



**INTERNATIONAL JOURNAL OF
PHARMACEUTICAL SCIENCES**
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: <https://www.ijpsjournal.com>



Research Article

Orodispersible Film from Herbal- *Tridax procumbens*: A Novel Approach for Antidiabetic Drug Delivery

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ARTICLE INFO

Published: 22 May 2026

Keywords:

Tridax procumbens, Mouth dissolving, Oral thin film, Anti diabetic activity, Herbal drug delivery system, Solvent casting method, Natural anti diabetic agent.

DOI:

10.5281/zenodo.20345633

ABSTRACT

High blood sugar, or hyperglycemia, is a defining feature of diabetes mellitus, a metabolic disease caused by issues with insulin action, manufacturing, or both. The increasing prevalence of diabetes globally and the associated side effects have prompted the hunt for safer herbal substitutes for conventional synthetic drugs. The medicinal plant *Tridax procumbens* is a member of the Asteraceae family and has long been used to treat diabetes and other conditions. Phytochemical research has revealed the presence of phenolic compounds, tannins, alkaloids, saponins, and flavonoids to enhance its therapeutic potential. The methanolic extract has demonstrated substantial alpha amylase inhibitory activity in in vitro studies, much to the widely used medication Acarbose, an alpha glucosidase inhibitor for type 2 diabetic mellitus. Additionally, alloxan has been demonstrated in in vivo studies to have an antihyperglycemic effect by rapidly reducing blood glucose levels and improving glucose tolerance in diabetic rats. Adding *Tridax procumbens* extract to a mouth-dissolving film has several benefits, including quick drug release, enhanced bioavailability, increased patient compliance, and simplicity of administration without the need for water, given its therapeutic efficacy and safety. As a result, this herbal mixture demonstrates a magical and promising method for successfully managing diabetes.

INTRODUCTION

Diabetes mellitus is a chronic metabolic disease characterized by persistent hyperglycemia caused by abnormalities in insulin secretion or action, or both. Type 2 Diabetes Mellitus (T2DM), the most prevalent form of the disease, accounts for nearly

90% to 95% of all diabetes cases worldwide. The main conditions that it frequently manifests in are insulin resistance and relative insulin insufficiency. The rising incidence of type 2 diet, excess body fat, inactivity, and an individual's genetics.

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



Chronic hyperglycemia in type 2 diabetes can lead to serious effects such as neuropathy, nephropathy, retinopathy, and cardiovascular disorders. Many synthetic oral hypoglycemic drugs, such as metformin, sulfonylureas, and DPP-4 inhibitors, are available; however, long-term use of these drugs has a risk of adverse effects, such as gastrointestinal issues, hypoglycemia, and weight gain. Herbal and plant-based medications are becoming more and more popular due to their low cost, relative safety, and absence of adverse effects.

Tridax procumbens, often known as coat buttons, belongs to the Asteraceae family. The plant has been used in traditional Ayurvedic and folk medicine to treat wounds, reduce inflammation, protect the liver, and manage diabetes. In tropical and subtropical nations, the plant is widely distributed. According to phytochemical research, its flavonoids, alkaloids, tannins, carotenoids, and phenolic compounds are likely to contribute to its hypoglycemic and antioxidant properties.

Recent pharmacological studies show that *Tridax procumbens* has significant anti-diabetic potential by improving insulin sensitivity, increasing glucose absorption, and reducing oxidative stress. Conventional herbal formulations, including tablets and decoctions, may have problems with patient compliance, uneven bioavailability, and a slow onset of action.

The oral fast-dissolving film, which offers rapid medicine release and improved patient compliance, is one creative and patient-friendly solution to these issues. Because oral films dissolve quickly in the mouth cavity without water, have better bioavailability, and promote patient compliance, they may be very beneficial for patients with swallowing problems, such as the elderly and those with diabetes.

Therefore, the goal of this study is to create and evaluate oral films containing *Tridax procumbens* for the treatment of type 2 diabetes. In comparison to traditional synthetic anti-diabetic treatments, this novel herbal delivery method may offer increased therapeutic efficacy, greater patient adherence, and a safer option.

ETHNOBOTANICAL BACKGROUND:

Tridax procumbens has been employed extensively in traditional treatment systems in many tropical and subtropical climates, according to ethnobotanical research. It is frequently found growing organically in wastelands, grasslands, agricultural fields, and wayside areas, where the local population has long known its medicinal benefits. Fresh leaves are frequently crushed in rural India to extract juice, which is then applied directly to cuts, wounds, and bug bites to halt bleeding and accelerate healing. Additionally, leaf pastes are made by traditional healers to treat small burns, irritation, and skin infections. Decoctions produced from the leaves or the entire plant are used in some areas to treat respiratory pain, diarrhea, fever, and stomach problems.

Since many indigenous cultures employ *Tridax procumbens* to treat chronic illnesses like diabetes and hypertension, its ethnobotanical significance goes beyond wound treatment. Regular use of regulated herbal formulations derived from the plant may help control blood sugar levels and enhance overall health, according to folk practitioners. The herb is also used in some tribes as a tonic for weakness and as a liver-supporting medication. Herbal remedies for boosting immunity and easing physical discomfort occasionally contain the flowers and aerial parts. The plant's antioxidant, antibacterial, anti-inflammatory, and antidiabetic qualities have drawn scientific attention as a result of these customs.



In ethnobotanical records, *Tridax procumbens* has agricultural and ecological relevance in addition to its medical benefits. The plant waste has occasionally been utilized by farmers as green manure or as a natural cure for minor cattle illnesses. It is a readily available home remedy for low-income populations due to its capacity to grow quickly in poor soils. This plant's ongoing usage in traditional medicine demonstrates the close relationship between indigenous knowledge and natural medical resources. The preservation of ancient knowledge and the advancement of herbal formulations and contemporary plant-based therapies are two benefits of documenting such ethnobotanical activities.

Ethnobotanical Data from Different Regions

Scientific name	<i>Tridax procumbens</i>
Family	Asteraceae
Common name	Coat button
Habitat	Creeping perennial herb
Leaves	Opposite, hairy, serrated
Flower	Yellow disc with white ray florets
Stem	Branched hairy

TRADITIONAL MEDICINAL USES OF TRIDAX PROCUMBENS:

1. **Wound Healing :** Cuts, burns, and wounds have historically been treated with fresh leaf paste to halt bleeding and encourage healing.
2. **Antidiabetic uses:** Folk medicine uses entire plant decoction and leaves to lower blood sugar levels.
3. **Anti-inflammatory uses:** It is used to treat inflammation, discomfort, arthritis, and bug bites.
4. **Hair Growth Promotion:** To stop hair loss, apply leaf juice to the scalp.

5. **Liver Disorder:** In rural medicine, it is used as a natural cure for jaundice and liver weakness.
6. **Gastrointestinal Problems:** Plant extract is used to treat indigestion, dysentery, and diarrhea.
7. **Respiratory Disorder:** Traditional healers use it to treat asthma, bronchitis and cough.

Phytochemical Constituents:

Bioactive substances like these are supported by ethnobotanical research.

- Flavonoids
- Alkaloids
- Tannins
- Saponins
- Terpenoids
- Steroids
- Phenolic substances

These substances have antibacterial, antioxidant, antidiabetic, and wound-healing properties.

HISTORICAL USES OF PLANT MEDICINE:

Due to its medicinal advantages, including wound healing, anti-inflammatory, antibacterial, and antidiabetic actions, *Tridax Procumbens* is more commonly employed in folk medicine than as a significant classical herb.

A. Ayurvedic System :

Medicinal plants have long been utilized in ancient Indian medical systems, particularly Ayurveda, to treat illnesses and preserve health. Coat buttons, or



Tridax procumbens, are employed in Ayurvedic and traditional medicine for their therapeutic and defensive qualities. Due to its medicinal potential, it has become more significant in regional and traditional medicine even though it was not a key classical herb in old Ayurvedic writings.

In the past, cuts, wounds, burns, and insect bites were treated topically using a paste made from the crushed leaves of *Tridax procumbens* to halt bleeding and hasten healing. The Ayurvedic concepts of *Ropana* (wound healing) and *Shodhana* (cleaning) are reflected in this application. Fever, inflammation, diarrhea, and liver problems were all historically treated with the plant's fresh juice or decoction.

The plant was thought to assist balance disrupted *Pitta* and *Kapha* doshas in rural Ayurvedic therapy, particularly in situations involving heat, swelling, and infection. The antidiabetic properties of *Tridax procumbens* have drawn scientific interest in recent years. In line with Ayurvedic treatment of *Madhumeha* (diabetes mellitus), traditional healers employed the plant extract to regulate excessive urine and tiredness linked to high blood sugar.

Tridax procumbens's effectiveness as a natural treatment for wound healing, inflammation, fever, and metabolic diseases is therefore demonstrated by its ancient Ayurvedic use, which supports its current significance in herbal therapy.

B. Unani System:

Tridax procumbens has long been valued for its healing and restorative properties in herbal therapy. Medicinal plants are chosen in the Unani medical system according to their inherent therapeutic properties and temperament (*Mizaj*). *Tridax procumbens* has been used in Unani-aligned techniques to cure common illnesses,

despite being more widely recognized in folk medicine.

The plant's capacity to halt bleeding and encourage tissue healing led to its usage as a wound healer in the past. Cuts, burns, ulcers, and other skin problems were treated externally using fresh leaf paste. Additionally, it was thought to be helpful in lowering edema and inflammation, which is consistent with the Unani idea of eliminating negative humors and reestablishing equilibrium.

Traditionally, the leaves' juice or decoction was used to treat digestive issues like diarrhea and upset stomachs. The herb was utilized as a moderate liver tonic and blood purifier in several Unani-based rituals in the area. It was also used to treat mild respiratory issues, fever, and cough.

The plant was occasionally suggested for skin conditions like rashes, boils, and itching due to its cooling and purifying properties. It was also utilized by traditional healers to promote scalp health and boost hair roots. As a result, *Tridax procumbens* gained significance in traditional Unani healing practices as a versatile medicinal plant for wound treatment, inflammation, digestive issues, skin issues, and general health support.

C. Siddha System:

The Siddha medical system has long used medicinal plants to treat a wide range of symptoms and maintain health. In traditional herbal traditions, coat buttons, or *Tridax procumbens*, are valued for their medicinal and protective properties. Despite the fact that many remedies were passed down through local healers and folk traditions, the plant's therapeutic efficacy is connected to the principles of Siddha medicine.



Fever, diarrhea, digestive problems, and general weakness were all treated internally with decoctions produced from the leaves or the entire plant in traditional Siddha medicine. Some ancient healers also recommended taking the plant to regulate blood sugar levels and boost vitality. The plant was valued for its capacity to promote healthy scalp and hair development, and fresh juice was applied to the scalp to stop hair loss. Due to its accessibility and range of medicinal advantages, *Tridax procumbens* became a major home remedy in rural regions influenced by Siddha traditions.

Therefore, in traditional Siddha-related herbal medicine, *Tridax procumbens* was recognized as a useful plant for wound healing, inflammation, digestive problems, skin care, and general wellness.

COMMONLY USED MEDICINAL PLANT WORLD WIDE:

Tridax procumbens is widely utilized as a medicinal plant in many tropical and subtropical parts of the world because of its extensive distribution, ease of availability, rapid growth, and variety of medicinal benefits. Because it grows naturally in fields, roadsides, gardens, wastelands, agricultural areas, and open grasslands, the plant is easy to find to rural inhabitants and traditional healers. It is frequently found in India, Sri Lanka, Bangladesh, Thailand, Nigeria, Brazil, Mexico, and many regions of Africa and Asia. Due to its extensive usage, the plant is an essential component of folk medicine and traditional healthcare systems.

Tridax procumbens has long been used as a natural treatment for burns, wounds, cuts, and bleeding injuries. The plant is said to encourage blood clotting, lessen infection, and hasten tissue healing when fresh leaves are ground into a paste and

administered directly to the afflicted region. Due to its instant effectiveness in treating small injuries, it is considered a first-aid herb in many areas. One of the primary reasons the plant is still well-liked around the world is its reputation for mending wounds.

Also, the plant is frequently used to treat metabolic diseases, including diabetes mellitus. Leaf juice, decoctions, or dried powder are prepared by traditional healers in different countries to control elevated blood sugar levels. Because phytochemical investigations indicate the presence of flavonoids, alkaloids, tannins, and phenolic substances that may promote antidiabetic action through antioxidant effects and better glucose metabolism, *Tridax procumbens* has attracted more attention from modern scientists. The plant is useful in herbal antidiabetic studies because of this traditional assertion.

Its anti-inflammatory and antibacterial properties are another important factor in its world wide medical significance. Traditionally, skin diseases, rashes, boils, insect bites, and swelling have been treated with extracts of the leaves and entire plant. The plant is said to lessen discomfort and redness while also preventing germ development. *Tridax procumbens* is occasionally included to herbal oils, ointments, and topical medicines because of these qualities.

Further, the plant is frequently used to treat gastrointestinal issues like indigestion, dysentery, diarrhea, and stomach pain. Small doses of herbal teas or aqueous extracts are taken for digestive help in certain cultures. Additionally, it has been used to treat respiratory conditions like fever, bronchitis, and cough. These applications mirror the plant's function in many traditional systems as a versatile home treatment.



Tridax procumbens leaves are often used for hair care and cosmetics. To encourage hair growth, lessen dandruff, and enhance scalp health, fresh juice or herbal oil mixtures are applied to the scalp. In South Asian societies, where medicinal plants are included into everyday wellness routines, this traditional usage is particularly prevalent.

From a scientific standpoint, *Tridax procumbens*'s rich phytochemical makeup is responsible for its global appeal. Flavonoids, carotenoids, saponins, steroids, tannins, and antioxidants have all been found in studies. These components may have antibacterial, hepatoprotective, anti-inflammatory, antidiabetic, and wound-healing properties.

Researchers are still investigating the plant for contemporary dosage forms such as oral thin films, herbal gels, pills, lotions, and extracts since it is affordable, natural, and accessible locally.

Because *Tridax procumbens* combines accessibility, traditional trust, several therapeutic applications, and increasing scientific backing, it is considered a worldwide significant medicinal plant. Its widespread use across continents shows how traditional medical knowledge may influence the creation of contemporary herbal medications and advancements in natural healthcare.

HEALTH BENEFITS:

Table no. 1 Health Benefits

Sr.no	Health Benefits	Plant part used	Traditional use and their uses
1.	Wound Healing	Leaves	Promotes faster healing of cuts, burns, wounds.
2.	Antidiabetic	Leaves/ Whole plant	Helps reduce blood glucose levels.
3.	Anti-inflammatory	Leaves	Reduces swelling, pain, redness.
4.	Antimicrobial	Leaves/ Extract	Helps fight bacteria and fungi.
5.	Antioxidant	Whole plant	Protects cells from oxidative stress.
6.	Hair Growth Promotion	Leaves	Applied on scalp to reduce hair fall and promote hair growth.
7.	Skin care	Leaves	Used for rashes, boils, irritation.
8.	Digestive Support	Leaves/ Decoction	Helps in diarrhea, indigestion.
9.	Liver protection	Whole plant	Traditionally used in jaundice and liver weakness.
10.	Fever Relief	Leaves/ Juice	Used in traditional remedies for fever.

Flavonoids, alkaloids, and tannins are among the many bioactive substances found in its leaves, stem, and roots that support the following health advantages.

A. Management of Diabetes:

Extracts from the plant's aerial portions may have hypoglycemic effects, according to research. It is a conventional supplemental medication for Type 2 diabetes because it can help reduce blood sugar levels.

B. Superior Wound Healing:

This is likely its most well-known use. The leaf juice has strong antibacterial and anticoagulant properties.

- **Stops Bleeding:** Applying fresh leaf juice to wounds can rapidly stop blood flow.
- **Quicker Recovery:** It strengthens collagen and encourages skin cell renewal, which speeds up the healing of wounds.

C. Liver Protection (Hepatoprotective):

It is frequently used in Ayurveda to treat liver diseases in place of *Bhringraj*. It has been



researched for its potential to treat diseases including jaundice and liver inflammation, as well as for protecting the liver from toxins.

D. Anti-Inflammatory & Pain Relief

Antioxidants found in the plant aid in lowering inflammation in the body.

- **Joint Pain:** Gout and arthritis have historically been treated with it.
- **Analgesic:** It relieves headaches and other bodily aches naturally.

E. Antimicrobial & Antifungal:

Strong inhibitory actions against a variety of bacteria and fungi are exhibited by *Tridax procumbens*. It is used to treat blisters, boils, and skin infections.

Additionally, it has long been used to treat gastrointestinal problems including dysentery and diarrhea brought on by bacterial infections.

F. Respiratory & Cardiovascular Support

- **Blood Pressure:** According to some research, it may help decrease high blood pressure since it contains hypotensive qualities.
- **Respiratory Problems:** It is used in traditional medicine to treat common colds and bronchial catarrh, which is an inflammation of the mucous membranes.

G. Hair Growth:

The leaf extract is occasionally used in hair oils to stop hair loss and encourage the growth of healthy, black hair because of its resemblance to *Bhringraj*.

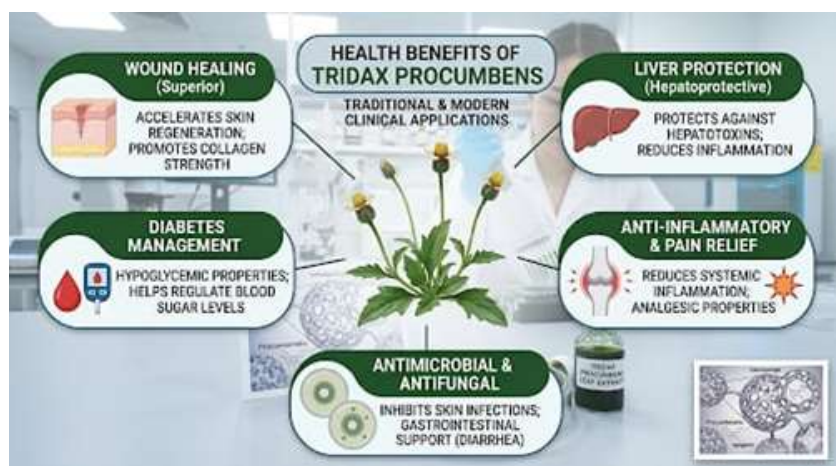


Fig no. 1 Benefits of *Tridax procumbens*

SAFETY, TOXICITY AND REGULATORY ASPECTS:

Tridax procumbens' dual character as a powerful ethnomedical resource and an internationally recognized invasive weed must be taken into consideration while evaluating its safety and regulatory profile.

The current scientific agreement about its toxicological and regulatory status is summed up in the following sections.

1. Toxicological Profile and Safety:

Although *Tridax procumbens* has been used traditionally for a long time, current toxicological research shows that it has a generally positive safety profile at low to moderate dosages, yet at

high concentrations, particular organ damage occurs.

blood cell counts, indicating that they do not induce acute anemia..

Acute and Sub-Chronic Toxicity

- **Lethal Dose (LD₅₀):** The LD₅₀ of ethyl acetate and methanolic extracts is often found to be around 2100 mg/kg body weight in studies conducted on animal models (rats and mice). This implies a comparatively low acute toxicity ranking.
- **Behavioural Observations:** Experimental participants have displayed symptoms of discomfort, such as salivation, restlessness, and localized irritation at the application site, at greater acute dosages.
- **Organ Specificity:** High dosages (800 mg/kg and above) have been connected to the following in sub-chronic studies (e.g., 14-day repeated dosing):
- **Hepatotoxicity:** Increased levels of ALT (alanine aminotransferase).
- **Endothelial Toxicity:** Haemosiderin deposits in the parenchyma of the kidney and liver indicates damage to blood vessels that causes bleeding, according to histopathological data.

Biochemical Impact:

- **Regulation of Glucose:** The plant has notable hypoglycemic effects. Although useful for diabetes research, if used in conjunction with conventional antidiabetic drugs, this might result in hypoglycemia.
- **Hematology:** Research indicates that under controlled circumstances, moderate dosages do not appreciably change hemoglobin or red

2. Regulatory Status:

Tridax procumbens is classified differently based on the locale and intended usage, the regulatory framework around it is complicated.

- **Agricultural/ Environmental Regulation:** The Federal Noxious Weed Act designates *T. procumbens* as a "Federal Noxious Weed." Because of the harm it poses to local ecosystems due to its tremendous seed output (about 1500 per plant), it is tightly restricted to stop its spread.
- **Global Status:** Because of its quick colonization of disturbed soils, it is classified as an invasive alien species in a number of tropical and subtropical climates.
- **Pharmacopoeial/ Medicine Status:** India: It is acknowledged by Ayurvedic and Unani medical systems. Although it is frequently used in private Ayurvedic medicines (PAM) for hepatoprotection and wound healing, it is not always the major constituent in mainstream licensed medications.
- **Functional Food Potential:** Although it has not yet received official GRAS (Generally Recognized as Safe) certification from the US FDA, recent study suggests that it should be included in the "functional food" category because of its high flavonoid and antioxidant content.

As a Botanical / Therapeutic Agent

- **Pharmacopoeial Status:** Despite being an essential of Ayurvedic treatment in India and folk medicine in West Africa and Central America, it has not received official clearance



as a pharmaceutical medication from important organizations like the FDA in the USA or the EMA in Europe.

3. Critical Research Consideration: Its usage in commercial supplements is frequently limited to traditional medicine frameworks rather than mainstream dietary goods because it is not now on the "Generally Recognized as Safe" (GRAS) list for food additives in many jurisdictions.

- **Standardization:** Standardized extraction procedures are lacking. Aqueous, ethanolic, and ethyl acetate extracts differ greatly in terms of toxicity.
- **Bioaccumulation:** Tridax is a weed that may absorb pesticides and heavy metals (such as lead or cadmium) from its surroundings because it grows well in disturbed soils. Strict purity testing is required for research samples.
- **Clinical Data:** Nowadays, in vitro or in vivo animal models provide almost all of the safety data. Phase-I human clinical studies to determine safe upper consumption limits for humans are conspicuously lacking.

Summary Table for Quick Reference:

Table no. 2 Summary table for safety, toxicity and regulatory affairs

CATEGORY	FINDING/ STATUS
Acute Toxicity [$\{LD_{50}\}$]	-2100 mg/kg (low toxicity)
Primary Risk	Endothelial damage and hemorrhage at high doses
US Regulatory Status	Federally Listed Noxious Weed
Therapeutic Status	Ethnomedicinal (unapproved by FDA/ EMA)
Major Bioactive Risk	Synergistic hypoglycemia (lowering blood glucose too much)

ADVANCED IN MEDICINAL PLANT RESEARCH :

The shift from conventional ethnobotanical validation to high-precision molecular and pharmaceutical engineering is reflected in recent developments in the pharmacological investigation of *Tridax procumbens*. Maximizing the bioavailability of its bioactive metabolites and comprehending its influence on intricate metabolic pathways are the main goals of current study.

Nanotechnology and Enhanced Delivery Systems:

Overcoming *Tridax procumbens* extracts' low solubility and stability is the biggest advancement in recent research.

- **Green Synthesis of Nanoparticles:** Researchers are use the plant's elevated phenolic content as a reducing agent to produce silver (Ag) and gold (Au) nanoparticles. When compared to bulk extracts, these "green" nanoparticles had better antibacterial and anti-inflammatory qualities.
- **Polymeric Mouth-Dissolving Films (MDFs):** Research has shifted toward MDFs, which use hydrophilic polymers to encapsulate *Tridax procumbens* phytochemicals in order to avoid first-pass metabolism. This ensures faster mucosal absorption and greater therapeutic plasma concentrations for the treatment of diabetes.

Molecular Insights into Antidiabetic Mechanisms:

Despite its well-established antihyperglycemic properties, recent research uses in silico (computational) docking to pinpoint particular molecular targets:



- **Enzyme Kinetics:** Alpha-amylase and alpha-glucosidase are competitively inhibited by *T. procumbens* metabolites, particularly certain flavonoids and tannins, according to sophisticated in vitro tests. This has much less gastrointestinal adverse effects than synthetic inhibitors like acarbose.
- **Insulin Sensitization:** According to recent in vivo models, the extract may increase GLUT4 translocation, which would improve peripheral tissue glucose absorption and improve the functional recovery of pancreatic beta-cells in models caused by alloxan.
- **Smart Bandages:** Researchers are incorporating the plant extract into cooling gels (hydrogels) and "bioactive" bandages.
- **Building Collagen:** The plant aids in the production of collagen, the "glue" that keeps skin together.
- **Faster Recovery:** It forces the body to swiftly transition from the uncomfortable, swelling phase of a wound to the phase when new, healthy skin develops. For wounds that often take a long time to heal, this is extremely beneficial.

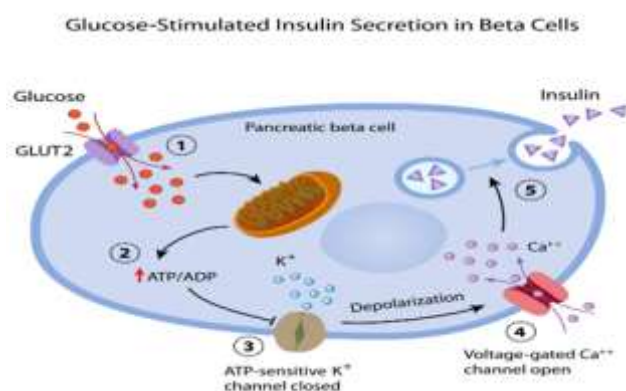


Fig no. 2 Glucose Stimulated Insulin Secretion In Beta Cell

Clinical and Industrial Potential:

Researchers and producers are now figuring out how to transform *Tridax procumbens* into superior items for pharmacies and medical facilities. They are concentrating on ways to make the plant usable on a wide scale rather than simply using raw leaves.

1. Advanced Healing and "Smart" Bandages:

In addition to being used to treat diabetes, the plant is starting to play a significant role in contemporary first aid.

2. Proven Safety for Long-Term Use:

A plant must be shown to be safe before it can be marketed as a medication or supplement.

- **Tested for Safety:** Recent research has examined the body's response to the plant over both brief and extended periods of time.
- **High Safety Margin:** According to these experiments, the plant is not harmful even at large doses (a value known as LD50).
- **Daily Use:** It is regarded as an excellent option for "nutraceuticals"—natural supplements that you may take daily like a vitamin to maintain long-term health—because it is so safe.

METHODOLOGY OF TRIDAX PROCUMBENS MOUTH DISSOLVING FILM:

1. Collection and Authentication of Plant Material:

Fresh *Tridax procumbens* leaves were collected from a pesticide-free location to ensure safety and purity. The Department of Pharmacognosy or a

professional botanist evaluated the plant sample to make sure it was authentic.

The leaves were examined for any indications of dirt or other impurities after being thoroughly cleaned with distilled water. After washing, they were shade-dried at room temperature to keep the active compounds from being deteriorated by direct sunlight. To make sure the particles were uniform in size, the leaves were crushed and run through a No. 40 sieve once they had completely dried. The powder was packed in an airtight container to prepare it for further research.

- **Preparation of Tridax Extract:**

The powdered leaves were extracted by maceration using the Soxhlet extraction method using a hydro-alcoholic solvent (70% ethanol). The mixture was let to stand in order to assist extract the active components as effectively as feasible.

After extraction, the solid residues were filtered out of the mixture. The filtrate was placed in a rotary evaporator with decreasing pressure concentration to extract the solvent. The concentrated extract was further dried to produce a solid extract. The dried extract was stored at 2–8 °C in an airtight container to preserve its freshness for use in future formulations.

2. Preformulation Studies:

Before formulation, preformulation studies evaluated the extract's physicochemical properties.

The organoleptic characteristics, such as flavor, scent, and appearance, were recorded. The extract was tested in water and several buffer solutions to see how it dissolved. The pH of the extract solution was measured. The moisture content was evaluated to ensure stability.

Researchers conducted drug-excipient compatibility testing to ensure the extract wouldn't react adversely with certain formulation components.

3. Selection of Film-Forming Agents:

The right excipients were selected to produce films that disintegrate in the tongue. Agents such as pullulan, HPMC E5, or HPMC E15 were utilized to create the film. Glycerine or PEG400 was used as a plasticizer to make the film pliable.

To improve the flavor, stevia, a natural sweetener, was added. Citric acid was utilized as a saliva-stimulating agent to aid in quick breakdown in the mouth. Mint or orange flavoring was added for improved taste. Potassium sorbate or sodium benzoate were used to stabilize the product, and ascorbic acid or another antioxidant was added if necessary.

4. Preparation of Mouth-Dissolving Films:

The solvent casting method was used to create the films that dissolve in the mouth. The first step involved dissolving the selected polymer in distilled water and continuously stirring until a clear solution was obtained. The plasticizer was added progressively to increase the film's elasticity. The polymer solution was added and well mixed to ensure that the Tridax extract and other excipients were dispersed uniformly.

Following homogenization, the mixture was placed in a sterile glass Petri dish and dried at a controlled temperature of 40–45 °C. To ensure the right dose, the films were carefully peeled off and cut into uniform sizes when they had fully dried.

Evaluation of Mouth-Dissolving Films:

On the generated films, several pharmacological and physical properties were examined.



To ensure uniformity, thickness and weight fluctuation measurements were made. The film was folded in the same location until it broke in order to assess its folding durability. Its surface pH was evaluated to ensure it wouldn't irritate the oral mucosa.

The disintegration time was tested to determine how quickly the film broke down in saliva. We looked for drug content homogeneity to ensure the extract was dispersed uniformly throughout each film. Experiments were conducted to quantify moisture absorption.

An in-vitro dissolving method was used to evaluate the release pattern of the film extract.

1. Stability Studies

After the films were created, they were preserved using blister packs or aluminum foil with a

desiccant. Stability tests were conducted under controlled conditions:

- $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and 60% relative humidity
- $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and 75% relative humidity

To determine how stable the formulation was, we examined the films' physical characteristics, disintegration time, medicine content, and moisture absorption at 0, 1, 3, and 6 months.

2. Data Analysis

Each experiment was conducted three times to ensure accuracy and reliability. The average plus or minus the standard deviation (SD) was used to display the data. We were able to assess the stability and performance of the formulation by contrasting the results with the data gathered during formulation.



FIG. NO.3: Methodology of Tridax procumbens Mouth Dissolving Films



FIG NO. 4: *Tridax procumbens* Mouth Dissolving Strips Biofilm

EVALUATION TEST:

- **Pre-Formulation Evaluation of Extract:**

- 1. Organoleptic Evaluation:**

The fundamental physical properties of the dried extract were assessed. A tiny amount of the extract was extracted, and its colour was examined in daylight. The sample was softly smelled to assess the odour. A very tiny amount was tested to find out how it tasted if it was safe. The physical characteristics of the extract were also noted, including whether it was coarse, crystalline, sticky mass, or fine powder. This assessment aids in determining the extract's general qualities and purity.

- 2. Phytochemical Screening:**

To find significant bioactive components that have antidiabetic properties, preliminary phytochemical screening was done.

- 1. Test for Flavonoids (Shinoda Test):**

A chemical test called the Shinoda test is used to determine if plant extract contains flavonoids. Flavonoids are significant secondary metabolites with therapeutic and antioxidant qualities. This test relies on the production of a pink or red color

following a reaction between hydrochloric acid and magnesium.

Principle: Red or pink coloration is produced when flavonoids combine with hydrochloric acid and magnesium.

- 2. Test for Alkaloids (Dragendorff's Test):**

A popular chemical technique for identifying alkaloids in plant extracts is Mayer's test. Alkaloids are substances that contain nitrogen and have potent pharmacological effects. Alkaloids and Mayer's reagent combine in this test to produce a cream-colored precipitate.

Principle: Mayer's reagent and alkaloids combine to produce a precipitate.

- 3. Test for Tannins:**

Tannins and phenolic substances in plant extracts can be identified using the ferric chloride test. Tannins are naturally occurring astringent compounds that have antioxidant and antibacterial properties. Tannins generate a blue-black or green color when ferric chloride solution is present.

Principle: Tannins react with ferric chloride to give blue-black or green colour.

OBSERVATION TABLE:**Table no. 3. Observation table for test**

Sr. No.	Test Name	Procedure	Observations	Result
1	Test for Flavonoids (Shinoda Test)	To the plant extract, add small magnesium ribbon pieces and a few drops of concentrated HCl.	Pink or red colouration appears.	Flavonoids are present.
2	Test for Alkaloids (Mayer's Test)	Add Mayer's reagent to acidic plant extract.	Cream or pale yellow precipitate forms.	Alkaloids are present.
3	Test for Tannins (Ferric Chloride Test)	Add few drops of ferric chloride solution to the extract.	Greenish-black or blue-black colour develops.	Tannins are present.

Evaluation of Mouth Dissolving Film**a) Appearance Test:****Introduction:**

When it comes to mouth-dissolving films, appearance is the first quality factor to be noted. It offers details on the formulation's overall beauty, acceptability, and consistency. Films should be smooth, flexible, aesthetically pleasing, and devoid of obvious flaws. Patient compliance is significantly impacted by appearance since oral films are inserted directly into the mouth.

- This test includes evaluation of:
 - Colour uniformity
 - Transparency or opacity
 - Smoothness of surface
 - Presence of air bubbles
 - Cracks or peel marks
 - Stickiness

Apparatus:

- Glass plate / Petri dish
- White and black background

Procedure:

1. Place the film on a clean glass plate.
2. Observe under daylight against white and black backgrounds
 - Check for:
 - Colour
 - Transparency
 - Smoothness
 - Air bubbles
 - Cracks or stickiness

Table no.4 Parameter and its observation

Parameter	Observation
Colour	Light green
Transparency	Slightly translucent
Smoothness	Smooth and glossy
Air bubbles	Absent
Cracks or stickiness	Absent

RESULT:

The created Tridax procumbens mouth dissolving film was found to have a nice physical appearance and acceptable quality. It was light green in colour, smooth, flexible, somewhat transparent, and devoid of air bubbles, cracks, and stickiness.

Standard:

Film should be uniform, smooth, non-sticky, bubble-free

$$\text{Average Thickness} = \frac{\text{Sum of readings}}{\text{Number of readings}}$$

b) Thickness Test:

$$\frac{0.21 + 0.22 + 0.21}{3} = 0.213$$

Introduction:

One crucial physical factor that affects the film's homogeneity is thickness. Every film strip has the same quantity of active substance and performs consistently thanks to uniform thickness. Additionally, mechanical strength, folding endurance, disintegration time, and drug release are all impacted by thickness. While extremely thin films may rip readily, very thick films may disintegrate slowly. Thus, it is crucial to maintain the ideal thickness throughout the production process.

Apparatus:

Digital micrometre screw gauge (least count 0.001 mm)

Procedure:

1. Select 3 to 5 films at random.
2. Take three measurements of thickness (centre + edges).
3. Determine the average thickness.

Standard:

Uniform thickness (~0.1–0.3 mm)

Table no.5 Standardization Table

Film No.	Point 1 (mm)	Point 2 (mm)	Point 3 (mm)
1	0.21	0.22	0.21
2	0.22	0.21	0.22
3	0.20	0.21	0.21

Formula:

Result:

The film's mean thickness of 0.213 mm demonstrated even drug distribution and consistent casting

c) Weight Variation:

Introduction:

The consistent distribution of substances in the film is ascertained using the weight variation test. If every film strip weighs almost the same, the formulation was properly mixed and cast. Variations in film weight may result in uneven medication dosages since herbal extracts and excipients are dispersed throughout the polymer matrix.

When films are manually cut from a bigger cast sheet, this test is very crucial.

Apparatus:

Digital weighing balance (sensitivity 0.1 mg)

Procedure:

- a. Cut equal-sized films (e.g., 2x2 cm).
- b. Weigh three to five separate films.
- c. Determine the deviation and mean weight

Standard:

Weight variation should be minimal (± 5 –10%)



Table no. 6 Weight variation

Film No.	Weight of film (mg)	% Deviation
1	46	2.2
2	43	-4.4
3	47	4.4
4	45	0
5	44	2.2

Result:

With a mean weight of 45 mg, the film demonstrated a consistent formulation with little variance.

d) Folding Endurance:**Introduction:**

Folding endurance gauges the film's mechanical strength and flexibility. It shows the number of times a film can be folded in one spot without shattering. This test aids in assessing the film's resistance to handling, packing, transportation, and administration.

Poor folding endurance can cause films to break while being used or stored.

Plasticizers such as glycerin or PEG are usually added to improve flexibility

Apparatus:

Manual (no special instrument)

Procedure:

1. Take one film.
2. Fold it repeatedly at the same point.
3. Count the number of folds until it breaks.

Standard:

150-200 folds = good flexibility

Table no. 7 Folding Endurance

Film No.	No. of Folds
1	168
2	182
3	195

Result:

The prepared Tridax procumbens mouth dissolving film showed average folding endurance of 182 folds, indicating good flexibility and satisfactory mechanical strength.

e) Disintegration Time:**Introduction:**

One of the most crucial aspects of mouth dissolving film performance is disintegration time.

It establishes how long it takes for the film to disintegrate into tiny particles when it comes into touch with saliva.

Rapid disintegration ensures:

- Rapid onset of action
- Easy swallowing
- Improved adherence to treatment
- Quick release of the medication
- Depending on the formulation type, an ideal mouth dissolving film should dissolve in a matter of seconds to a minute.

Apparatus:

- Petri dish / USP disintegration apparatus
- Simulated saliva fluid (pH 6.8 buffer)

Procedure:

1. Fill the Petri dish with the film.
2. Add 5 to 10 mm of artificial saliva.



3. Time how long it takes for the film to totally crumble.

Standard:

Should disintegrate within 20–40 seconds .



Fig no. 5. Disintegration time

f) Surface Ph Test:

Introduction:

To make sure the film doesn't irritate the oral mucosa after being placed in the mouth, surface pH is evaluated. The film's surface should be close to neutral pH since it continues to come into direct touch with saliva and soft tissues.

Highly acidic or alkaline films may cause:

- A burning feeling
- Ulceration
- Discomfort

Therefore, maintain PH between 6.8 to 7.0 which is similar to saliva.

Apparatus:

- pH meter / pH paper

- Petri dish
- Distilled water

Procedure:

1. Fill a Petri dish with film.
2. Pour in one to two milliliters of distilled water.
3. Give it a minute or two to swell.
4. Use a pH meter to measure the pH .

Standard:

pH should be 6.5–7.5 (neutral)

Result:



Fig no. 6 Surface PH Test

g) Drug Content Uniformity Test:

Introduction:

Drug content homogeneity guarantees that the desired quantity of active ingredient is present in every single film. This is particularly crucial for low-dose films since even little changes might have a big impact on the therapeutic response.

Uniformity verifies that the plant extract is properly dispersed in the polymer matrix of herbal films containing Tridax procumbens extract.

Sedimentation, inadequate mixing, or precipitation during drying can all lead to uneven drug concentration.

Apparatus:

- UV-Visible spectrophotometer
- Volumetric flask
- Magnetic stirrer
- Filter paper

Procedure:

1. Take one known-sized film.
2. Dissolve in 100 milliliters of pH 6.8 phosphate buffer.
3. Stir for half an hour.
4. Filter the mixture.
5. Use a UV spectrophotometer to measure absorption.
6. Use the calibration curve to determine the drug content.

Standard: within 85%–115%.

Calculation:

- **Calibration readings:**

Table no. 8 Calibration table

Concentration (ppm/ $\mu\text{g mL}^{-1}$)	Absorbance
10	0.034
20	0.074
30	0.117
40	0.157

50	0.191
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• Sample Film Reading:

Absorbance = **0.200** at **310 nm**

Step 1: Calibration Curve Equation:

Using a linear equation: $A = mC + b$

From given readings: $A = 0.00393C - 0.0053$

So, concentration: $C = \frac{A + 0.0053}{0.00393}$

Step 2: Calculate sample Concentration:

Sample absorbance = **0.200**

$C = \frac{0.200 + 0.0053}{0.00393}$

= 52.24 $\mu\text{g/mL}$

Step 3: Calculate Total Drug in 100 mL

If final diluted volume = **100 mL**

Drug Amount = $C \times V$

= 52.24×100

= 5224 μg

= **5.224 mg**

Step 4: Drug Content Uniformity %:

If label claim = 5 mg per film

% Drug content = $\frac{\text{Actual} \times 100}{\text{Theoretical}}$

= $(5.224/5) \times 100$

= **104.48**



Result:**Table No. 9**

Parameter	Result
Sample Absorption	0.200
Calculated Concentration	52.24 $\mu\text{g} / \text{mL}$
Drug Amount in 100 mL	5.224mg
% Drug Content Uniformity	104.48

The drug concentration of the manufactured Tridax procumbens mouth dissolving film was 104.48%, indicating adequate mixing and content consistency during film casting.

IDENTIFICATION TEST:**Amylase Inhibition:****Reagent Preparation****1) 1% Starch Solution (Substrate)**

- In 100 milliliters of DW, dissolve 1 gram of starch.
- Heat it until the mixture turns transparent.

DNSA Reagent

- In 20 mL of 2N NaOH, dissolve 1 g DNSA.
- In 50 mm of DW, dissolve 30 grams of sodium potassium tartrate.
- Combine the two solutions, then use DW to increase the total volume to 100 mL.

2) Standard Glucose Solution (500 $\mu\text{g}/\text{mL}$)

Add 0.05 g standard glucose in 100 mL DW.

3) Phosphate Buffer (0.2 M, pH 6.9)

- Potassium dihydrogen phosphate (KH_2PO_4) = 30.87 g
- Sodium hydrogen phosphate (Na_2HPO_4) = 35.084 g
- Use DW to create the final volume up to 1000 mL after dissolving in enough water.

Calculation for 50 mL Solution:

$$\text{KH}_2\text{PO}_4 = 30.87 \times 50 / 1000 = 1.5435 \text{ g}$$

$$\text{Na}_2\text{HPO}_4 = 35.084 \times 50 / 1000 = 1.7542 \text{ g}$$

4) Salivary amylase (Enzyme)

1 gm amylase powder dissolved in 100 ml DW.

0.02 mg dissolved in 20 ml buffer.

Procedure – For Standard

- Label six test tubes that have been cleaned and dried.
- Fill each test tube with 0.0, 0.2, 0.4, 0.6, 0.8, and 1.0 milliliters of standard glucose solution.
- Use DW to create a volume of 1 ml.
- Then add 2.5 ml DNSA in each test tube.
- Keep test tubes in boiling water bath for 10 min.
- OD recorded at 530 nm.

Table no.10: Observation of salivary amylase

Sr. No	Std. Glucose (mL)	D/W (mL)	DNSA (mL)		OD at 530nm
1	0.0	1.0	2.5	Take test tubes In boiling water Bath for 10 min Then cool the Tubes and take	0.0
2	0.2	0.8	2.5		0.14
3	0.4	0.6	2.5		0.27
4	0.6	0.4	2.5		0.37
5	0.8	0.2	2.5		0.46



6	1.0	0.0	2.5	O.D at 530nm	0.52
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For Plant Sample (Without Activators)

1) To produce the reaction mixture, take three more clean, dry test tubes and label them according to the table below.

2) Next, add the buffer, substrate, and enzyme as shown in the table.

3) Transfer 0.5 ml of the reaction mixture from the three test tubes above into three more test tubes

that are dry and clean. Add DNSA and DW as shown in the table.

4) Measure the OD at 530 nm after keeping the tubes in a hot water bath for ten minutes.

5) Use a plant sample in phosphate buffer and repeat these steps. In a 10 ml buffer, add 1 ml of the sample.

OBSERVATION TABLE:

Reaction mixture without plant sample

Table no.11

Sr. No		Substrate(ml)	Enzyme(ml)	Buffer(ml)	Incubate at R.T for 3 min Then stop reaction keeping tubes in water bath For 5 min
1.	Enzyme Blank	0.5	-	2	
2.	Substrate blank	-	0.5	2	
3.	Test	0.5	0.5	1.5	

- Enzyme Activity**

Table no.12

Sr. No		Mixture (ml)	D/W (ml)	DNSA (ml)		OD at 530 nm
1	Enzyme Blank	0.5	0.5	2.5	Keep the tube In boiling water Bath for 10 min	0.13
2	Substrate Blank	0.5	0.5	2.5		0.14
3	Tast	0.5	0.5	2.5		0.55

- Reaction mixture with plant Sample:**

Table no.13

Sr. No		Substrate (ml)	Enzyme (ml)	Buffer (ml)	Incubation Tubes at R.T for 3 min Then stop the reaction by Keep tubes in boiling water bath for 5 min
1	Enzyme blank	0.5	-	2	
2	Substrate blank	-	0.5	2	
3	Test	0.5	0.5	1.5	

- Enzyme Activity :(With Plant Sample)**

Table no.14

Sr. no		Mixture	D/w	DNSA		OD at 530 (ml)
1	Enzyme Blank	0.5	0.5	2.5	Keep test tubes in boiling water bath for 10 min	0.09
2	Substrate Blank	0.5	0.5	2.5		0.17
3	Test	0.5	0.5	2.5		0.58



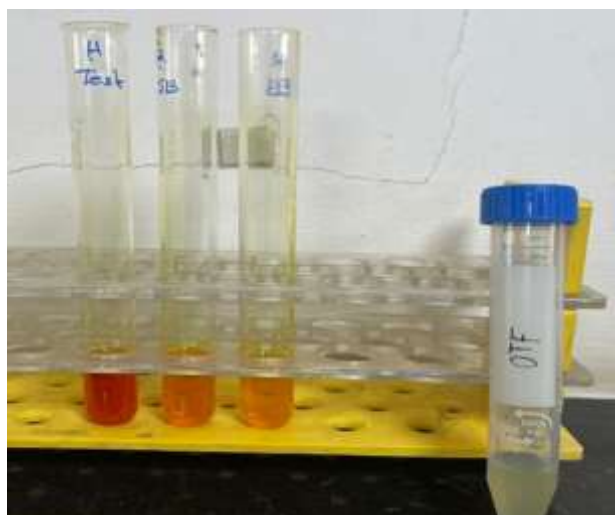


Fig no. 7: Reaction mixture



Fig No. 8 Enzyme Activity With Plant Sample

CONCLUSION

In conclusion, using a novel oral thin film drug delivery method, the current study successfully proved that *Tridax procumbens*' potential as a herbal option for the treatment of diabetes mellitus. The existence of bioactive components including flavonoids, alkaloids, tannins, and phenolic compounds—which are in charge of its significant antidiabetic activity—was verified by the phytochemical analysis. The extract has promising glucose-lowering capability equivalent to current medicines, according to α -amylase inhibition.

The solvent casting process proven to be an effective way to manufacture mouth-dissolving oral thin films, offering good mechanical qualities,

consistent drug distribution, and quick disintegration. This unique administration method increases bioavailability, guarantees a quicker onset of action, and boosts patient compliance—particularly in elderly and diabetic patients who have trouble swallowing.

Overall, this study shows that oral thin films based on *Tridax procumbens* can be a safe, efficient, and patient-friendly substitute for traditional antidiabetic treatments. To confirm its therapeutic effectiveness and long-term safety in human subjects, further clinical research is advised.

RESULTS:

The antidiabetic potential of *Tridax procumbens* herbal oral thin films was successfully formulated, assessed, and validated in this study.

The existence of important bioactive components including flavonoids, alkaloids, and tannins—which are in charge of major therapeutic activity—was verified by the phytochemical screening. Through processes including enzyme inhibition and antioxidant activity, these components contributed to the reported antidiabetic impact.

Excellent physicochemical qualities were displayed by the mouth-dissolving films that were developed. Good formulation quality was indicated by the films' smoothness, flexibility, lack of stickiness, and absence of air bubbles. The films' average thickness was around 0.213 mm, which is within the permissible limit and guarantees even medication distribution. Studies on weight Changes revealed little variance, indicating that drug content was consistent throughout movies.

Strong glucose-lowering potential was shown by the extract's high level of α -amylase inhibitory activity, which was similar to that of conventional

antidiabetic medications, according to in vitro experiments. In addition, by lowering blood glucose levels and increasing glucose tolerance, documented in vivo results validated its antihyperglycemic action.

The oral thin film delivery technology showed increased bioavailability, better drug release, and quick breakdown. Because it is simple to administer without water, this innovative approach also increases patient compliance.

Overall, the findings show that *Tridax procumbens* oral thin films have high stability, safety, and therapeutic potential and are a promising, successful, and novel herbal method for the treatment of diabetes mellitus.

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HOW TO CITE: Rajshri Ballal, Tejaswini Maske, Vedika Patil, Rohit Bhusare, Anuradha Bhoi, Dr. Shobhraj Malavi, Orodispersible Film from Herbal-Tridax procumbens: A Novel Approach for Antidiabetic Drug Delivery, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 5, 5958-5981. <https://doi.org/10.5281/zenodo.20345633>