was prepared by transferring 100 g of powder to a wide-mouth sterile beaker and adding ethanol solvent 1000 ml to the powdered samples, which were allowed to soak for 1 week at normal room temperature in sterile conditions. After 1 week, heat the extract for an hour at 100°C. The mixture was then centrifuged at 2000 rpm for 10 minutes at 4°C. The supernatants were filtered through a sterile funnel containing sterile Whatman filter paper No.1.

2.Analytical Method for Estimation of drugs

2.1 Preparation of Simulated Salivary Fluid

64 g of Sodium chloride, 19.04 g of disodium hydrogen phosphate and 1.53 g of potassium dihydrogen phosphate were weighed and dissolved in 1000 ml of water. Make up to a volume of 7500 ml with water. pH of the solution was adjusted to 6.8 with ortho-phosphoric acid.

2.2 Preparation of stock solution

Stock solution of *Solanum trilobatum* was prepared by dissolving 100 mg of *Solanum trilobatum* extract in 100 ml of water using sonicator. 1 ml of stock solution is diluted to 100 ml using ortho phosphoric acid.

2.3 Determination of λ max

Stock solutions were scanned against SSF as blank with the range of 200 - 400 nm in UV Visible



Spectrophotometer. The wavelength of the maximum absorption was noted and UV spectrum were constructed.

2.4 Construction of Calibration curve

From this stock solution, 6, 7, 8, 9, and 10 ml were pipetted out and transferred into 10 ml volumetric flasks and make up to 10 ml with SSF. Then the solutions were measured at previously noted λ max against SSF. The results were noted and calibration curve were constructed.

1. Anti-Bacterial Activity by Disk Diffusion Method

Bacterial strains were tested using Mueller-Hinton Agar (MHA), which is a standard medium for antimicrobial susceptibility testing, contains beef extract, casein hydrolysate, starch, and agar. It supports the growth of non-fastidious organisms and is ideal for the disc diffusion (Kirby-Bauer) method.

Weigh 38 g of Mueller-Hinton Agar (MHA) and dissolve it in 1 L of distilled water. Boil to ensure complete mixing, then autoclave at 121°C for 15 minutes. After sterilization, allow the medium to cool, pour it into sterile petri dishes, and let it solidify. Ensure the final pH is 7.3 ± 0.1 at 25°C. Store the prepared plates at 2-8°C.

Stock of antibiotic disk should preferably be kept at 20°C; the freezer compartment of a home refrigerator is convenient. On removal from the refrigerator, the container should be left at room temperature for about one hour to allow the temperature to equilibrate.

Inoculate the fresh plate by the inoculum (sample) using a swab and streak all over the surface of the

medium three times rotating the plate through an angle of 60°C after each application leave the inoculum to dry for a few minutes at room temperature with the lid closed. The antibiotic discs placed on the inoculated plates using a pair of sterile forceps. A sterile needle tip may also be used to place the antibiotic disc on the plate.

Alternatively, an antibiotic disc dispenser can be used to apply the discs to the inoculated plate. Then the plate should be placed in an incubator at 35°C within 30 mins of preparation for 16-18 hrs generally and 24 hrs for *Staphylococcus aureus*. After incubation measure the zone of inhibition in mm diameter, the presence of anti-microbial activity (inhibition of bacterial growth) is indicated by zone of inhibition. The antibacterial agent diffuses in the agar medium and inhibits the growth of the bacterial strain tested.

Here our plant *Solanum trilobatum* linn. extracts (Ethanol extract) are tested with bacterial species *Klebsiella pneumonia* & *Staphylococcus aureus*. The standard for bacterial species used for comparison of the antibacterial activity of the extracts is Amikacin.

2. Formulation Development of MDFs

Mouth-dissolving films of *Solanum trilobatum* were prepared using the solvent casting method. The ethanolic extract was mixed with HPMC 15cPs, sucralose, ginger flavour, and glycerin to form a uniform solution. After removing air bubbles, 5 ml of the solution was poured into an 8 cm petri dish and dried at 50°C for 45 minutes, followed by vacuum drying at 35°C. The films were then cut into 3 cm circular discs containing 150 mg or 200 mg of extract and stored in Alu-Alu pouches.

Table 1: Formulation of *Solanum trilobatum* MDF with different concentrations of HPMC 15cPs

Batch code		F1 (150 mg)	F2 (200 mg)
S. No.	Ingredients	Quantity / film	
1.	<i>Solanum trilobatum</i> extract	150 mg	200 mg
2.	Hypromellose (Hydroxypropyl methyl cellulose 15 cPs)	150 mg	150 mg
3.	Sucralose	5 mg	5 mg
4.	Ginger flavour	50 mg	50 mg
5.	Glycerin	65 mg	65 mg
6.	Distilled water	5 ml	5 ml



1. Evaluation of *Solanum trilobatum* Linn MDF

The prepared *Solanum trilobatum* Linn. MDFs were evaluated for uniformity of weight, thickness of film, disintegration time, *in vitro* dispersion time, surface pH, and folding endurance.

5.1 Uniformity of weight

Each film was individually weighed on an analytical balance, and the average weight of 3 films was found. A large difference in weight denotes the non-uniform distribution of the drug in the film.

5.2 Thickness of film

The thickness of the different films was measured using a calibrated dial gauge (Baker Precision measuring instruments, China) with an accuracy of 0.001 mm. Thickness was measured by placing each film between the anvil and the presser foot of the dial gauge in 5 different locations, and the average thickness was calculated.

5.3 *In vitro* dispersion time

In-vitro dispersion time was measured by the Petri dish method. A film was dropped in a culture dish of 8 cm in diameter, containing 10 ml of simulated salivary fluid. 6 MDFs from each formulation were randomly selected, and the *in vitro* dispersion time was performed.

5.4 Disintegration time

The *in vitro* disintegration time was determined using a disintegration test apparatus. 6 MDFs were placed in each of the six tubes of the basket, and the apparatus was operated with 900ml of purified water as the immersion fluid, maintained at $37 \pm 2^\circ\text{C}$. The time in seconds taken for complete disintegration of the film with no palpable mass remaining in the apparatus was recorded in seconds. The FDA recommends a disintegration time of 30 s or less for ODTs, based on the USP disintegration test, which was also taken as a limit for MDFs.

5.5 Surface pH

MDF with a highly acidic or basic pH causes discomfort while taking it. To know the surface pH of

the film, the film was placed in a petri dish and moistened with 0.5 ml of distilled water and kept for 30 seconds. The surface pH was measured by means of pH paper placed on the surface of the swollen films. The average of 3 determinations for each formulation was calculated.

5.6 Folding endurance

Folding endurance was measured manually for the prepared films. A 7.07 cm^2 MDF was repeatedly folded at an 180° angle of the plane at the same place up to 300 times, which was considered satisfactory to reveal good film properties. The number of times the film could be folded at the same place without breaking was noted for 3 films of the same batch.

5.7 Drug content and UOD

Drug content and Uniformity of dosage units of *Solanum trilobatum* MDF by the content uniformity method were also performed for formulated films. One film is transferred into a 150mL volumetric flask. Added 50mL of water sonicated for 10 minutes and kept for cooling, made volume with water. The solution was filtered through 0.45-micron filter. 5mL of the above solution diluted to 100mL with water.

5.8 *In vitro* dissolution studies

In vitro drug release studies of *Solanum trilobatum* MDFs were carried out in simulated salivary fluid to simulate dissolution in the mouth. The Lab India DS 8000 dissolution apparatus was used. The parameters of the dissolution study are,

Medium	:	Simulated salivary fluid
Volume	:	900 ml
Apparatus	:	USP Type II(Paddle)
Paddle RPM	:	50
Profiling time points	:	2,5,10 and 15 minutes.
Temperature	:	$37 \pm 0.5^\circ\text{C}$

RESULTS & DISCUSSION

1. Determination of λ_{max}



λ max of *Solanum trilobatum* was determined with solution of SSF and graph was given in Figure 2.

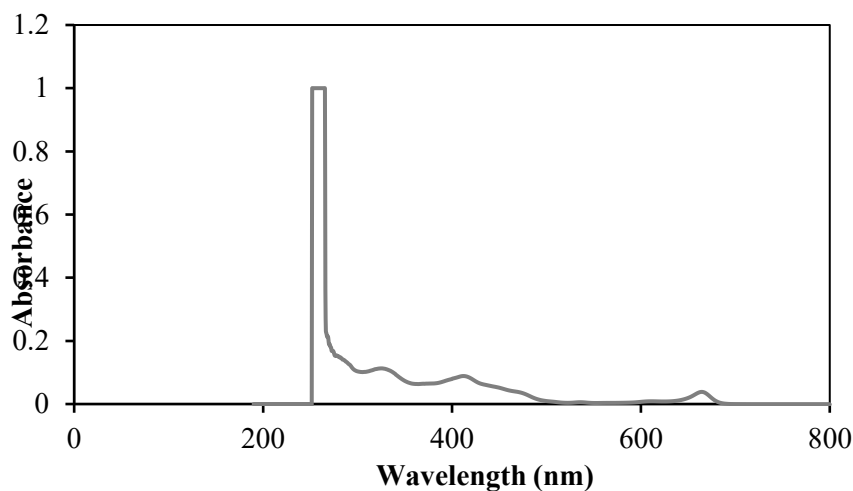


Figure 2: λ max of *Solanum trilobatum* in SSF

Discussion

λ max of *Solanum trilobatum* was found to be 253 nm in SSF.

The stock solution of *Solanum trilobatum* were diluted and analysed in UV spectrophotometer at the wavelength of 253 nm. The results were given in Table 2 and Figure 3.

2. Construction of Calibration curve

Table 2: Absorbance of *Solanum trilobatum* at different concentrations in SSF

Concentration ($\mu\text{g/ml}$)	Absorbance (253 nm)
60	0.37
70	0.56
80	0.74
90	0.92
100	1.10

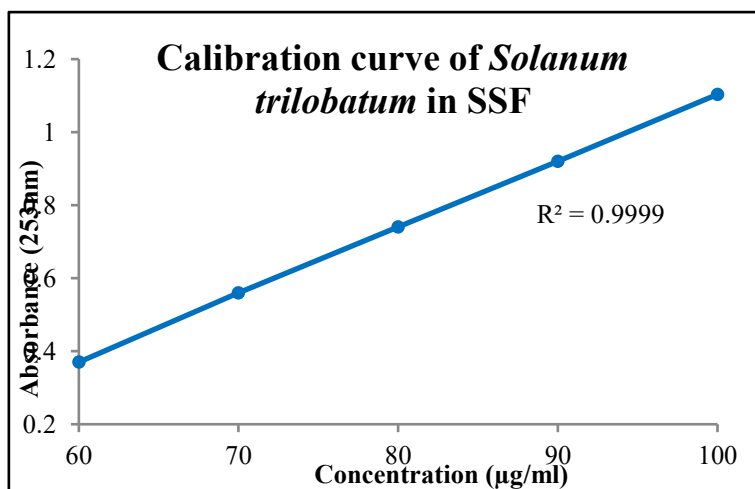


Figure 3: Standard Calibration Curve of *Solanum trilobatum* in SSF

2. Anti-Bacterial Activity

The anti-bacterial activity of the ethanolic extract of *Solanum trilobatum* against bacterial species,

Klebsiella pneumoniae & *Staphylococcus aureus* show a zone of inhibition to the ethanolic extract which is presented in Table 3.

Table 3: Zone of inhibition of *Solanum trilobatum*

SAMPLE CODE	<i>Klebsiella Pneumoniae</i>	<i>Staphylococcus Aureus</i>
Extract (<i>Solanum trilobatum</i>)	10 mm	11 mm
Control (Alcohol dipped)	7 mm	7 mm
Standard (Amikacin)	17mm	17mm

3. Evaluation of mouth-dissolving film

The results of the physical characterisation of *Solanum trilobatum* Linn. MDFs were given in Table 4.

4.1 Uniformity of weight

Films are prepared using the solvent casting technique and evaluated for weight uniformity. The films were obtained in the acceptable range of weight variation as per USP specification. The results are given in Table 4, which shows that all the batches were found to have the maximum Standard Deviation of ± 0.80 mg and within the USP limit. Hence, all batches passed the weight uniformity test.

4.2 Thickness of the film

The thickness of the film was calculated by a calibrated dial gauge and found in the acceptable range 40.13 - 46.89 μm .

4.3 In vitro dispersion time

The in vitro dispersion time was measured by the Petri dish method. Where the film is found to be within the acceptable range of dispersion time as per USP specification.

4.4 Disintegration time

The in vitro disintegration time was determined using a disintegration test apparatus. And the film is found to be disintegrate in range of 7-20 seconds which shows all batches found to be within the limit given by USP.

4.5 Surface pH

The film's surface pH was found to be in the range of 7. As the surface pH of the film was around the neutral pH, irritation would not be produced when administered.

4.6 Folding Endurance

The folding endurance of the film was found to be 5, which indicates the film is less flexible.

4.7 Drug content and UOD

The percentage drug content in all the formulations varied between 98.5 and 101.5, as depicted in Table 4. The uniformity of dosage units of formulation showed an L1 value of less than 15 indicating the accuracy and uniform distribution of quetiapine fumarate in the formulated MDF.

Table 4: Physical Properties of *Solanum trilobatum* mouth dissolving films

Parameters	Batch code	
	F1(150mg*)	F2 (200mg)
Weight (mg)	38.11 $\pm$ 0.79	40.10 $\pm$ 0.78
Thickness (μm)	42.20 $\pm$ 1.19	44.07 $\pm$ 2.14
Folding endurance	>300	> 300



Surface pH	7	7
<i>In vitro</i> dispersion time (sec)	9.50 ± 1.44	16.71 ± 1.48
Disintegration time (sec)	7.23 ± 0.987	17.37 ± 0.96
Drug content (%)	100.54 ± 0.46	99.30 ± 0.47
UOD (Acceptance value)	2.11	1.49

*150 mg and 200mg indicate the concentration of HPMC present in a film

In vitro drug release studies of *Solanum trilobatum* MDFs were carried out in SSF for 15 mins. Dissolution profiles are given in Figure 4.

4.8 In Vitro Dissolution Studies

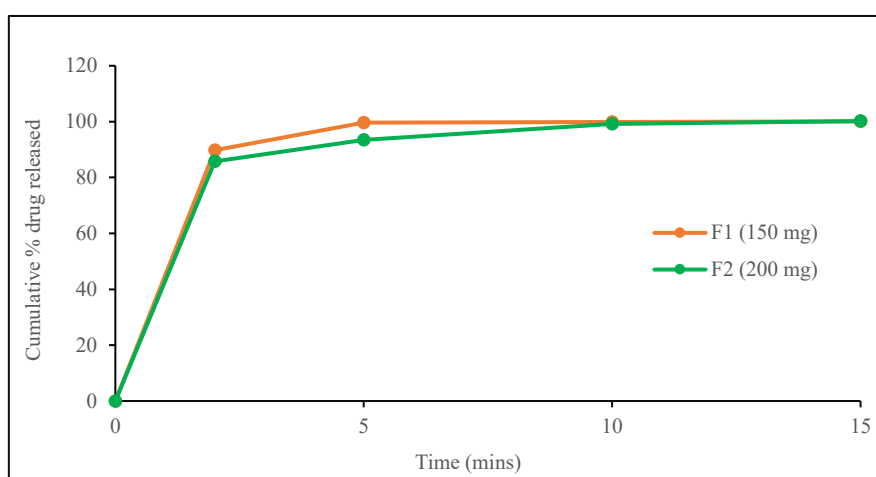


Figure 4: Comparative dissolution profiles of *Solanum trilobatum* MDFs

CONCLUSION

The formulation of *Solanum trilobatum* mouth-dissolving films meets all the requirements of mouth-dissolving films as per USP standards was successfully formulated. The mouth dissolving film formulated with hydrophilic polymers HPMC 15cps is most suitable for *Solanum trilobatum*. By its reduced dose frequency, rapid release and enhanced bioavailability, it could give excellent patient compliance. It showed faster disintegration, and enhanced solubility in oral and gastric pH. Both MDFs (F1, F2) prepared in this study was found to have higher dissolution rates. All the formulations found to be dissolved within 30 seconds. The prepared formulations F1, F2 have drug content of 98% with uniform distribution. So, it was concluded that the intent of this research was successfully made and after requisite stability and clinical studies, this patient-friendly dosage form can be made commercialised which will result in great patient compliance and a more effective treatment.

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- HOW TO CITE:** Senthilkumar*, Raj Priya, Babu Thandapani, Formulation Development Of Mouth Dissolving Films Of *Solanum Trilobatum*, J. Pharm. Sci., 2026, 2 (1), 1117-1124. <https://doi.org/10.5281/zenodo.18365805>

