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PREPARATION AND EVALUATION OF ORAL THIN FILMS OF HERBAL EXTRACTS OF TINOSPORA CORDIFOLIA AND CINNAMOMUM CASSIA FOR ITS ANTIDIABETIC ACTIVITY

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ABSTRACT

The present research project aims to design, develop, and evaluate oral thin films (OTFs) incorporating *Tinospora cordifolia* (Guduchi) and *Cinnamomum cassia* (Cinnamon) extracts for their antidiabetic activity. The study focuses on creating a novel herbal-based drug delivery system that offers improved bioavailability, therapeutic efficacy, and safety. The project encompasses a comprehensive formulation process that begins with the careful selection of suitable excipients and herbal active ingredients, guided by extensive literature review and experimental validation. Extraction of the active phytoconstituents from *Tinospora cordifolia* and *Cinnamomum cassia* was carried out using standardized methods to ensure maximum yield and potency. These extracts were then incorporated into oral thin films through a solvent casting technique, followed by rigorous optimization to attain desirable film characteristics. Key physicochemical parameters such as film thickness, tensile strength, disintegration time, folding endurance, and surface pH were evaluated to ensure consistency, stability, and patient compliance. The films demonstrated promising properties that indicate potential for effective antidiabetic action via buccal administration, bypassing first-pass metabolism and enhancing drug absorption. The findings suggest that the developed oral thin film can serve as an innovative and efficient alternative for diabetes management, especially in populations seeking herbal and user-friendly therapeutic options.

KEYWORDS: Antidiabetic Activity, Oral Thin Films, *Tinospora cordifolia*, *Cinnamomum cassia*.

INTRODUCTION

Diabetes mellitus (DM) is a multifaceted endocrine disorder marked by elevated blood glucose levels. According to the WHO, over 422 million people worldwide suffer with diabetes, with nearly 46% of cases going untreated. The most effective and widely used method of consuming the drug is the Oral Route of Administration. However, certain patient groups, including paediatric, geriatric, psychiatric, and unconscious individuals, often face difficulties in swallowing solid dosage forms due to a fear of choking. Therefore, OTF's are considered as a game-changer in the pharmaceutical industry as they are essential for emergency situations and have immediate onset of action. Moreover, they have enhanced bioavailability, quicker effects, and superior patient compliance. This approach of administering the OTF's improves bioavailability by avoiding first-pass metabolism in the liver and pre-systemic elimination in the gastrointestinal tract. Because of the substantial health advantages, these dosage formulations have the potential to be nutraceuticals. Various phytochemical constituents present in the Tinospora cordifolia and Cinnamomum cassia extracts were screened through phytochemical screening. Three different formulations of oral thin films have been developed out of which one was optimized. Oral thin films were formulated with Tinospora cordifolia and Cinnamomum cassia as the active ingredients and hydroxy propyl methyl cellulose, sodium alginate, glucose, guar gum, polyethylene glycol and water were used as excipients.[1]

AIM

The research initiates with a clear identification of its aim, which is to formulate and evaluate oral thin films incorporating *Tinospora cordifolia* and *Cinnamomum cassia* for their potential antidiabetic effects. This is followed by the establishment of specific, measurable research objectives that guide the entire study, such as enhancing bioavailability, ensuring effective drug delivery, and validating therapeutic efficacy. A comprehensive literature review is then conducted to

gain in-depth knowledge of existing formulations, pharmacological activities of the selected herbal extracts, previous methods used in oral thin film development, and the challenges associated with herbal drug delivery systems. This step not only provides a scientific foundation but also helps in identifying research gaps that the current study aims to address.

Following the literature review, the core phase involves the formulation and development of the oral thin films. This includes the extraction and standardization of active constituents from *Tinospora cordifolia* and *Cinnamomum cassia*, selection of appropriate film-forming polymers and plasticizers, and the application of a suitable film formation technique—typically the solvent casting method. The prepared films undergo detailed characterization, where various physicochemical properties such as uniformity of thickness, folding endurance, tensile strength, surface pH, moisture absorption, disintegration time, and drug content uniformity are assessed using standardized protocols.

Subsequently, data obtained from these evaluations are systematically analysed using statistical tools to determine the reliability and significance of the results. This analysis provides critical insights into the performance of the developed oral thin films in terms of stability, efficiency, and potential therapeutic impact.

Based on the analysed data, meaningful conclusions are drawn regarding the feasibility and effectiveness of the formulated oral thin films as a novel drug delivery system for diabetes management. Recommendations for future research or clinical studies are proposed to further validate and potentially commercialize the findings. Finally, the outcomes of the study are documented in detail and prepared for publication in scientific journals or presentation at academic conferences, ensuring the dissemination of knowledge to the broader scientific community and relevant stakeholders.

Aim of the Study

1. To formulate oral thin films containing *Tinospora cordifolia* and *Cinnamomum cassia* extracts for antidiabetic therapy.
2. To enhance the bioavailability and therapeutic efficacy of herbal antidiabetic agents through an innovative drug delivery system.
3. To optimize the formulation by selecting appropriate excipients and standardizing film characteristics.
4. To evaluate the physicochemical properties of the developed oral thin films.
5. To assess the potential of the oral thin films as an effective and patient-friendly alternative for diabetes management.
6. To contribute to the development of safe, efficient, and natural therapeutic strategies using herbal medicine.[1][2]

Objective

The antidiabetic benefits of *Tinospora cordifolia* and *Cinnamomum cassia* have been well-recognized due to their ability to enhance insulin sensitivity and exhibit strong antioxidant properties. *Tinospora cordifolia* and *Cinnamomum cassia* individually contribute to better glycaemic control, and when combined, they offer a synergistic effect that amplifies their therapeutic potential. Incorporating these herbal extracts into oral thin films further enhances their efficacy by utilizing the advantages of this novel drug delivery system. Herbal oral thin films allow the combination of synergistic herbs, thus improving overall antidiabetic activity. They also ensure faster absorption of the active constituents, which leads to quicker onset of action. Additionally, oral thin films increase patient compliance by offering a non-invasive, easy-to-administer dosage form that does not require water for consumption. The films provide a convenient, portable, and discreet method of drug delivery while offering improved bioavailability of the active compounds, thereby enhancing therapeutic outcomes for diabetes management.[3]

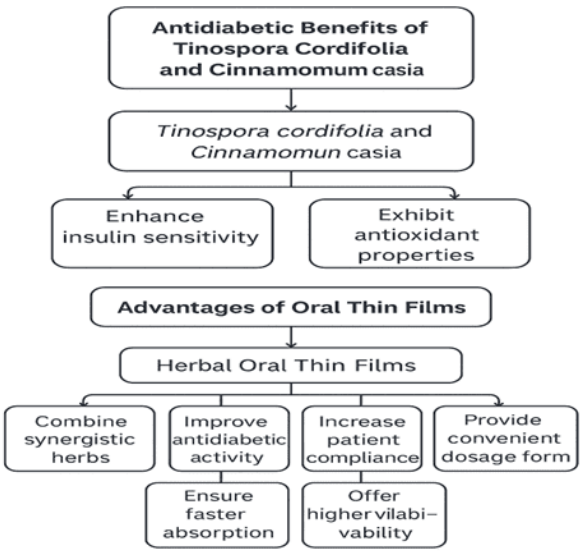

Figure 1: Objectives.

Rational

This study acknowledges the importance and need for innovative therapeutic strategies in Diabetic drug treatment, leveraging the ability of natural excipient in a modern drug delivery format. The findings could contribute to the development of complementary therapies that enhance glycaemic control and improve the quality of life for individuals living with diabetes. Synthetic sources like hypoglycaemic agents are commonly used as traditional diabetes treatment which can have various side effects. However, there is a growing interest in alternative therapies especially those derived from the natural sources because of their low side effects.[4]

Tinospora cordifolia and Cinnamomum cassia extract oral thin films are being prepared and evaluated with the goal of developing a new antidiabetic medication. It involves extracting herbal plants, creating oral thin films, and evaluating their physicochemical and antidiabetic properties. For patients who have difficulty ingesting or digesting solid medications, oral thin-film drug delivery technologies are a faster and safer alternative to ODTs, which can shatter during handling and transit.[5]

Plan Of Work

The **Plan of Work** for this research project is systematically structured to ensure thorough execution and reliable outcomes. The process begins with a **Literature Review and Project Design**, where extensive research is conducted on previous studies related to oral thin films (OTFs), *Tinospora cordifolia*, *Cinnamomum cassia*, and their antidiabetic properties. This step lays the foundation for designing the research framework, setting clear objectives, and identifying suitable methodologies.

Following this, the **Formulation Development** phase is carried out, where the focus is on selecting appropriate excipients, optimizing the extraction of herbal actives, and preparing the oral thin films using suitable techniques like solvent casting. Various formulations are tried and optimized to achieve the best physicochemical properties.

The next phase is the **Characterization of OTFs**, where the prepared films are evaluated through several parameters including thickness, tensile strength, folding endurance, disintegration time, surface pH, and drug content uniformity. This stage ensures that the films meet the necessary standards for effective drug delivery and patient compliance.

After characterization, the research moves into the **Data Analysis and Interpretation** phase. Here, the experimental results are statistically analysed to determine the significance, reliability, and effectiveness of the developed formulations. The data interpretation provides valuable insights into the overall performance and feasibility of the oral thin films for antidiabetic therapy.

Subsequently, the **Documentation** phase involves compiling all research findings, methodologies, analyses, and conclusions in a structured format. Proper documentation ensures clarity, reproducibility, and transparency of the study, which is critical for academic and scientific integrity.

Finally, the **Finalization and Submission** stage concludes the project. This includes reviewing the entire document, making necessary revisions, preparing it for publication, and submitting it to the concerned academic or research bodies. This last step ensures the dissemination of the research outcomes to the scientific community and stakeholders.

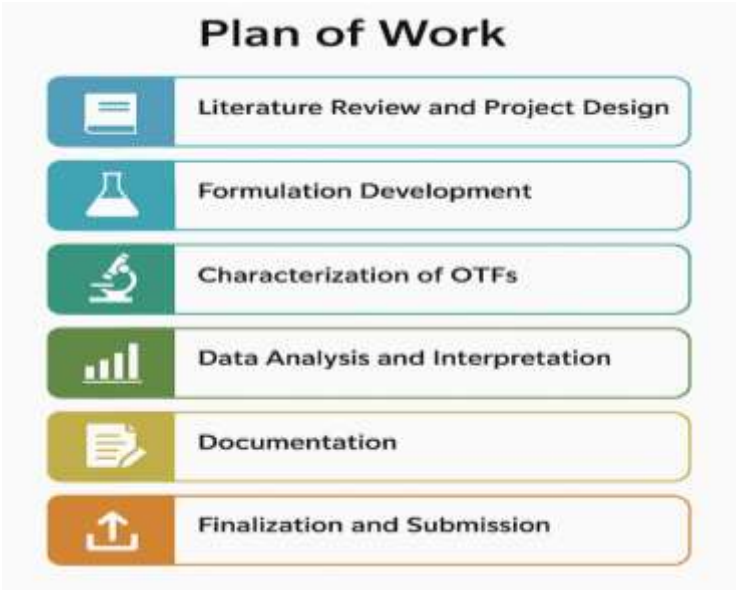

Figure 1: Plan of Work.

MATERIALS AND METHODS

Materials

The materials utilized in this study included various herbal powders, excipients, solvents, and laboratory equipment necessary for the preparation and evaluation of oral thin films (OTFs). The primary active ingredients were *Tinospora cordifolia* powder, sourced from Carmel Organics (certified under Jaivik Bharat and USDA Organic standards), and *Cinnamomum cassia* powder, procured from Pure Tree (certified by India Organic, Jaivik Bharat, and Bureau Veritas). For the extraction processes, distilled water and ethanol were employed as solvents. The formulation of the oral thin films involved the use of Hydroxypropyl Methylcellulose (HPMC) at 450 mg for formulation F1, Sodium Alginate at 150 mg for formulation F2, and Guar Gum at 100 mg for formulation F3. Additional excipients included Glucose (40 mg per film) as a sweetener, Citric Acid (20 mg per film) as a pH stabilizer and preservative, and Polyethylene Glycol (PEG) (1 mL per film) as a plasticizer. Water was added quantity sufficient (q.s.) to make up the final volume of 20 mL for each formulation batch. Other chemicals required for various analyses and evaluations included Methanol, Acetic Acid, and Phosphate Buffer (pH 6.8). Analytical and evaluation procedures utilized equipment such as a Magnetic Stirrer, Ultrasonic Bath, Soxhlet Extractor, Solvent Casting Setup, Vernier Calliper, Digital pH Meter, Disintegration Test Apparatus, UV-Visible Spectrophotometer, Whatman No.1 Filter Paper, TLC Plates (Silica Gel 60), TLC Chamber, UV Lamp (254 nm and 366 nm), Analytical Balance, Desiccator with Calcium Chloride, and Centrifuge for glucose adsorption assays. All materials and reagents used were of analytical grade and were handled following standard laboratory practices to ensure the reliability and reproducibility of the results.

Methods

1. Collection of Plants

Giloy: The plant powder was purchased from ‘Carmel Organics’ which is certified under multiple organic certifications, it carries certification from Jaivik Bharat which is India’s official organic certification mark and reflects adherence to the National Programme for Organic Production (NPOP) standards. Additionally, certain listings of the product also reflect USDA Organic certification, which reflects adherence to the United States Department of Agriculture (USDA) organic standards.[6]

Cinnamon: The powder was purchased from ‘Pure Tree’ Which has certifications from various reliable organic bodies to ensure authenticity and quality. It is certified by India Organic, Jaivik Bharat, and Bureau Veritas through the National Programme for Organic Production (NPOP/NAB/001). Such certifications confirm that the cinnamon powder is grown and processed under high-level organic agricultural methods, unpolluted with synthetic additives, pesticides, and toxic chemicals. In addition, the product is marked as chemical and pesticide-free, pointing to its focus on purity and natural processing techniques.[7]

2. Extraction

Sonication Extraction for Berberine:

80 grams of dried plant material was taken and placed in a beaker. To that, 100 ml of distilled water was added, keeping the ratio 4:5 (w/v). The mixture was stirred in order to properly immerse the plant material in the solvent and allow for equable contact between the solid matrix and the extracting medium. The pre-treated mixture was subsequently subjected to sonication for a period of one hour in an ultrasonic bath (or probe-type sonicator). The procedure was carried out at room temperature (or under controlled temperature conditions if necessary), preferably between the range of 25°C and 40°C, to avoid degradation of thermolabile constituents like berberine. The ultrasonic waves produced during the process of sonication created cavitation bubbles within the liquid that collapsed violently and broke plant cell walls. This increased the intracellular compound release, facilitating the efficient extraction of bioactive components such as berberine into the aqueous phase. The mixture was left to cool and subsequently filtered on Whatman No. 1 filter paper to eliminate insoluble plant residues. The obtained filtrate, containing the aqueous extract enriched with berberine and other soluble phytochemicals, was transferred to a clean container.[8]

Figure 3: Sonication Of Berberine Extract.

Figure 4: Extract Filtration.

Soxhlet Extraction method for Cinnamaldehyde

20 g of cinnamon powder was carefully measured out and deposited into a thimble made of thick filter paper. The thimble was then carefully inserted into the main chamber of Soxhlet extractor, for continuous extraction. Ethanol was selected as the extraction solvent due to its high efficiency in dissolving both polar and non-polar phytochemicals. The solvent was placed in a round-bottom flask connected to the Soxhlet apparatus and heated to reflux at a temperature exceeding 100°C, allowing ethanol vapours to rise, condense, and percolate through the cinnamon powder repeatedly. This process ensures thorough extraction of cinnamaldehyde. The extraction was carried for over 5-10 hours. After completion, the ethanol extracts were collected and subjected to distillation for one hour to concentrate the final product. Proper precautions were taken to ensure that all the ethanol was fully vaporized, leaving behind concentrated cinnamon extract.[9]

Figure 5: Soxhlet extraction of Cinnamaldehyde.

Formulation of oral thin films (Solvent Casting Method)

The oral thin films were formulated using the solvent casting method, a widely accepted technique for developing uniform and flexible drug delivery films. Initially, polymers such as Hydroxypropyl Methylcellulose (HPMC), sodium alginate, and guar gum were accurately weighed according to predetermined formulation requirements. These polymers were carefully dissolved in an appropriate quantity of distilled water under continuous stirring to obtain a smooth and homogenous polymeric solution without any lumps.

To impart flexibility and prevent the films from becoming brittle upon drying, Polyethylene Glycol (PEG) was incorporated into the solution, acting as an effective plasticizer. Additionally, to improve the overall organoleptic and physicochemical properties, glucose was added as a sweetening agent to mask the possible bitterness of herbal extracts, and citric acid was introduced as a pH stabilizer and preservative to maintain the chemical integrity of the formulation and enhance shelf life.[10]

After ensuring complete dissolution of excipients and polymers, herbal extracts of *Tinospora cordifolia* and *Cinnamomum cassia* were introduced into the mixture. The entire formulation was subjected to continuous stirring for one hour using a magnetic stirrer to guarantee uniform dispersion of the active constituents within the polymeric matrix, thus ensuring consistency of the final product.

The resulting solution was then carefully poured into glycerine-coated Petri dishes. The glycerine coating served two purposes: preventing the formulation from sticking to the surface during drying and facilitating easy removal of the formed films. The films were then air-dried at ambient room temperature for approximately 24 hours to allow gradual evaporation of the solvent, leading to the formation of clear, flexible oral thin films.[11]

Post drying, the films were delicately peeled off and cut into uniform strips for further evaluation. To optimize the best formulation, different batches were prepared by varying the polymer concentrations (100 mg, 150 mg, and 450 mg) while maintaining a constant concentration of excipients across all formulations. This approach allowed systematic evaluation and comparison. The batch exhibiting the most desirable physical appearance, mechanical flexibility, disintegration time, and ease of handling was selected as the optimized formulation for subsequent detailed characterization and biological evaluation.[12]

Figure 6: Magnetic Stirrer.

Figure 7: Oral Thin Film.

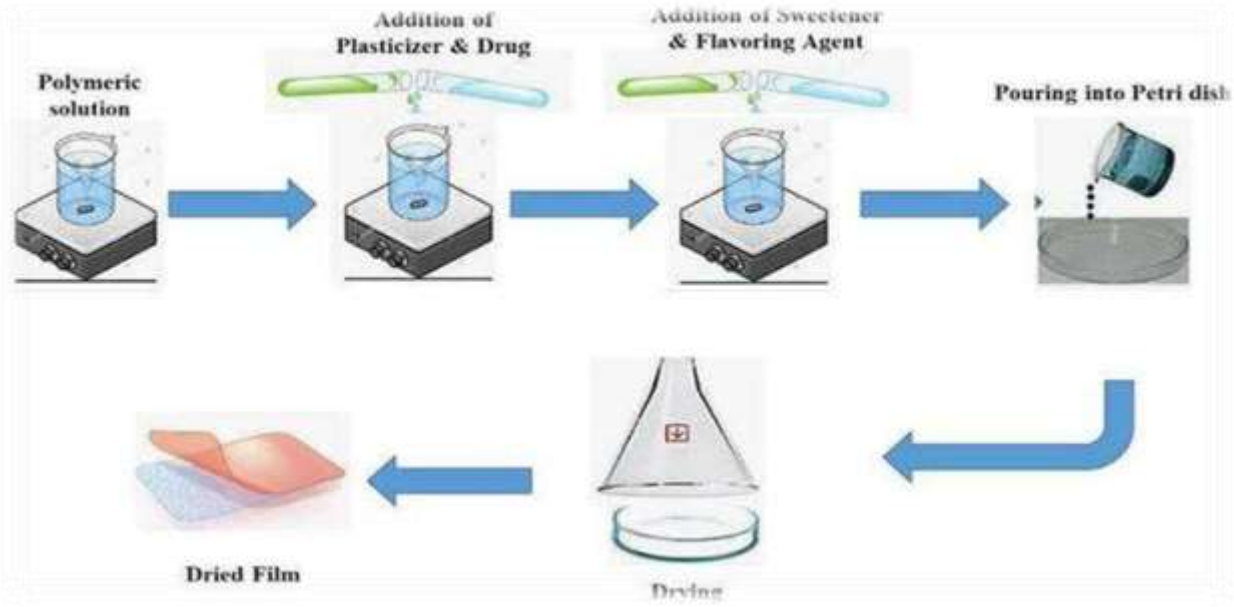

Figure 8: Solvent Casting Method.

Formulation Table

Table 1: formulation table of oral thin film.

	F1	F2	F3
Berberine extract	1ml	1ml	1ml
Cinnamon extract	1ml	1ml	1ml
HPMC	450 mg	-	-
Sodium alginate	-	150 mg	-
Guar Gum	-	-	100 mg
Glucose	40 mg	40 mg	40 mg
Citric acid	20 mg	20 mg	20 mg
PEG	1 ml	1 ml	1 ml
Water	q.s to 20 ml	q.s to 20 ml	q.s to 20 ml

Evaluation Test

1. Phytochemical Screening

Phytochemical screening is essential for identifying the types of secondary metabolites present in plant extracts. These bioactive constituents are often responsible for the observed pharmacological effects. In this study, various qualitative chemical tests were conducted on the aqueous extract of Berberis aristata to determine the presence of major phytoconstituents such as alkaloids, carbohydrates, proteins, glycosides, steroids, tannins, and saponins.

Alkaloids, particularly berberine, are known for their antimicrobial and anti-inflammatory properties. Carbohydrates and proteins contribute to the nutritional and functional profile of the extract. Saponins enhance absorption and exhibit surface activity, while tannins and glycosides play roles in antioxidant and cardiac effects respectively. The positive responses in these tests indicate a rich profile of pharmacologically active components.

Berberine (Aqueous Extract)

Table 2: tests for berberine extract.[13]

Name of Test	Procedure	Observation
Salkowski Test	Sample + 2 mL chloroform + 2 mL conc. H2SO4; shake	Red color appears
Molisch's Test	2 mL sample + 2 drops Molisch's reagent, shake, add 1 mL co	H2SO4 slowly purple ring at junction
Benedict's Test	4 mL sample + 1 mL Benedict's reagent, heat	Color: green to red
Fehling's Test	1 mL Fehling A + 1 mL Fehling B + 2 mL sample, heat	Brick red precipitate
Barfoed's Test	Sample + Barfoed's reagent, heat	Red precipitate
Ferric Chloride Test	Sample + 5% FeCl3 solution in alcohol	Deep blue color
Lead Acetate Test	Sample + 10% lead acetate in water	Precipitate develops
Potassium Dichromate Test	Test sol. + potassium dichromate	Dark color appears
Dragendorff's Test	Sample + 2 mL Dragendorff's reagent	Orange precipitate
Wagner's Test	Sample + few drops Wagner's reagent	Reddish-brown ppt

Hager's Test	Sample + Hager's reagent	Orange/yellow ppt. appears
Ninhydrin Test	Sample + Ninhydrin solution, heat	Yellow color appears
Biuret Test	Sample + 1 mL 4% NaOH + 1 drop 1% CuSO4	Violet color appears
Xanthoproteic Test	Sample + 2 mL water + 0.5 mL conc. HNO3	Development of yellow color
Millon's Test	Sample + 2-3 mL Millon's reagent	White precipitate appears
Foam Test	Sample + water, shake vigorously	Honeycomb-like foam appears
Borntrager's Test	1 mL benzene + 0.5 mL dil. NH4OH + sample	Reddish pink color appears
Phenolic Test	Sample + 2 mL FeCl3 solution	Blue color appears

Cinnamaldehyde (aqueous Extract)

Table 3: tests for cinnamon extract.[14]

Name of Test	Procedure	Observation
Test for Carboxylic acid (Ester formation)	Sample + 3 ml solution of NaHCo3 + conc. HCL	Strong effervescence A solid appears
Test for Anilide	Sample + 1 ml conc. HCL for 2 min, cool + 5 ml water + few drops of cold NaNO2 + cold solution of β-naphthol	Orange red dye
Test for Phenol (Liebermann test)	Sample + 1 ml conc. H2SO4 + 2 crystals of NaNO2+ heat + dilute with water + 20% NaOH solution	Red coloration which turns to bluish greenish color
Test for Aldehyde (Schiff's test)	Sample + 2/3 ml of Schiff's reagent	Pink color slowly develops

Thin layer chromatography

TLC Procedure for Berberine extract Estimation

Materials Required:

Standard Berberine rf (literature) = ~0.71

Silica gel 60

Solvent system: methanol: Acetic acid: Water (8:1:1 v/v/v)

Sample extract (e.g., berberine-loaded oral thin film dissolved in methanol)

Capillary tubes

Chamber for TLC development

UV chamber (254 nm and 366 nm)

Procedure

The presence of berberine in the test sample was identified by Thin Layer Chromatography utilizing a silica gel 60 TLC plate and solvent system made up of methanol, acetic acid, and water in the volume ratio 8:1:1. The freshly prepared solvent mixture was introduced into the developing chamber, which was sealed and allowed to saturate for about 15 min for a uniform solvent atmosphere. The test sample was dissolved in a small volume of methanol to get a clear solution. A pencil was used to mark the TLC plate, and an origin line was drawn about 1 cm from the bottom edge. With the help of a capillary tube, a small drop of the test solution was spotted on the origin line and allowed to dry completely. The TLC plate containing the absorbed sample was carefully placed in the saturated developing chamber in the upright position, while ensuring that the solvent level remained below the origin line. This fitment was allowed to stand undisturbed until the solvent front moved approximately 1 cm from the upper edge of the plate, at which point the plate was taken out of the chamber, and the solvent front was immediately marked using a pencil. The plate was left to dry completely before visualization of the obtained spots under a UV lamp at 254 or 366 nm. The visual observation under UV light exhibited one bright yellow fluorescent spot that testified to the presence of some UV-active compounds. A measurement was taken for the distance covered by a berberine spot, Then, the Rf value was calculated using the following formula: Rf = distance travelled by the spot / distance travelled by the solvent front.[15]

UV-Vis Absorbance Procedure for Berberine extract

Materials Needed:

UV-Visible spectrophotometer

Quartz cuvettes (1 cm path length)

Test extract/sample

Solvent: distilled water (based on solubility)

Volumetric flasks, pipettes

Berberine standard reference values

Procedure

The UV-Visible absorption spectroscopy study of berberine was performed for the identification in a test sample and possible anti-diabetic activity. A standard solution of pure berberine and extract of the test sample were prepared in methanol. The absorbance of both standard and test sample extracts was measured using a UV-Visible spectrophotometer at wavelengths of 266 nm, 348 nm, and 430 nm, the wavelength maxima of berberine. The instrument was first calibrated with distilled water as a blank, and the absorbance values of test solutions were recorded. The reference solution gave absorbance values of 0.33 at 266 nm, 0.20 at 348 nm, and 0.22 at 430 nm. This was found out from research articles. The results, therefore, served to highlight the possible use of berberine in the management of diabetes, given its known action primarily the activation of AMP-activated protein kinase (AMPK) that regulates glucose uptake and lipid metabolism. Thus, the UV-Visible spectral data provided corroboration for the identification of berberine in the test sample and validation for its relevance to anti-diabetic studies.[16]

Evaluation of Oral Thin Films

1. Organoleptic Properties

Table 4: Organoleptic characteristics.[17]

Parameter
Colour: Color of the oral thin films was assessed visually under natural daylight against a white background.
Odour: Odour was evaluated by sensory inspection to detect any characteristic or unpleasant smell.

2. Evaluation Test for oral thin film

FILM THICKNESS

A vernier calliper was used to measure the thickness of the oral thin film samples with precision. Each film, prepared in a 2-inch square dimension, was measured by taking three readings across the film surface to ensure consistency and accuracy. The average thickness was then calculated, along with the relative standard deviation to assess the uniformity of the film thickness across different samples. The thickness was measured at different points to minimize any variations that might occur during the manufacturing process, ensuring a highly uniform product. Variations in thickness can influence the film's disintegration, drug release, and overall efficacy.[3]

SURFACE pH STUDY

To evaluate the surface pH of the films, each 2-inch square film was carefully placed in a clean petri dish. A measured volume of 0.5 ml of distilled water was evenly sprayed onto the surface, and the films were left undisturbed for 30 minutes to allow for proper hydration and interaction. After this period, a digital pH meter was gently placed in contact with the moistened surface of the film to record the ph. This procedure was repeated three times per sample, and the average pH value was calculated to ensure reliability and reproducibility of the results. The pH of the film surface is crucial as it can influence the solubility and absorption of the active ingredient. A neutral pH range is typically desired to avoid irritation to the oral mucosa and ensure effective drug delivery.[18]

DISINTEGRATION TEST

The disintegration test was performed utilizing a disintegration test apparatus. A film segment measuring 2-inch² was positioned in the basket, which was then raised and lowered in a manner that achieved a full cycle of movement at a frequency of 30 times per minute. The duration necessary for the film to disintegrate completely, with no remnants remaining above the gauze, was recorded. The test is crucial to determine the time required for the film to disintegrate upon contact with saliva, ensuring the timely release of the active pharmaceutical ingredient (API). The disintegration time is also essential for assessing the film's effectiveness in achieving the desired therapeutic effect.[19]

FOLDING ENDURANCE

The folding endurance of a material is indicated by the number of folds needed to either rupture a specimen or produce visible fractures. This was determined by consistently folding a film measuring 2-inch² at the same point until it failed. The folding endurance test is important in evaluating the mechanical properties and flexibility of the oral film. A higher folding endurance indicates a more durable film that is less likely to break during handling, packaging, and administration.[10]

WEIGHT VARIATION TEST

For the weight variation test, ten individual film strips, each measuring 2-inch², were carefully cut from different areas of the larger film sheet to ensure representative sampling. Each piece was weighed individually using a precision analytical balance. The average weight of the ten samples was then calculated and compared to the weight of each individual strip. This comparison was conducted to assess the uniformity of film thickness and content distribution, ensuring consistency in formulation and manufacturing. Any significant deviation from the average weight would indicate potential variability in the film casting process, which could affect the dosage uniformity and therapeutic outcomes.[17]

PERCENTAGE OF MOISTURE LOSS

One of the factors that characterize the hygroscopicity of a film is the percentage of moisture lost. In this specific test, the initial weight of the film is measured, after which the film is placed in a desiccator containing calcium carbonate for three days. After this duration, the films are taken out, and their weight is measured again. The amount of moisture lost is calculated using.

Equation

Percentage of moisture loss = [(Initial weight – Final weight) / Initial weight] × 100 This test is important to understand the film's stability under various environmental conditions. Films with higher moisture content may be more susceptible to degradation, affecting their mechanical properties and drug release performance.[3]

IN VITRO DISSOLUTION TEST

For the dissolution test, a medium was prepared using 900 millilitres of phosphate buffer at a pH of 6.8. The temperature of this medium was maintained at 37 ± 2°C, and the apparatus was set to a rotational speed of fifty. A film segment measuring 2-inch² was cut and placed in the basket. Throughout the experiment, 0.5 ml samples were extracted at odd minute intervals for a total duration of 45 minutes, during which an equivalent volume of the dissolving medium was replenished with fresh phosphate buffer. The volume of the extracted samples was adjusted to 10 millilitres using phosphate buffer. Subsequently, the samples were analysed using an ultraviolet spectrophotometer calibrated to a wavelength of 263 nm.

The in vitro dissolution profile provides insight into the release behaviour of the drug from the film and its potential for achieving the desired therapeutic effect. This test is essential for confirming the bioavailability of the drug in a controlled release system.[20]

DRUG CONTENT UNIFORMITY TEST

A 2-inch² film was placed in a 100 ml volumetric flask. Subsequently, 60 ml of a pH 6.8 phosphate buffer was introduced and sonicated for 30 minutes to ensure complete dissolution. Following this, additional phosphate buffer at pH 6.8 was added to achieve a final volume of 100 ml. The resulting solution was then filtered using Whatman filter paper. After filtration, 1 ml of the filtrate was taken and diluted to a total volume of 10 ml with the pH 6.8 phosphate buffer. The absorbance of the solution was measured at a wavelength of 276 nm using a UV-VIS spectrophotometer. This test ensures that the active pharmaceutical ingredient (API) is evenly distributed across all film samples. The uniformity of drug content is crucial for ensuring consistent therapeutic effects and ensuring that each dose delivers the intended amount of the drug.[21]

GLUCOSE ADSORPTION ASSAY

The glucose adsorption capacity of the oral thin films was assessed using a standard in vitro glucose adsorption method. In this procedure, 1 gram of the film sample was added to 100 mL of an aqueous glucose solution with concentrations ranging from 5 mM to 30 mM. The mixture was incubated under continuous shaking at room temperature for 6 hours, allowing interaction between glucose molecules and the film matrix.

After incubation, the mixture was centrifuged at 4800 rpm for 20 minutes to separate the film from the remaining glucose solution. The initial glucose concentration (G1) and the final glucose concentration after 6 hours (G2) were determined using a UV-Visible spectrophotometer at 195 nm, which corresponds to the absorbance maximum for glucose in the UV range.

The amount of glucose adsorbed by the film was calculated using the formula:

Bounded Glucose (mg/g) = (G1 − G2) × V / Weight of Sample (g)

Where:

G1 = Glucose concentration before incubation (mg/mL)

G2 = Glucose concentration after 6 hours (mg/mL)

V = Volume of glucose solution used (mL)

This value represents the glucose binding capacity per gram of oral thin film, indicating its potential role in reducing free glucose concentration through adsorption.[12]

Stability Studies

The stability of the oral thin films was assessed by storing the samples at room temperature (25°C / 60% RH) for a period of 45 days under controlled conditions. Throughout the storage period, the films were regularly observed for any changes in physical appearance, texture, flexibility, and integrity. At the end of the study period, the films exhibited no significant changes in colour, Odor, surface texture, or mechanical properties, indicating that the formulation remained stable under ambient conditions.[22]

Figure 9: OTF After 45 Days Storage.

Figure 10: Stability Testing.

RESULT AND DISCUSSION

Phytochemical screening for Berberine and cinnamon

Test for berberine (aqueous extract)

Table 5: Result for Phytochemical tests of berberine extract.

Name of Test	Observation	Result
Test for carbohydrate Molish test Benedict test Fehling test	Purple color ring Orange red ppt Brick red ppt	Carbohydrate Present Present Present
Test for alkaloid	Orange ppt appear	Alkaloid

Dragendorff test Wagner test Hager test	Reddish brown ppt Orange/yellow ppt	Present Present Present
Test for protein Biuret test Millon test	Violet color appears White ppt appears	Protein Present present
Test for saponin Foam test	Honeycomb like structure	 Present
Test for glycosides Borntrager test	Reddish pink color appears	Glycoside Present
Test for steroids Salkowski test	Red color appears	Steroid Present
Test for tannins Fecl3 test Lead acetate test	Deep blue color Precipitate develops	Tannins Present Present

Figure 11: Dragendorff and Mayers test.

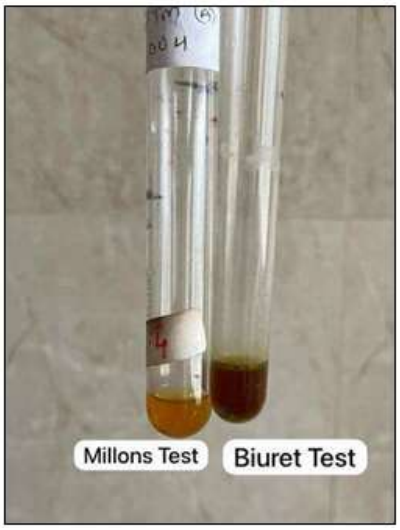

Figure 12: Millon's and Biuret test.

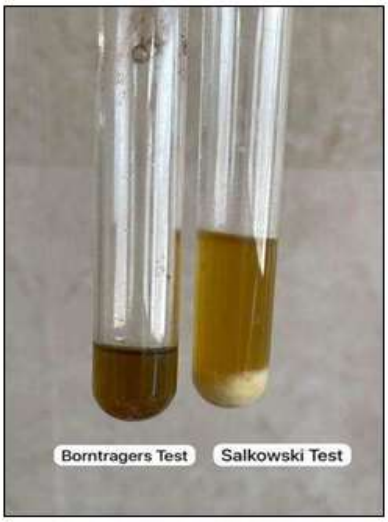

Figure 13: Bontrager's and Salkowski test.

Test for Cinnamon (ethanolic extract)

Table 6: Result for Phytochemical test of cinnamon extract.

Name of test	Observation	Inference
Test for carboxylic acid	Strong effervescence	Carboxylic acid present
Test for anilide	Orange red dye	Anilide group present
Test for phenol (Libermann test)	Red coloration which turns to bluish greenish coloration	Phenol present
Test for aldehyde (Schiff's test)	Pink color slowly develops	Aromatic aldehyde present

Figure 14: Chemical Test of Cinnamon Extract.

Thin layer chromatography results

Solvent system: methanol: acetic acid: water (8:1:1)
TLC plate: Silica gel 60
Standard berberine Rf (literature): ~0.71
Rf calculation of test sample
Rf = distance travelled by berberine spot
Distance travelled by solvent front
= 4.9
6.9
= 0.7101
This sample likely contains berberine if observed under identical conditions.

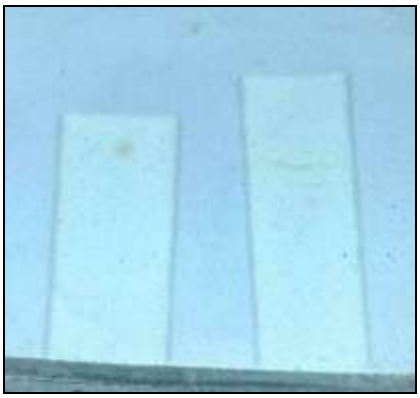

Figure 15: TLC of Berberine Extract.

UV spectroscopy of berberine extract

Table 7: Result of UV spectroscopy of berberine extract.

Wavelength	Reference absorbance	Test sample absorbance
266	0.33	0.2974
348	0.20	0.2016
430	0.22	0.2158

Results for preparation and evaluation of oral thin film

Three different oral thin film formulations were prepared using the solvent casting method, as shown in the figure, with compositions detailed in the accompanying table. Formulation F1 used Hydroxypropyl Methylcellulose (HPMC) as the polymer, F2 incorporated sodium alginate, and F3 included guar gum without any synthetic polymer. Glucose was added as a sweetening agent to mask the taste of the extract. Citric acid was used as a preservative, and polyethylene glycol (PEG) served as a plasticizer in all formulations. HPMC films in F1 were found to be suitable and were further evaluated, while guar gum films in F3 were discontinued due to excessive stickiness. As a result, only the films prepared using HPMC (F1) and sodium alginate (F2) were selected for further evaluation, including weight variation, thickness, tensile strength, folding endurance, disintegration time, and surface ph.

Organoleptic properties

Parameter
Colour: The oral thin films exhibited an amber to brownish-orange appearance.
Odor: The films had a characteristic warm, sweet, and spicy Odor typical of cinnamaldehyde

Evaluation tests

1. Thickness of Film

It was measured by vernier calliper
3 readings for each batch were taken and average thickness was noted.

Figure 16: vernier calliper showing thickness of film.

Table 8: Result for Thickness of Film.

Thickness(mm)	F1	F2
1	0.45	0.095
2	0.43	0.100
3	0.42	0.098
average	0.43	0.098

Result: Uniform and acceptable film thickness

2. Surface pH

It was measured using pH meter
3 readings for each batch were taken and average was calculated

Table 9: Result for Surface pH.

Surface pH	F1	F2
1	6.55	6.58
2	6.53	6.59
3	6.46	6.50
Average surface pH	6.51	6.56

Result: The film's surface pH is close to neutral pH of saliva (6.5-7.0), indicating its non-irritating and suitable for oral/transmucosal application.

Figure 17: pH meter Showing neutral pH.

3. Disintegration time

Film was placed in disintegration tester, 30cycles/min
Time until complete disintegration.

Figure 18: Disintegration Test Apparatus.

Figure 19: Basket showing disintegration of film.

Batch F1= 1min 45 seconds Batch F2= 53 seconds
Result: Rapid disintegration, suitable for fast acting delivery

4. Folding endurance

2cm film was folded repeatedly until cracking
Number of folds before cracking:
Batch F1: 98
Batch F2: 15
Result: it was found that batch F1 showed a greater number of folds and had good flexibility while batch F2 showed less folds and was brittle. Hence for further evaluation testing's batch F1 was continued.

5) Weight variation test

10 film strips (2inch2 each) were randomly cut from cast film and weighed.

Table 10: Weight Variation Data.

Sample	Weight(mg)
1	130
2	134
3	135
4	130
5	131
6	128
7	126
8	134
9	136
10	132
average	131.6

Average weight =131.6
Standard deviation = 3.20 mg
% relative standard deviation: (SD/Mean) x 100 = 2.43%
Result: The standard deviation is within acceptable limits, indicating good uniformity in film weight across the samples

Figure 20: Weight of single OTF.

6) Percentage of moisture loss

A 2inch2 film was weighed and placed in a desiccator containing fused calcium chloride for 3 days. final weight was recorded and % moisture loss was calculated as

$$\text{Moisture loss (\%)} = \frac{\text{initial weight} - \text{final weight} \times 100}{\text{Initial weight}}$$

Observed values:
Initial weight = 136mg
Final weight = 128mg
Moisture loss = 136-128/136 x100 = 8 /136 X 100 = 5.88%

Result: film showed a 5.88% moisture loss, indicating acceptable dryness and minimal residual water content.

7) In vitro dissolution study

Performed using USP dissolution apparatus type II (paddle method).

Medium: 900 mL of phosphate buffer (pH 6.8), maintained at 37 ± 0.5°C.

Paddle speed: 50 rpm.

One film (2-inch²) placed in the dissolution medium.

Samples (5 mL) withdrawn at fixed time intervals and analysed at mix of 348 nm using a UV-Vis spectrophotometer.

Replaced with fresh medium to maintain sink conditions. %Drug release data.

Figure 21: In Vivo Dissolution Test Apparatus.

Table 11: % Drug Release Data.

Time (min)	%Drug Release
2	18.375
5	18.575
10	20.36666667
15	24.425
20	28.5
25	36.91666667
30	41.08333333
35	41.16666667
40	53.075
45	55.16666667
50	48.5

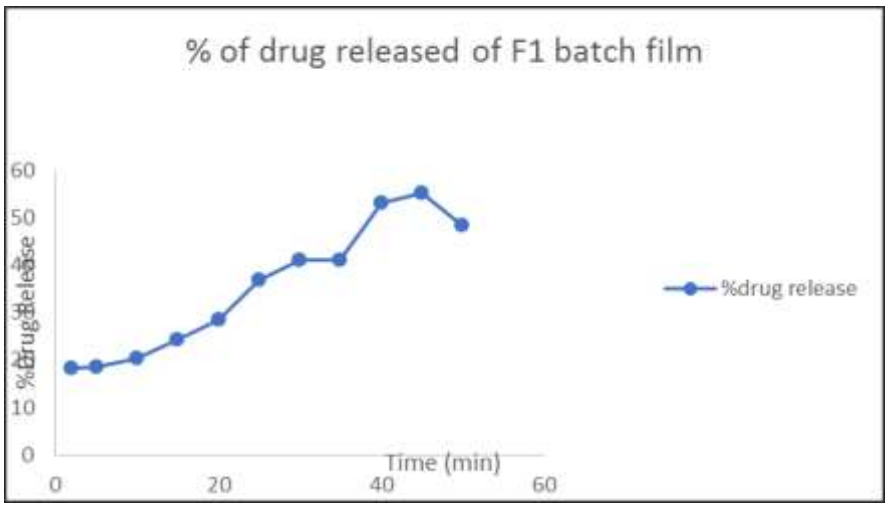

Figure 22: % Drug Released of F1 Batch Film.

8) Drug content uniformity

Three film strips (2-inch² each) were cut randomly from the cast film.

Each strip was dissolved in a suitable solvent (e.g., phosphate buffer), filtered, and analysed using a UV-Vis spectrophotometer at mix 348 nm.

The drug content in each sample was calculated from a standard calibration curve.

Calculation:
Theoretical drug per 2inch2 film = 12.56 mg
Calculation of actual drug content:
A= m x c
C =A/m
% drug content = actual/theoretical x100

Table 12: Result for content uniformity of film strip.

content uniformity of Film strip			
sample	**absorbance**	**drug content**	**% drug content**
1	0.2258	11.29	89.88%
2	0.2313	11.56	92.07%
3	0.2503	12.59	99.64%

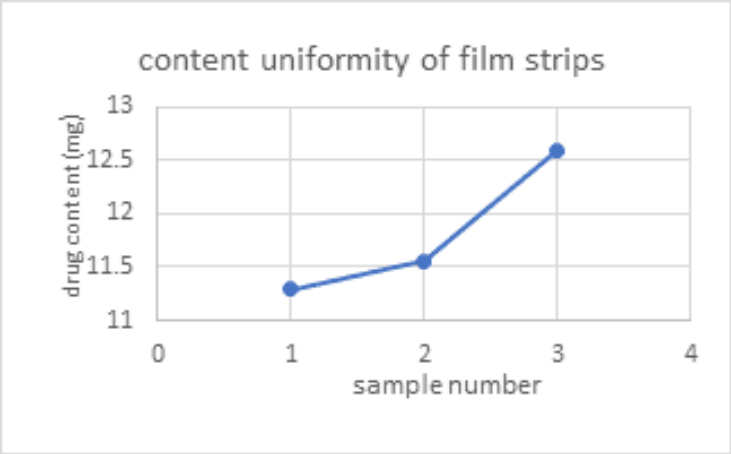

Figure 23: Content uniformity of film strips.

Result: all the samples fall within the acceptable ±15% range, indicating good uniformity

9) Glucose adsorption assay
Calculation
Glucose adsorbed = $(G_1 - G_2) \times V$
= (10 - 4.98) × 100
= 502 mg
Adsorption per gram of film = 502 mg / 0.5 g
= 1004 mg/g
% Adsorption = $[(G_1 - G_2) / G_1] \times 100$
= [(10 - 4.98) / 10] × 100
= 50.2%

Figure 24: Centrifugation for glucose adsorption assay.

Summary of Results
Initial glucose concentration: 10mg/ml
Final glucose conc.: 4.98 mg/mL
Glucose adsorbed: 502 mg
Adsorption per gram of film: 1004 mg/g
% glucose adsorbed: 50.2%
The oral thin film adsorbed 50.2% of glucose, corresponding to 502 mg or 1004 mg/g of film, reducing the final glucose concentration to 4.98 mg/milk

CONCLUSION AND DISCUSSION

The present research successfully demonstrates the potential of using Tinospora cordifolia (Guduchi) and Cinnamomum cassia (Cinnamon) in the formulation of oral thin films (OTFs) as a novel approach for antidiabetic therapy. The study was methodically conducted from the initial phases of plant collection and authenticated procurement of organically certified raw materials, to precise extraction processes including sonication and Soxhlet methods, targeting bioactive compounds such as berberine and cinnamaldehyde—both of which are known for their antidiabetic and pharmacologically beneficial properties.

The OTFs were developed using the solvent casting method with carefully selected polymers (HPMC, sodium alginate, and guar gum) and excipients (PEG, glucose, citric acid). Among the three formulations, the HPMC-based film (F1) displayed superior characteristics in terms of mechanical strength, flexibility, uniformity, and patient acceptability, making it the optimized formulation for further evaluation.

Extensive physicochemical and mechanical evaluation confirmed the effectiveness of the developed OTFs:
The films exhibited rapid disintegration times (as low as 53 seconds for F2), which is crucial for prompt therapeutic action.

Folding endurance, thickness uniformity, and surface pH values were within the acceptable range, indicating suitability for oral mucosal delivery.

Drug content uniformity and low standard deviation in weight variation ensured consistency in dosage, vital for clinical reliability.

Phytochemical screening and TLC analysis validated the presence of desired active compounds, particularly berberine, which was confirmed via Rf values and UV-Vis spectrophotometry at specific absorbance maxima. Furthermore, the glucose adsorption assay revealed a significant 50.2% glucose binding, correlating with a measurable reduction in glucose concentration—an encouraging indicator of in vitro antidiabetic activity.

The stability studies performed over 45 days further affirmed that the oral thin films maintained their integrity, texture, and therapeutic potential under ambient conditions, reinforcing their practical viability in pharmaceutical settings.

Final Insights
This research bridges the gap between traditional herbal knowledge and modern pharmaceutical drug delivery systems. The oral thin film format not only enhances patient compliance—especially for paediatric, geriatric, and dysphagic populations—but also bypasses first-pass metabolism, thereby improving the bioavailability and onset of action of phytoconstituents.

The use of Tinospora cordifolia and Cinnamomum cassia as natural, safe, and effective therapeutic agents aligns with the increasing demand for plant-based alternatives to synthetic antidiabetic medications, which are often associated with adverse effects.

In conclusion, the formulated OTFs represent a promising, patient-friendly, and innovative platform for diabetes management. With further clinical validation and scale-up, these herbal OTFs could serve as a revolutionary nutraceutical product in the diabetic care domain.

REFERENCES

1. "Enteral Drug Administration - an overview | ScienceDirect Topics." Accessed: Feb. 19, 2025. [Online]. Available: https://www.sciencedirect.com/topics/nursing-and-health-professions/enteral-drug-administration
2. R. SeviNç Özakar and E. Özakar, "Current Overview of Oral Thin Films," Turk. J. Pharm. Sci., Feb. 2021; 18(1): 111–121. doi: 10.4274/tjps.galenos.2020.76390.
3. S. M. Akter, S. C. Bhowmik, M. Alam, S. Shahriar, T. Saha, and M. S. I. Pathan, "Formulation and Estimation of Rapidly Dissolving Sublingual Thin Film of Vildagliptin," Bangladesh Pharm. J., Aug. 2023; 26(2): 212–218. doi: 10.3329/bpj.v26i2.67811.
4. V. Shende, "FORMULATION AND EVALUATION OF HERBAL TOOTH GEL CONTAINING ALOE VERA: COMPARED STUDY WITH MARKETED PREPARATIONS".
5. M. S. Rekha, G. S. S. Lakshmi, N. V. Lakshmi, A. Tejasree, and D. S. Reddy, "A Comprehensive Review on Formulation and Evaluation of Herbal Films," Int. J. Pharm. Sci. Rev. Res., Jun. 2023; 80(02). doi: 10.47583/ijpsrr.2023.v80i02.025.
6. https://www.silkrute.com/health-and-personal/diet-and-nutrition/raw-herbs/carmel-organics-giloy-guduchi-gulvel-stem-powder-340-grams-jaivik-bharat-certified/?page=7&selected_section=product_reviews&srsltid=AfmBOooz5lhjh5aMtE7RpRSCUUmksHSKSV8zjxOxpy8jjvEhFVUiMJl8
7. https://puretreefoods.com/products/organic-cinnamon-powder-dal-chini?_pos=2&_sid=b73701a67&_ss=r

8. https://journals.sagepub.com/doi/epub/10.1177/2058738419855567
9. https://naturalingredient.org/wp/wp-content/uploads/Cinnamon-extraction.pdf
10. S. S. Palakurthi, D. Jakka, and D. N. Pinnamraju, "Preparation and Evaluation of Oral Thin Films of a Natural Product: Syzygium cumini seed powder," J. Drug Deliv. Ther., Feb. 2022; 12(1): 64–70. doi: 10.22270/jddt.v12i1-S.5343.
11. R. Kaza, Y. Raju, and R. Nagaraju, "Formulation and Characterization of Gliclazide Oral Dissolving Films," Drug Deliv. Lett., Oct. 2014; 4(3): 185–192. doi: 10.2174/2210303111303660013.
12. G. Rehman et al., "Green Synthesis and Characterization of Silver Nanoparticles Using Azadirachta indica Seeds Extract: In Vitro and In Vivo Evaluation of Anti-Diabetic Activity," Pharmaceuticals, Dec. 2023; 16(12): 1677. doi: 10.3390/ph16121677.
13. https://impactfactor.org/PDF/IJPQA/12/IJPQA,Vol12,Issue2,Article4.pdf
14. https://iscnagpur.ac.in/study_material/dept_chemistry/3.1_MIS_and_NJS_Manual_for_Qrganic_Qualitative_Analysis.pdf
15. Satija, S., Malik, S., & Garg, M. Development of a new, rapid, and sensitive validated high-performance thin-layer chromatographic method for the estimation of berberine in Tinospora cordifolia. Journal of Planar Chromatography – Modern TLC, 2016; 29(3): 209–215. https://doi.org/10.1556/1006.2016.29.3.7
16. https://sielc.com/uv-vis-absorption-spectrum-of-berberine
17. https://www.researchgate.net/publication/327721385_Formulation_and_Evaluation_of_Fast-Dissolving_Film_of_Cetirizine_and_Dextromethorphan
18. https://www.researchtrend.net/bfij/pdf/Review-on-Nanoparticle-Loaded-Oral-Film-an-Innovative-Approach-for-Poorly-Water-Soluble-Drug-Delivery-Dipak-P-Kardile-22.pdf
19. https://www.researchgate.net/publication/357684336_FORMULATION_DEVELOPMENT_AND_EVALUATION_OF_FAST_DISSOLVING_ORAL_FILM_OF_ANTI-MIGRAINE_DRUG_RIZATRIPTAN
20. Development of Oral Dissolvable Films of Diclofenac Sodium for Osteoarthritis Using Albizia and Khaya Gums as Hydrophilic Film Formers
21. https://doi.org/10.1155/2016/6459280
22. DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRICMETHOD FOR QUANTITATIVE ESTIMATION OF GLIPIZIDEIN PHARMACEUTICAL DOSAGE FORM | International Journal of Current Pharmaceutical Research SURYAWANSHI A, AFAQUEANSARI, KALSHETTI M. DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRICMETHOD FOR QUANTITATIVE ESTIMATION OF GLIPIZIDEIN PHARMACEUTICAL DOSAGE FORM. Int J Curr Pharm Sci [Internet]. 2020 Mar. 15 [cited 2025 Apr. 26]; 12(2): 104-7. Available from: https://journals.innovareacademics.in/index.php/ijcpr/article/view/37502
23. CD Formulation. (n.d.). Stability Testing for Oral Thin Film. Retrieved from https://www.formulationbio.com/oral-thin-film/stability-testing-for-oral-thin-film.html