

DEVELOPMENT AND EVALUATION OF CORN SILK (*ZEAMAYS* L.) EXTRACT-LOADED ORAL FAST-DISSOLVING FILM

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ABSTRACT

The present study was undertaken to develop and evaluate an herbal oral fast-dissolving film (OFDF) containing corn silk (*Zea mays* L.) extract. Fresh corn silk was collected, shade-dried, powdered and extracted by maceration using 70% ethanol. Preliminary phytochemical screening of the extract revealed the presence of carbohydrates, alkaloids, tannins, flavonoids, saponins, proteins and amino acids, cardiac glycosides, terpenoids, phenolic compounds, gums, resins, mucilage, quinones and coumarins, while anthraquinone glycosides, volatile oils, fixed oils and emodins were not detected. The oral fast-dissolving film was prepared by the solvent casting method using methyl cellulose as the film-forming polymer, glycerol as plasticizer, sucrose as sweetener, citric acid as saliva stimulant and taste enhancer, and peppermint oil as flavouring agent. The prepared film exhibited a smooth, uniform and pale-yellow translucent appearance without visible cracks or air bubbles. The optimized film showed a weight of 48.6 ± 1.25 mg, thickness of 0.118 ± 0.006 mm, folding endurance of 128 ± 5 folds and surface pH of 6.7 ± 0.12 . The extract content uniformity was found to be $97.8 \pm 1.46\%$, while the disintegration time was 38 ± 3 seconds. The film showed $96.4 \pm 1.82\%$ release within 10 minutes. Tensile strength and percentage elongation were found to be 18.6 ± 1.14 N/mm² and $14.8 \pm 1.21\%$, respectively. The moisture content was $3.72 \pm 0.31\%$, swelling index was $142 \pm 4.6\%$, and in-vitro residence time was 4.2 ± 0.3 minutes. The formulation remained physically stable during the stability study, with no significant changes observed. The corn silk extract also demonstrated concentration-dependent antimicrobial activity against *Staphylococcus aureus*, *Escherichia coli* and *Pseudomonas aeruginosa*. Overall, the findings indicate that corn silk extract can be successfully incorporated into an oral fast-dissolving film, providing a convenient and rapidly disintegrating herbal dosage form with promising antimicrobial activity.

KEYWORDS: Corn silk, *Zea mays* L., herbal oral film, oral fast-dissolving film, solvent casting, methyl cellulose, maceration, phytochemical screening, antimicrobial activity.

1. INTRODUCTION

Oral route is the most preferred route for the delivery of the drugs still date as it bears various advantages over the other route of drug administration, but oral drug delivery systems still need some advancements to be made because of their some drawbacks related to particular class of patients which includes geriatric, pediatric and dysphasic patients associated with many medical conditions as they have difficulty in swallowing or chewing solid dosage forms. Many pediatric and geriatric patients are unwilling to take solid preparations due to fear of choking.

Even with fast dissolving tablets there is a fear of choking due to its tablet type appearance. To overcome this problem using Oral fast dissolving film (OFDFs). Research and development in the oral drug delivery field has led to transition of dosage forms from simple conventional tablet/capsules to the development of oral thin strips. Based on strips that can be placed on the patient's tongue. The strip rapidly hydrates when comes in contact with saliva and quickly absorbed in the systemic circulation. The strip offers the advantage like convenience of dosing and portability that leads to its wider acceptability by pediatric as well as geriatric patients.

Oral Fast Dissolving Films (OFDFs) are thin, flexible polymeric films designed to dissolve or disintegrate rapidly when placed on the tongue or oral mucosa, usually within 30–60 seconds, without the need for water. They contain the active pharmaceutical ingredient (API), film-forming polymers, plasticizers, sweeteners, flavouring agents, and other excipients. The drug is released quickly after the film dissolves and is absorbed through the oral cavity or gastrointestinal tract, depending on its properties. OFDFs are commonly prepared by methods such as solvent casting and hot-melt extrusion. Oral fast dissolving films offer several advantages over conventional tablets and capsules. They provide rapid onset of action, improve patient compliance, and are especially suitable for pediatric, geriatric, and dysphagic patients who have difficulty swallowing. These films require no water for administration, making them convenient for use during travel and emergencies.

They also provide accurate dosing, are easy to carry, and can improve the taste of bitter drugs through the use of sweeteners and flavouring agents. Due to their ease of use, convenience, and potential to enhance drug bioavailability for suitable drugs, OFDFs have become an important and innovative oral drug delivery system.

1.1 Overview of the Oral Cavity

The oral mucosa is composed of an outermost layer of stratified squamous epithelium. Below this lies a basement membrane, a lamina propria followed by the sub-mucosa as the innermost layer. The oral mucosa, in general is intermediate between that of the epidermis and intestinal mucosa in terms of permeability.

It is estimated that the permeability of the oral mucosa is 4-4000 times greater than that of the skin. There are considerable differences in permeability between different regions of the oral cavity because of the diverse structures and functions of the oral mucosa.

1.2 Permeability

The oral mucosa in general is an intermediate between that of the epidermis and intestinal mucosa. The permeability's of the oral mucosa decrease in the order of sublingual greater then the buccal and degree of keratinization of these tissues, with the sublingual mucosa being relatively thin and non-keratinized, the buccal thicker and non-keratinized. In terms of permeability, the sublingual area of the oral cavity (the floor of the mouth) is more permeable than the buccal (cheek) area, which in turn is more permeable than the palatal (roof of the mouth) area.

1.3 Mechanism of Absorption

Sublingual administration drug solutes are rapidly absorbed into the reticulated vein, which lies underneath the oral mucosa and transported through the facial veins, internal jugular vein, and brachiocephalic vein and are then drained into the systemic circulation. Upon sublingual administration drug reaces directly into the blood stream through ventral surface of the tongue and the floor of the mouth. The main mechanism for the absorption of the drug into the oral mucosa is via passive diffusion into the lipoidal membrane. The absorption ofthe drug through the sublingual route is 3 to 10 times greater than the oral route and is only surpassed by the hypodermic injection.

1.4 Various Conventional Approaches For Manufacturing The Oral Films:

- ❖ Solvent casting method
- ❖ Semi-solid casting method
- ❖ Hot melt extrusion
- ❖ Solid dispersion extrusion
- ❖ Rolling method

Solvent Casting Method: In solvent casting method, film forming agent, plasticizer, and saliva stimulating agent are dissolved in distilled water, solution is then stirred up to 45 minutes continuously in a magnetic stirrer at 60°C and 1000rpm. After that the solution is kept stand for 1 hour to remove all the air bubbles entrapped.

At the same time in a separate container remaining excipients i.e. sweetening agent, disintegrating agent, flavouring agent and the active pharmaceutical drug are dissolved in distilled water with continuous stirring for 45minutes. Both the solutions are mixed together in a separate container and stir up to 1 hour in magnetic stirrer at room temperature and 1000 rpm. Standby the solution for 1 hour to let the foams settle down. Finally, the solution is cated on petriplate and dired then cut the strip into desired size.

Semisolid Casting Method: In this method, solution of water soluble film forming polymer are mixed to solution of acid insoluble polymer to form homogenous viscous solution(e.g. cellulose acetate phthalate, cellulose acetobutyrate). After sonication it is coated on non-treated casting film. On drying the thickness of the film is about 0.381-1.27cm. the ratio of the acid insoluble polymer of film forming polymer should be 1:4.

Hot-Melt Extrusion: In hot melt extrusion method firstly the drug is mixed with carriers in solid form under the control of temperature and steering speed. Afterwards, the film is coated and dried in a drying tunnel, once again the temperature, air circulation and line speed are controlled. Then the extruder having heaters which melts the mixture. Finally melt is shaped into the films by the dies.

Then follows a slitting and in the last step are punched, pouched and sealed. There are certain benefits of hot melt extrusion.

- ❖ Fewer operation units
- ❖ Better content uniformity
- ❖ An anhydrous process.

Solid Dispersion Extrusion: In solid dispersions are prepared by immiscible components and drug. Finally the solid dispersions are shaped in to films by means of dies.

Rolling Method: In this method a solution or suspension containing drug is rolled on a carrier. The solvent is mainly water and mixture of water and alcohol. The film is dried on the rollers and gives desired shape and size.

Table: 1 Comparison of Conventional Oral Film Manufacturing Methods.

Method	Main Principle	Solvent Requirement	Major Advantage
Solvent casting	Polymer solution is cast and dried	Usually required	Simple and widely used
Semi-solid casting	Viscous polymeric mass is cast and dried	Usually required	Produces uniform films
Hot-melt extrusion	Polymer/drug mixture is melted and extruded	Not required	Solvent-free and continuous
Solid dispersion extrusion	Drug-polymer solid dispersion is extruded	Usually not required	Improves dissolution of poorly soluble drugs
Rolling method	Drug solution/suspension is spread on a moving carrier and dried	Usually required	Suitable for continuous production

VARIOUS CONVENTIONAL APPROACHES FOR MANUFACTURING ORAL FILMS

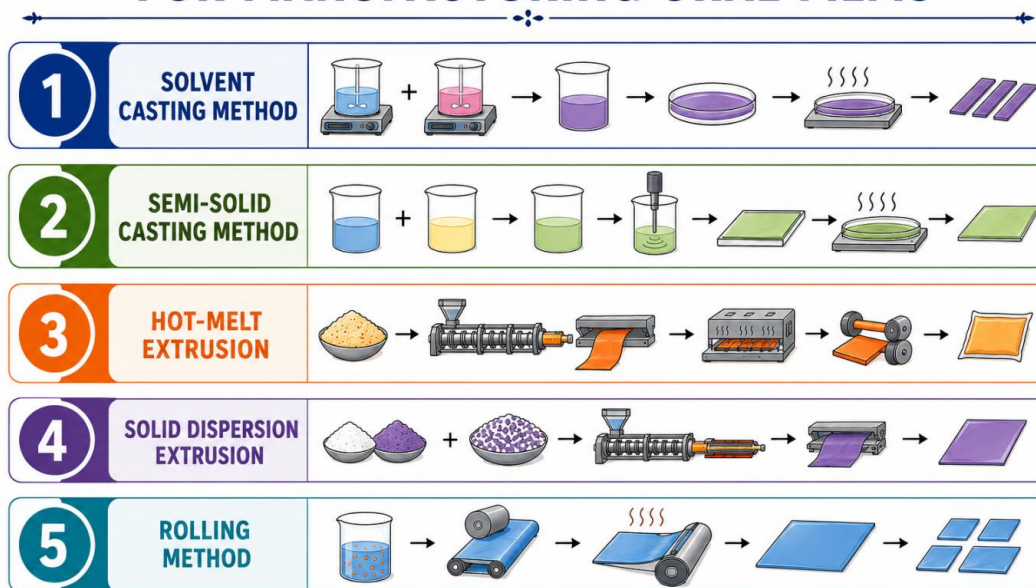


Fig: 1 Comparison of Conventional Oral Film Manufacturing Methods.

2. PLANT PROFILE



Fig: 2 Corn Silk.

Corn Silk (*Zea mays* L.)

2.1 Physical Description of Corn Silk

Corn silk is the long, soft, silky thread-like structure that emerges from the tip of the maize ear. It is the stigma and style of the female flower of the maize plant.

2.2 Characteristics

- ❖ **Color:** Light green when young; turns yellow, reddish-brown or dark brown on drying.
- ❖ **Length:** 10–30 cm.
- ❖ **Diameter:** 0.2–0.5 mm.
- ❖ **Texture:** Soft, silky, smooth, flexible.
- ❖ **Odor:** Slight or characteristic.
- ❖ **Taste:** Mildly sweet to slightly bland.
- ❖ **Moisture content:** Low after drying.
- ❖ **Appearance:** Fine, glossy, thread-like fibers.

2.3 Botanical Description

Corn belongs to the grass family and is one of the world's most important cereal crops.

- ❖ **Root:** Fibrous root system, Includes seminal, adventitious and brace roots, Provides anchorage and water absorption.
- ❖ **Stem:** Erect, cylindrical and solid, Height: 1–4 m, Composed of distinct nodes and internodes.
- ❖ **Leaves:** Long, narrow and lanceolate, Alternate arrangement, Parallel venation, Rough margins.
- ❖ **Flower:** Monoecious plant (male and female flowers occur separately on the same plant), Male inflorescence (tassel) at the top, Female inflorescence (ear/cob) develops on the side.
- ❖ **Fruit:** Caryopsis (kernel), Kernels are arranged on the cob.
- ❖ **Corn Silk:** Long styles ending in feathery stigmas, One silk corresponds to one ovule, Receives pollen for fertilization.

2.4 Scientific Classification

Classification	Details
Kingdom	Plantae
Division	Magnoliophyta (Angiosperms)
Class	Liliopsida (Monocotyledons)
Order	Poales
Family	Poaceae
Genus	<i>Zea</i>
Species	<i>Zea mays</i> L.
Common Name	Corn, Maize
Part Used	Corn silk (Stigma and Style)

Table: 2 Scientific Classification.

2.5 Functions of Corn Silk

- ❖ **Anti-oxidant:** Neutralizes free radicals, Protects cells from oxidative stress.
- ❖ **Diuretic:** Increases urine production, Helps eliminate excess body fluids.
- ❖ **Anti-inflammatory:** Reduces inflammation, Relieves swelling.

- ❖ **Anti-diabetic:** Helps regulate blood glucose, May improve insulin sensitivity.
- ❖ **Antihypertensive:** Supports healthy blood pressure, Promotes vascular relaxation.
- ❖ **Hepato-protective:** Protects liver cells from damage.
- ❖ **Nephroprotective:** Helps protect kidney function, Supports urinary tract health.
- ❖ **Antimicrobial:** Inhibits growth of certain bacteria and fungi.
- ❖ **Immuno-modulatory:** Supports immune function.

2.6 Phyto-chemical Composition of Corn Silk:

Corn silk contains numerous bioactive constituents.

Table: 3 Phyto-chemical Constituent.

Compound	Examples
Flavonoids	Maysin, Luteolin, Quercetin, Apigenin
Phenolic acids	Ferulic acid, Vanillic acid, Chlorogenic acid
Alkaloids	Small quantities
Saponins	Present
Tannins	Present
Terpenoids	Present
Steroids	β -Sitosterol
Polysaccharides	Water-soluble polysaccharides
Vitamins	Vitamin C, Vitamin K
Minerals	Potassium, Calcium, Magnesium, Sodium
Proteins	Amino acids
Sugars	Glucose, Fructose
Essential oils	Trace amounts
Mucilage	Present

2.7 Applications of Corn Silk

- ❖ **Pharmaceutical Applications:** Herbal diuretic preparations, Capsules and tablets, Oral fast dissolving films, Herbal teas, Syrups, Nutraceutical formulations.
- ❖ **Traditional Medicine:** Urinary tract infections, Kidney stones, Cystitis, Edema, Hypertension, Diabetes management (adjunct use).
- ❖ **Cosmetic Applications:** Antioxidant skincare formulations, Anti-aging creams, Herbal facial masks, Moisturizers.
- ❖ **Food Industry:** Functional beverages, Herbal tea, Nutraceutical ingredients, Dietary supplements.
- ❖ **Biomedical Research:** Drug delivery system, Antioxidant studies, Anti-inflammatory research, Wound healing investigations.
- ❖ **Therapeutic Properties:** Antioxidant, Anti-inflammatory, Diuretic, Anti-diabetic, Antihypertensive, Hepato-protective, Nephro-protective, Antimicrobial, Anti-obesity, Anticancer (preclinical studies), Cardio-protective.

2.8 Significance of Corn Silk in Oral Fast Dissolving Films:

Corn silk is a promising herbal active ingredient for oral fast dissolving films because it:

- ❖ Is rich in flavonoids and phenolic compounds with antioxidant activity.
- ❖ Can provide anti-inflammatory and diuretic effects.
- ❖ Is a low-cost, natural, and biodegradable herbal material.
- ❖ Is widely available as an agricultural by-product.
- ❖ Can be incorporated into polymeric films using solvent casting with polymers such as methyl cellulose, hydroxypropyl methylcellulose (HPMC), sodium alginate, starch, or gelatin.
- ❖ Has potential for rapid drug release and improved patient compliance when formulated as an oral fast dissolving film.

3. MATERIALS AND METHODS

3.1 LIST OF INGREDIENTS

Table: 4 List of Chemicals.

S. NO.	INGREDIENTS	QUANTITY (20ml)	USES
1.	Corn Silk Extract	0.5 ml	Active Ingredient
2.	Methyl Cellulose	2.0 g	Film-Forming Polymer
3.	Sucrose	0.5g	Sweetener
4.	Citric Acid	0.1g	Saliva Stimulant And Taste Enhancer
5.	Glycerol	0.5ml	Plasticizer
6.	Peppermint Oil	0.1ml	Flavouring Agent
7.	Distilled Water	Q.S. to 20 ml	Solvent

3.2 COLLECTION AND PREPARATION OF PLANT MATERIAL

Fresh corn silk (*Zea mays* L.) was collected from healthy corn cobs and carefully separated from the cobs. The collected corn silk was washed thoroughly with clean water followed by distilled water to remove dust and other impurities. It was then spread in a thin layer and shade-dried at room temperature until completely free from moisture. The dried corn silk was cut into small pieces and powdered using a suitable grinder. The powdered material was passed through a sieve to obtain a uniform coarse powder and stored in a clean, dry, airtight container until extraction.



Fig: 3 Fresh Corn Silk



Fig: 4 Dried Corn Silk



Fig: 5 (Maceration of Corn silk in 70% Ethanol)

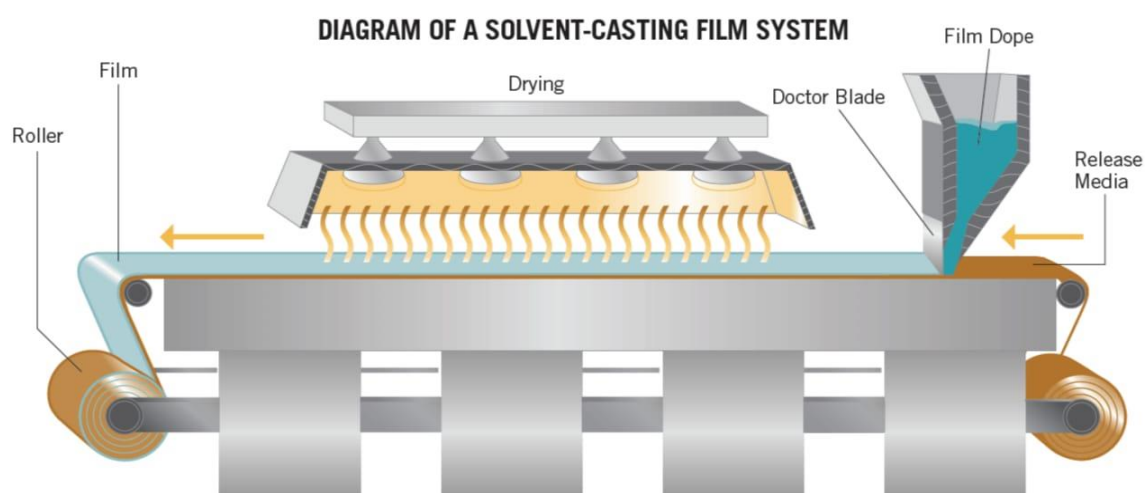


Fig: 6 Solvent Casting Machine.

3.3 EXTRACTION OF CORN SILK BY USING MACERATION

The prepared coarse corn silk powder was subjected to maceration using 70% ethanol as the extraction solvent. A suitable quantity of the powder was placed in a clean, closed container and 70%

ethanol was added in a 1:10 w/v ratio (e.g., 5 g powder with 50 mL solvent). The mixture was stirred well and kept covered at room temperature for 24–48 hours, with occasional stirring. After maceration, the mixture was filtered through suitable filter paper, and the filtrate containing the corn silk extract was collected and concentrated at a low temperature using a water bath.

3.4 PRELIMINARY PHYTOCHEMICAL ANALYSIS

- ❖ Test For Carbohydrates: (Molisch's Test)
- ❖ Test For Alkaloids: (Mayer's Test)
- ❖ Test For Tannins: (Ferric Chloride Test)
- ❖ Test For Flavonoids: (Lead Acetate Test)
- ❖ Test For Saponins: (Froth Test)
- ❖ Test For Proteins And Amino Acids: (Biuret Test)
- ❖ Test For Cardiac Glycosides (For Deoxysugar): (Keller Killani Test)
- ❖ Test For Anthraquinone Glycosides: (Borntrager's Test)
- ❖ Test For Terpenoids
- ❖ Test For Phenolic Compounds: (Ferric Chloride Test)
- ❖ Test For Volatile Oils
- ❖ Test For Fixed Oils
- ❖ Test For Gums
- ❖ Test For Resin
- ❖ Test For Mucilage
- ❖ Test For Quinone
- ❖ Test For Emodins
- ❖ Test For Coumarin

3.5 FORMULATION OF ORAL FAST DISOLVING FILM (OFDFs)

Solvent Casting Method

The oral film was prepared by the solvent casting method. Initially, 15 mL of distilled water was taken in a beaker and placed on a magnetic stirrer at 500–700 rpm. 2 g of methyl cellulose was slowly added to the distilled water with continuous stirring to prevent lump formation. The temperature was maintained at 40–45°C, and the mixture was stirred for 30–45 minutes until a uniform polymer solution was obtained. Separately, 0.5 g of sucrose and 0.1 g of citric acid were dissolved in a small quantity of distilled water and added to the methyl cellulose solution, followed by stirring for 5–10 minutes. Then, 0.5 mL of glycerol was incorporated as a plasticizer and stirred for 10 minutes. Subsequently, 0.5 g of corn silk extract was added slowly to the polymer solution and stirred for 15–20 minutes to ensure uniform mixing. 2–3 drops of peppermint oil were then added and the mixture was stirred for another 5–10 minutes. Distilled water was added to make the final volume up to 20

mL, followed by stirring for an additional 5 minutes. The prepared solution was allowed to stand for 15–30 minutes to facilitate the removal of entrapped air bubbles. The bubble-free solution was then carefully poured onto a clean and level Petri dish and spread uniformly to obtain a thin film. The film was dried at 40–45°C until completely dry. After drying, the film was carefully peeled from the Petri dish, cut into suitable-sized strips, and stored in an airtight container until further evaluation.

3.6 EVALUATION PARAMETER

1. Appearance

The prepared corn silk OFDF is visually examined for colour, odour, smoothness, transparency, and uniformity. The film is checked for cracks, air bubbles, holes, and surface roughness. It should have a smooth and uniform surface without visible defects. The colour should be evenly distributed throughout the film. Good appearance indicates proper mixing and casting of the formulation.

2. Weight Variation

Weight variation is performed to determine the uniformity of individual film strips. Six strips of equal dimensions are selected randomly and weighed individually. The average weight is calculated from the six individual weights. The percentage variation from the average weight is then determined. Low weight variation indicates uniform distribution of the formulation ingredients.

3. Thickness

Thickness is measured to determine the uniformity of the prepared OFDF. Six film strips are selected randomly and measured using a digital micrometer or vernier caliper. Measurements are taken at different points of each strip. The average thickness is calculated from the obtained readings. Uniform thickness helps ensure consistent extract content and disintegration.

4. Folding Endurance

Folding endurance indicates the flexibility and mechanical strength of the film. A film strip is folded repeatedly at the same point until it breaks. The number of folds required to produce a crack or break is recorded. A higher folding endurance indicates better flexibility of the film. It also indicates that the film can withstand handling during packaging and use.

5. Surface pH

Surface pH is determined to evaluate the compatibility of the film with the oral mucosa. The film strip is moistened with a small quantity of distilled water. It is allowed to equilibrate before measuring the pH. The pH is determined using a calibrated pH meter or suitable pH paper. A pH close to the normal oral range is desirable to minimize mucosal irritation.

6. Extract Content Uniformity

Extract content uniformity determines the uniform distribution of corn silk extract in the film. Six individual film strips are separately dissolved or extracted using a suitable solvent. The solutions are filtered and analyzed for extract or selected marker content. The amount present in each strip is compared with the intended amount. Uniform content indicates consistent dosing of corn silk extract.

7. Disintegration Time

Disintegration time determines how rapidly the film breaks down after contact with aqueous or salivary fluid. A film strip is placed in a suitable medium and the stopwatch is started. The film is observed continuously until it completely breaks apart. The time required for complete disintegration is recorded. A short disintegration time is desirable for an oral fast-dissolving film.

8. Dissolution/Release Study

The dissolution study determines the release of corn silk extract or its selected marker from the film. The film is placed in a suitable dissolution medium maintained at approximately $37 \pm 0.5^\circ\text{C}$. Samples are withdrawn at predetermined time intervals and replaced with fresh medium. The samples are filtered and analyzed using a suitable analytical method. The results are expressed as percentage release against time.

9. Tensile Strength

Tensile strength determines the ability of the film to withstand mechanical stress. A film strip of uniform dimensions is fixed in a suitable tensile testing instrument. The film is pulled at a constant rate until it breaks. The force required to break the film is recorded and tensile strength is calculated. Adequate tensile strength indicates that the film can withstand handling without tearing.

10. Percentage Elongation

Percentage elongation measures the stretching ability of the film before breaking. The initial length of the film is measured before applying the test. The film is stretched until it breaks and the final length is recorded. The percentage increase in length is calculated using the initial and final lengths. Suitable elongation indicates good flexibility and elasticity of the film.

11. Moisture Content

Moisture content determines the amount of moisture present in the prepared film. A known weight of film is dried using a suitable oven or moisture analyzer. The film is dried until a constant weight is obtained. The difference between initial and final weight is used to calculate moisture content. Controlled moisture content helps maintain the stability, flexibility, and mechanical properties of the film.

12. Swelling Index

Swelling index determines the extent to which the film absorbs an aqueous medium. The film is accurately weighed before being placed in the selected medium. After a predetermined time, the film is removed and excess liquid is removed. The swollen film is weighed and compared with its initial weight. The change in weight indicates the swelling behaviour of the formulation.

13. In-vitro Residence Time

In-vitro residence time determines the time required for the film to lose its integrity or completely dissolve. The film strip is placed in a suitable simulated saliva or aqueous medium. The test is conducted under conditions simulating the oral environment where appropriate. The film is observed

until it completely dissolves or loses its physical integrity. The recorded time provides information about the film's behaviour after oral administration.

14. Stability Study

Stability testing determines whether the optimized film maintains its quality during storage. The films are packed in suitable moisture-protective packaging and stored under selected conditions. Samples are periodically evaluated for appearance, weight, thickness, pH, and folding endurance. Disintegration time, moisture content, and extract/marker content can also be compared. Minimal changes during storage indicate good physical and chemical stability of the formulation.

15. Antimicrobial Activity

The antimicrobial activity of the prepared Corn Silk extract and optimized oral fast-dissolving film was evaluated by the agar well diffusion method against selected bacterial and fungal strains. The zone of inhibition was measured in millimeters (mm).

Procedure – Agar Well Diffusion Method

1. Nutrient agar was used for bacterial organisms and suitable fungal agar medium was used for the fungal organism.
2. The prepared sterile agar plates were inoculated uniformly with the respective microbial cultures.
3. Wells of approximately 6 mm diameter were prepared aseptically in the agar plates using a sterile cork borer.
4. Different concentrations of the Corn Silk extract were prepared, for example 25, 50, 75 and 100 mg/mL.
5. The prepared samples were carefully introduced into the respective wells.
6. A suitable standard antimicrobial agent was used as the positive control, while the solvent/vehicle was used as the negative control.
7. The plates were allowed to stand for a short period to facilitate diffusion of the test samples into the agar.
8. The bacterial plates were incubated under appropriate conditions, while fungal plates were incubated under suitable fungal-growth conditions.
9. After incubation, the plates were examined for clear zones surrounding the wells.
10. The diameter of the zone of inhibition (ZOI) was measured in mm.
11. The antimicrobial activity was compared with the standard drug and control.

4. RESULTS AND DISCUSSION

4.1 PHYTO-CHEMICAL TEST

Table: 5 Phyto-Chemical Test.

S. NO.	PHYTO-CONSTITUENTS	TEST	OBSERVATION	RESULT
1	Carbohydrates	Molisch's test	Violet ring formed	+
2	Alkaloids	Mayer's test	Cream-coloured precipitate formed	+
3	Tannins	Ferric chloride test	Bluish-black colour developed	+
4	Flavonoids	Lead acetate test	Yellowish precipitate formed	+
5	Saponins	Froth test	Persistent froth formed	+
6	Proteins & Amino acids	Biuret test	Violet colour developed	+
7	Cardiac glycosides	Keller–Killiani test	Reddish-brown ring observed	+
8	Antraquinone glycosides	Borntrager's test	No pink/red colour observed	–
9	Terpenoids	Terpenoid test	Pink colour developed	+
10	Phenolic compounds	Ferric chloride test	Dark green colour developed	+
11	Volatile oils	Hydro-distillation	No appreciable oil obtained	–
12	Fixed oils	Filter paper test	No persistent translucent spot	–
13	Gums	Alcohol precipitation test	White precipitate observed	+
14	Resins	Acetone–water test	Turbidity observed	+
15	Mucilage	Ruthenium red test	Pinkish-red colour developed	+
16	Quinones	Conc. H ₂ SO ₄ test	Red colour developed	+
17	Emodins	Ammonia test	No cherry-red colour observed	–
18	Coumarins	Ammonium hydroxide test	Red colour developed	+

4.2 EVALUATION OF ORAL FILM

Table: 6 Evaluation of Oral Film.

S. NO.	EVALUATION PARAMETER	RESULT
1	Appearance	Smooth, uniform, pale yellow, translucent, no cracks or air bubbles
2	Weight Variation	48.6 ± 1.25 mg
3	Thickness	0.118 ± 0.006 mm
4	Folding Endurance	128 ± 5 folds
5	Surface pH	6.7 ± 0.12
6	Extract Content Uniformity	97.8 ± 1.46 %
7	Disintegration Time	38 ± 3 sec
8	Dissolution/Release	96.4 ± 1.82 % in 10 min
9	Tensile Strength	18.6 ± 1.14 N/mm ²
10	Percentage Elongation	14.8 ± 1.21 %
11	Moisture Content	3.72 ± 0.31 %
12	Swelling Index	142 ± 4.6 %
13	In-vitro Residence Time	4.2 ± 0.3 min
14	Stability Study	No significant change observed



Fig: 7 Solvent Casting of Prepared.

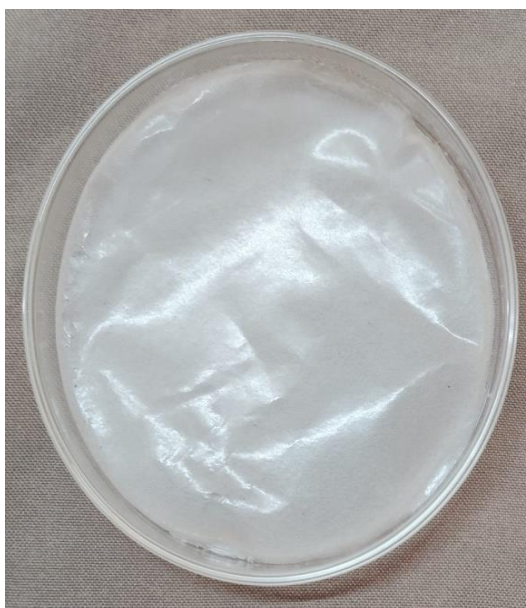


Fig: 8 Dried Film OFDF Solution.



Fig: 9 Oral Film.

4.3 ANTI-MICROBIAL ACTIVITY

Table: 7 Anti-Microbial Activity.

S. No.	Test Organism	25 mg/ml	50 mg/ml	75 mg/ml	100 mg/ml	Standard Drug
1	<i>Staphylococcus aureus</i>	8	11	14	17	Ciprofloxacin – 22 mm
2	<i>Escherichia coli</i>	7	10	13	16	Ciprofloxacin – 21 mm
3	<i>Pseudomonas aeruginosa</i>	6	9	12	15	Ciprofloxacin – 20 mm

DISCUSSION

The present investigation focused on the development of an oral fast-dissolving film containing corn silk extract using methyl cellulose as the principal film-forming polymer. The use of corn silk as a herbal active ingredient provides an opportunity to develop a convenient oral dosage form that can rapidly disintegrate in the oral cavity. The solvent casting technique was selected because it allows uniform distribution of the extract and excipients and produces thin, flexible films suitable for oral administration.

The preliminary phytochemical screening demonstrated the presence of several classes of phytoconstituents. Carbohydrates, alkaloids, tannins, flavonoids, saponins, proteins and amino acids, cardiac glycosides, terpenoids and phenolic compounds were detected. Gums, resins, mucilage, quinones and coumarins were also present. The presence of these phytochemical groups suggests the chemical complexity of the corn silk extract and may contribute to its biological properties. Anthraquinone glycosides, volatile oils, fixed oils and emodins were not detected under the test conditions employed.

The prepared oral film exhibited a smooth, uniform and pale-yellow translucent appearance without cracks, holes or air bubbles. The satisfactory appearance indicates proper mixing of the formulation components and uniform casting of the film. The absence of visible defects is important because surface irregularities can affect mechanical properties, patient acceptability and drug/extract release.

The weight variation of the film was 48.6 ± 1.25 mg, indicating relatively consistent film formation and uniform distribution of the formulation mass. The thickness was 0.118 ± 0.006 mm, demonstrating that the solvent casting process produced a relatively thin and uniform film. Uniform thickness is important because considerable variation may result in differences in extract content and disintegration behaviour between individual strips.

The folding endurance of 128 ± 5 folds indicates good flexibility and mechanical resistance of the prepared film. Adequate folding endurance is desirable for oral films because the strips must withstand handling during peeling, cutting, packaging and administration. The surface pH of 6.7 ± 0.12 was close to the physiological oral environment, suggesting that the formulation is less likely to cause discomfort due to extreme pH conditions.

The extract content uniformity was $97.8 \pm 1.46\%$, demonstrating satisfactory distribution of corn silk extract throughout the film. Uniform extract distribution is essential to provide consistent dosing from one film strip to another. The disintegration time of 38 ± 3 seconds indicates rapid breakdown of the film, which is an important characteristic of an oral fast-dissolving dosage form.

The dissolution/release study demonstrated $96.4 \pm 1.82\%$ release within 10 minutes. The rapid release may be associated with the thin structure of the film, the hydrophilic nature of methyl cellulose and the relatively large surface area available for contact with the dissolution medium. Rapid release is advantageous for an oral film intended to provide quick availability of the incorporated herbal extract.

The mechanical properties of the formulation were also satisfactory. The tensile strength was 18.6 ± 1.14 N/mm² and percentage elongation was $14.8 \pm 1.21\%$. These findings indicate that the film possessed adequate strength while retaining flexibility. The moisture content of $3.72 \pm 0.31\%$ suggests controlled residual moisture, which can influence flexibility, stability and mechanical properties of oral films.

The swelling index of $142 \pm 4.6\%$ indicates considerable uptake of aqueous medium by the film. This behaviour may facilitate hydration and subsequent disintegration of the film. The in-vitro residence time was 4.2 ± 0.3 minutes, indicating that the film maintained its physical integrity for a short period before dissolving or losing its structure under the test conditions.

The stability study showed no significant change in the evaluated physical parameters during the study period. This suggests that the prepared film maintained acceptable physical characteristics under the selected storage conditions. However, longer-term stability studies under standard ICH conditions would be required to establish definitive shelf-life.

The antimicrobial study showed concentration-dependent activity of corn silk extract against the tested bacterial organisms. Against *Staphylococcus aureus*, the zones of inhibition increased from 8 mm at 25 mg/mL to 17 mm at 100 mg/mL, compared with 22 mm for ciprofloxacin. Against *Escherichia coli*, the zone increased from 7 mm to 16 mm, while ciprofloxacin produced a 21 mm zone. Against *Pseudomonas aeruginosa*, the zone increased from 6 mm to 15 mm, compared with 20 mm for ciprofloxacin. These findings demonstrate that increasing the concentration of corn silk extract produced progressively greater inhibition of bacterial growth. Although the activity was lower than that of the standard antibiotic, the results indicate promising antimicrobial potential of the plant extract.

Overall, the evaluation results demonstrate that the developed corn silk oral fast-dissolving film possessed acceptable physical, mechanical and performance characteristics. The rapid disintegration, high extract content uniformity, rapid release and concentration-dependent antimicrobial activity support the potential of the formulation as a convenient herbal oral dosage form.

5. CONCLUSION

The present study successfully demonstrated the feasibility of formulating corn silk (*Zea mays* L.) extract into an oral fast-dissolving film by the solvent casting method. The developed film showed satisfactory appearance, uniformity, flexibility, surface pH, extract content, rapid disintegration and efficient release characteristics. The presence of several phytochemical constituents in the corn silk extract and its concentration-dependent antimicrobial activity against the tested bacterial strains indicate promising biological potential. The optimized film exhibited good mechanical properties and maintained acceptable characteristics during the stability study. Thus, the developed corn silk oral fast-dissolving film may serve as a convenient and patient-friendly herbal oral dosage form. Further studies involving standardized marker estimation, detailed antimicrobial investigations, toxicity

evaluation, optimized stability studies and appropriate in-vivo evaluation are recommended to establish its therapeutic potential and suitability for further development.

6. REFERENCES

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