



Research Article

Fast-Dissolving Oral Thin Film of Solanum Virginianum Leaves: A Novel Delivery System for Hepatic Health

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Fast-dissolving oral thin films (FDOTFs) are a patient-friendly drug delivery system that provides rapid drug release, improved bioavailability, and better patient compliance. The present study aimed to formulate and evaluate a fast-dissolving oral thin film containing Solanum virginianum leaf extract for its hepatoprotective potential. Solanum virginianum is a medicinal plant known for its antioxidant, anti-inflammatory, antimicrobial, and hepatoprotective properties due to the presence of phytoconstituents such as alkaloids, flavonoids, tannins, and saponins. The leaf extract was prepared by Soxhlet extraction using ethanol and subjected to phytochemical screening. Fast-dissolving oral thin films were prepared by solvent casting method using HPMC (0.600 g) as film-forming polymer and PEG 6000 (0.300 g) as plasticizer. The prepared films were evaluated for thickness, folding endurance, surface pH, disintegration time, and in-vitro drug release. The optimized formulation showed uniform thickness, good mechanical strength, and surface pH near neutral, and rapid disintegration within 52 seconds. The in-vitro dissolution study revealed about 96% drug release within 5 minutes, indicating fast and efficient drug release. FTIR studies confirmed compatibility between drug and excipients. In conclusion, the formulated fast-dissolving oral thin film of Solanum virginianum leaf extract showed satisfactory physicochemical properties and rapid drug release, indicating its potential as a simple, effective, and patient-compliant herbal drug delivery system.

Keywords: Fast-dissolving oral thin films, Solanum virginianum, in-vitro drug release, FTIR studies.

INTRODUCTION

Solanum virginianum L, also known as Yellow Berried Nightshade, is a prominent medicinal plant recognized in Ayurveda and traditional medicine, particularly in regions with limited modern healthcare, such as India and China. As an integral component of Ayurvedic practices, this plant gained traction due to its safety, efficacy, and affordability, appealing to both urban and rural populations. Belonging to the Solanaceae family, Solanum virginianum thrives in arid regions of India and is distinguished by a diverse array of pharmacological properties. The plant is rich in bioactive compounds, including alkaloids, flavonoids, glycosides, and terpenoids, which underpin its therapeutic applications. Traditional medicinal uses encompass a broad spectrum, addressing conditions such as throat infections, asthma, skin disorders, headaches, and hair

fall. Moreover, the plant is noted for its significant pharmacological activities, including antimicrobial, antitumor, anti-inflammatory, antioxidant, antidiabetic, hepatoprotective, and antifertility effects. A wide range of phytochemicals can be extracted from various parts of Solanum virginianum, including flavonoids, saponins, alkaloids, sterols, fatty acids, glycosides, phenolics, amino acids, and tannins. These compounds enhance its potential as a natural remedy, further substantiating its place within herbal medicine and traditional healing practices.

Oral Film

The oral route remains the most preferred method for drug administration due to its safety, convenience, and cost-effectiveness. However, challenges such as poor solubility and significant first-pass metabolism hinder the bioavailability of conventional dosage

forms. To address these issues, various strategies have been implemented to enhance the oral bioavailability of poorly soluble and highly metabolized therapeutic agents. One of the innovative solutions is the development of oral disintegrating or dissolving films, defined as drug delivery systems that rapidly release active ingredients by dissolving or adhering to the mucosa when they come into contact with saliva; this occurs within seconds due to the presence of water-soluble polymers. Oral thin films (OTFs) are gaining significant attention in the nutraceutical delivery space. These ultra-thin, flexible sheets can be conveniently placed on the tongue or applied to sublingual and buccal mucosa. The design of rapidly dissolving polymer thin films positions them as a favorable oral drug delivery vehicle, capable of bypassing first-pass liver metabolism, offering longer shelf life, and simplifying transport and distribution compared to traditional tablets and liquid formulations. Oral films can be classified into three main categories: oral fast dissolving films, buccal slow-release films, and transdermal films. Each type serves distinct purposes in drug administration, reflecting the versatility and advancements in oral delivery systems.

Oral Fast Dissolving Film

Oral fast dissolving films are thin films that dissolve quickly in the mouth within seconds to one minute and release the drug through the oral mucosa. They improve patient convenience and are useful for drugs with poor solubility, low bioavailability, or for patients who have difficulty swallowing tablets.

Advantages:

- Easy and convenient to use, improving patient compliance.
- Faster onset of action than conventional oral dosage forms.
- Better bioavailability due to absorption through the oral mucosa.
- Suitable for pediatric, geriatric, and dysphagic patients.

Disadvantages:

- Limited drug loading because the film is very thin.

- Difficult formulation due to the need for proper mechanical strength and drug release.
- Sensitive to moisture and temperature, which may affect stability.

Buccal Slow-Release Film

Buccal slow-release films are thin films placed on the buccal mucosa (inside of the cheek) that release the drug slowly and continuously over an extended period, from hours to days. They are useful for drugs with a short half-life and help improve bioavailability by avoiding the hepatic first-pass metabolism.

Advantages:

- Provides prolonged and controlled drug release.
- Avoids hepatic first-pass metabolism, increasing bioavailability.
- Suitable for drugs with short half-life or requiring sustained delivery.
- Non-invasive and convenient drug delivery method.

Disadvantages:

- Limited drug loading due to thin film thickness.
- Formulation difficulties in maintaining film strength and proper drug release.
- Possible irritation or allergic reactions in the buccal mucosa.

Transdermal Film

Transdermal films deliver drugs through the skin into the systemic circulation. They are commonly used for drugs that require long-term therapy or have a high first-pass effect. This method provides a convenient and non-invasive drug delivery system.

Advantages:

- Bypasses the gastrointestinal tract and hepatic first-pass metabolism.
- Provides prolonged and controlled drug release.
- Non-invasive and convenient method of drug delivery.
- Maintains steady drug concentration in the bloodstream.

Disadvantages:

- Limited drug loading due to thin film thickness.
- Formulation challenges in maintaining film strength and drug release.
- Possible skin irritation or allergic reactions.
- Suitable mainly for lipophilic drugs that can penetrate the skin.

Hepatomegaly (Enlarged Liver)

Hepatomegaly refers to the enlargement of the liver and is usually a sign of an underlying liver disease or medical condition.

Causes:

- Fatty liver disease due to alcohol use or metabolic problems like obesity and insulin resistance.
- Chronic alcohol-related damage causing inflammation and scarring.
- Viral hepatitis (B and C) leading to liver inflammation.
- Cirrhosis, where the liver may enlarge in early stages.
- Liver cysts or abscesses that increase liver size.
- Excess alcohol consumption.
- Infections caused by bacteria, parasites, or viruses.
- Overuse of vitamins, supplements, or medications.

Signs and Symptoms:

- Abdominal pain
- Fatigue
- Nausea and vomiting
- Jaundice (yellowing of skin and eyes)

MATERIALS AND METHODS**Collection of Plant:**

Solanum virginianum leaf was collected from nearby town in Thirunelveli. Hydroxypropyl methylcellulose (HPMC) was used as the film-forming polymer, while polyethylene glycol 6000 (PEG 6000) served as the plasticizer. Citric acid was incorporated to adjust pH, enhances drug solubility, improves taste, dissolution and saliva-stimulating agent and ethanol was used as

the solvent for film preparation. All chemicals and reagents used in the study were of analytical grade

Extraction Method:**Soxhlet extraction method for *Solanum virginianum* L.:**

25 g of *Solanum virginianum* powder was placed in a filter-paper thimble and inserted into a Soxhlet extractor for continuous extraction. Ethanol was used as the solvent because it can dissolve both polar and non-polar phytochemicals. The ethanol in a round-bottom flask was heated above 40 °C to reflux, allowing the vapors to condense and repeatedly pass through the plant powder for 5–10 hours. After extraction, the ethanol extract was collected and distilled for about one hour to concentrate it, ensuring complete evaporation of ethanol and leaving behind the concentrated *Solanum virginianum* extract.

Phytochemical Screening:

The presence of phytoconstituent in *solanum xanthocarpum* leaf extract can be identified by using simple qualitative chemical analysis for alkaloids, flavonoids, tannins and saponins.

Formation of Oral Thin Film:**Design of fast dissolving oral thin film by solvent casting method:**

Accurately weighed quantities of polymers (HPMC) were dissolved in distilled water. The solution was heated and bubble free, to this plasticizer, (PEG6000) and sweetener, (SUCROSE) were added and mixed thoroughly, drug was added to above solution and dissolve completely, now clear solution was poured into clean Petri dish. It was dried in hot air oven up to 24 hours then peeled off from the Petri dish stored in desiccators for further study.

Evaluation Method:**Thickness:**

Film thickness was measured using a micrometer screw gauge at five positions (center and four corners), and the average value was calculated to ensure uniform thickness and accurate dosing.

Weight Variation:

Each film was weighed using an analytical balance to determine the average weight and ensure uniform distribution of excipients and active pharmaceutical ingredient (API).

Folding Endurance:

The film was repeatedly folded at the same point until it broke. The number of folds before breaking indicates the film's mechanical strength.

Surface pH:

One film was dissolved in 10 ml of distilled water, and the pH of the solution was measured using a pH meter.

Content Uniformity:

A film (2.2 cm diameter) was dissolved in purified water and diluted to obtain a 1 µg/ml solution. The drug content was determined using UV spectrophotometry at 245 nm with the help of a standard calibration curve.

Disintegration Test:

The film was placed in 900 ml phosphate buffer and swirled at 30 cycles per minute. Disintegration time was recorded when the film began to break apart.

In-vitro Dissolution Study:

The in-vitro release of drug from all formulations was determined using USP apparatus type II (Paddle method). The following conditions were followed to study the invitro dissolution study of fast dissolving

oral thin film. USP dissolution apparatus: Type II (Paddle method), volume of dissolution medium: 900 ml of pH 6.8 simulation saliva, speed: 50 rpm, Temperature: $37 \pm 0.5^\circ\text{C}$, Dissolution medium: 0.1N HCl, Sampling interval: 1min. Quantity of sample withdrawn: 5 ml were withdrawn at 1min interval for 5 min. The volume withdrawn was replaced by fresh volume dissolution medium. The filtered samples were analysed by UV visible spectrophotometer at 230 nm and absorbance was noted. Cumulative percent drug release was calculated.

RESULTS AND DISCUSSION**Extraction of Leaf Powder:**

The leaf powder of solanum virginianum was repeatedly extracted with ethanol in a soxhlet apparatus. After the completion of extract, the solvent having the extract in the round bottomed flask was taken and concentrated by mild heating and evaporate the excess solvent.

Phytochemical Screening:

The presence of phytoconstituent in Solanum Virginianum leaf extract can be identified by using Simple qualitative chemical analysis and it shows the presence of alkaloids flavonoids tannins and saponnis.

FTIR Spectroscopic Analysis:

The FTIR absorption spectra of the solanum virginianum were taken in the range 3600-600 cm^{-1} using KBr disc method. The major peaks were reported evaluation of purity in fig 1

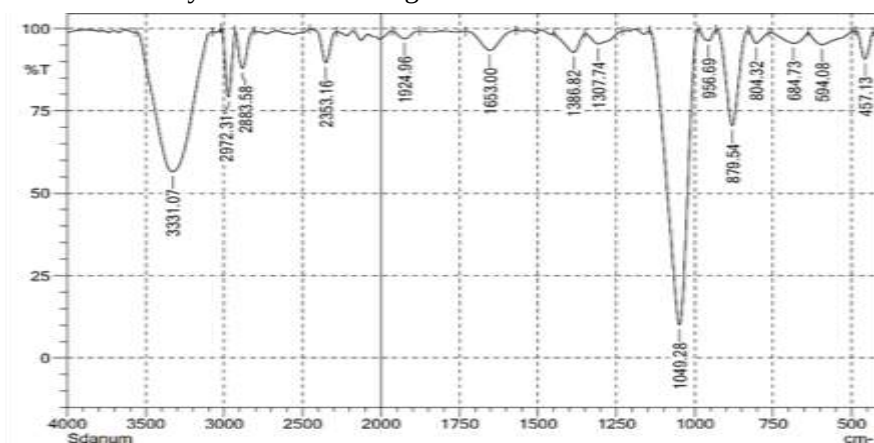


Fig 1: Solanum virginianum

The FTIR absorption spectra of the HPMC were taken in the range 3600-900 cm^{-1} using KBr disc method.

The major peaks were reported evaluation of purity in fig 2:

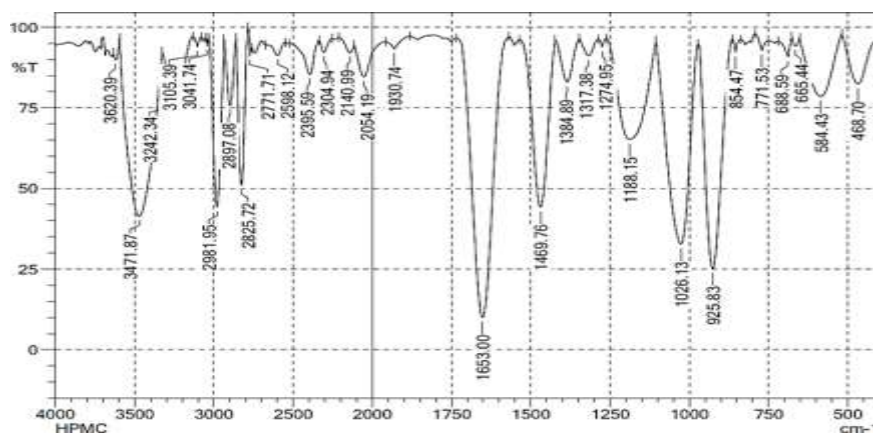


Fig 2: HPMC

The FTIR absorption spectra of the PEG 6000 were taken in the range 3600-650 cm^{-1} using KBr disc

method. The major peaks were reported evaluation of purity in fig 3:

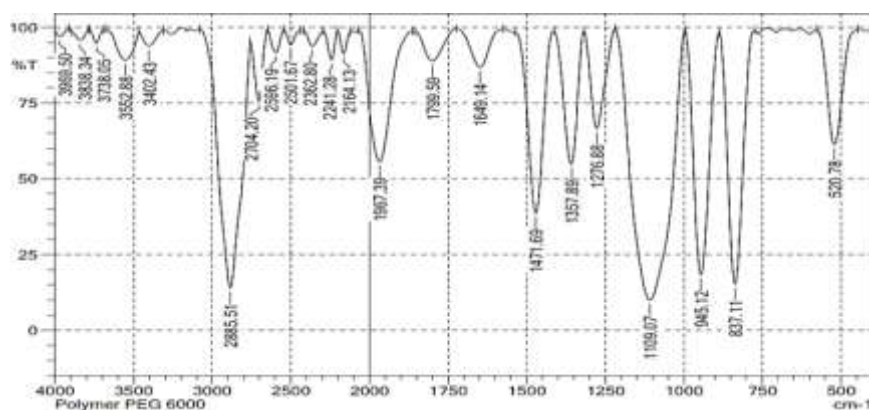


Fig 3: PEG 6000

The FTIR absorption spectra of the HPMC with PEG 6000 were taken in the range 3600-900 cm^{-1} using

KBr disc method. The major peaks were reported evaluation of purity in fig 4:

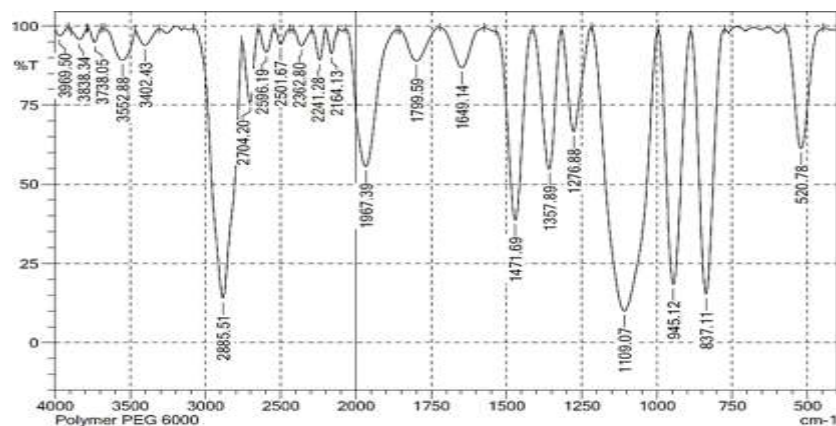


Fig 4: HPMC with PEG 6000

The FTIR absorption spectra of the solanum virginianum with HPMC and PEG 6000 were taken in the range 3600-600 cm⁻¹ using KBr disc method. The

major peaks were reported evaluation of purity in fig 5:

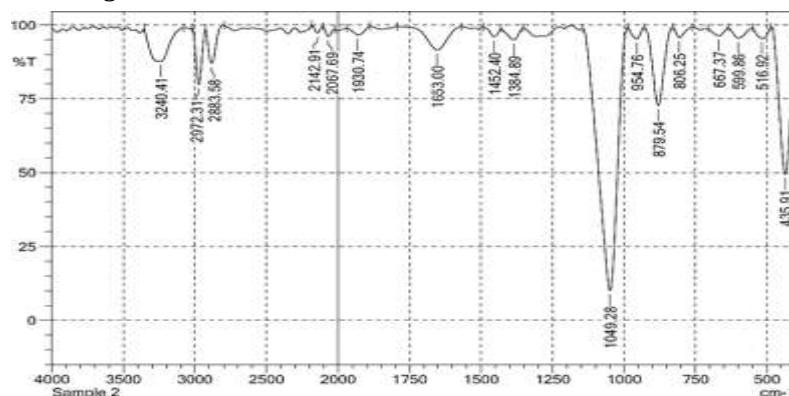


Fig 5: solanum virginianum with HPMC and PEG 6000

The characteristic functional group of drugs along with wave numbers were showed the FTIR spectrum API of Solanum virginianum. Based upon the above IR reports of drug and polymer compatible studies the must the functional group are same. Result indicates that, there is compatibility between the drug and excipient used in the formulation. The main functional group of Solanum virginianum (OH group).

The antioxidant activity by using hydrogen peroxide free radical scavenging assay of solanum virginianum ethanolic extract at the concentration 100,200,300,400 mg/ml showing the sample absorbance value of 0.65, 1.27, 2.04, 2.20 and the standard (Ascorbic acid) shows the absorbance value 0.73, 1.35, 2.14, 2.68 and the IC₅₀ value is 0.159mg/ml. By comparing with standard (Ascorbic acid) the solanum virginianum ethanolic leaf extract shows better anti-oxidant activity.

Anti –Oxidant Activity

Table1: antioxidant activity

S. No	Concentration (Mg/MI)	Standard (Ascorbic Acid)	Sample
1	100	0.73	0.65
2	200	1.35	1.27
3	300	2.14	2.04
4	400	2.68	2.20
IC ₅₀			0.159 mg/ml

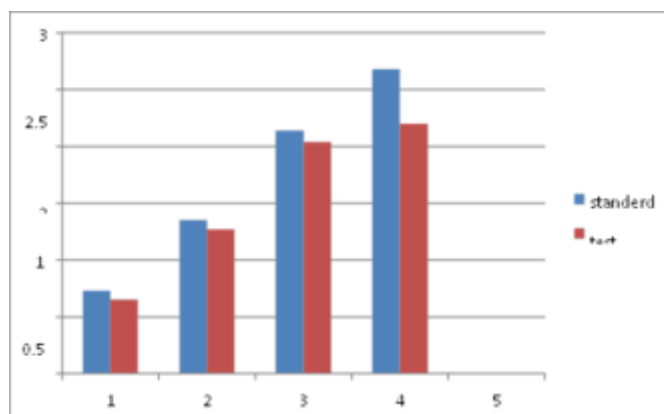


Fig 6: antioxidant activity

Formulation of fast dissolving oral thin film

In the present study, five oral thin film formulations (F1-F5) were prepared using different concentrations of polymer and evaluated for various physicochemical and performance parameters such

as appearance, thickness, folding endurance, surface pH, disintegration time, and in-vitro dissolution. Among all the formulations, Formulation F3 showed the most satisfactory results compared to other formulations.



Figure 7: Fast dissolving Oral thin film

Table 2: formulation of oral thin film

Formulation	F1	F2	F3	F4	F5
API	141mg	141mg	141mg	141mg	141mg
HPMC	500mg	550mg	600mg	650mg	700mg
PEG6000	300mg	300mg	300mg	300mg	300mg
Sucrose	19mg	19mg	19mg	19mg	19mg
Citric Acid	10mg	10mg	10mg	10mg	10mg
Ethanol	5ml	5ml	5ml	5ml	5ml
Water	15ml	15ml	15ml	15ml	15ml
Glycerine	0.5ml	0.5ml	0.5ml	0.5ml	0.5ml

Evaluation

Appearance and thickness

All formulations were smooth, uniform, and free from air bubbles. Formulation F3 showed uniform thickness (0.12 ± 0.01 mm), indicating good film-forming ability and proper distribution of polymer and plasticizer.

Uniformity of weight

The weight of prepared film was determined using electronic balance and the average weight of the film was given in the table. The weight of FDOTF were about 63 ± 1.25 mg. the calculated standard deviation value was very low which suggest that the prepared film was uniform in weight.

Folding Endurance

Formulation F3 exhibited higher folding endurance, suggesting good mechanical strength and flexibility of the film without breaking

Surface pH

The surface pH of all formulations was found to be within the acceptable range. F3 showed surface pH close to neutral (≈ 6.8), indicating that it is non-irritant to the oral mucosa.

Drug content

The drug content of solanum virginianum FDOTF was in the range of 98.6%. The drug content and content uniformity were found within pharmacopeial

limit. Both the result suggesting that drug was uniformly dispersed throughout all film.

Disintegration Time

Disintegration time is a critical parameter for oral thin films. Formulation F3 showed the shortest

disintegration time, (52sec) indicating rapid film hydration and breakdown in the oral cavity.

In vitro drug release study

We took the f3 formulation that showed rapid and maximum drug release within the initial minutes, indicating best dissolution performance.

Table3: In vitro drug release

Time(min)	Absorbance(230nm)	Concentration(μ g/ml)	% Drug released
0.5	0.215	21.5	28.6
1.0	0.365	36.5	48.7
2.0	0.520	52.0	69.3
3.0	0.635	63.5	84.6
4.0	0.695	69.5	92.6
5.0	0.720	72.0	96.0

CONCLUSION

The present study concludes that fast-dissolving oral thin films of *Solanum virginianum* leaf extract were successfully formulated using the solvent casting method. The prepared films exhibited acceptable physicochemical and mechanical properties, including uniform thickness, uniformity of weight, good folding endurance, suitable surface pH, drug content, rapid disintegration, and dissolution. The presence of bioactive phytoconstituents such as flavonoids and phenolic compounds contributed to significant antioxidant activity, which plays a key role in the hepatoprotective potential of the extract. FTIR studies confirmed the compatibility between the plant extract and excipients, indicating formulation stability.

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