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Polyherbal Orodispersible Films: An Emerging Herbal Strategy for Effective Diabetes Management

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Abstract: Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from impaired insulin secretion, insulin action, or both. The increasing global prevalence of diabetes highlights the need for safe, effective, and patient-friendly therapeutic approaches. Herbal medicines have gained significant attention because of their antidiabetic potential, lower incidence of adverse effects, and long history of traditional use. Medicinal plants such as *Momordica charantia*, *Trigonella foenum-graecum*, *Emblica officinalis*, *Syzygiumcumini*, and *Costus igneus* contain bioactive phytochemicals that improve glycemic control through multiple mechanisms, including enhanced insulin secretion, improved insulin sensitivity, antioxidant activity, and inhibition of carbohydrate metabolism. Oral dispersible films (ODFs) represent an innovative drug delivery system that rapidly dissolves in the oral cavity without the need for water, improving patient compliance, particularly among pediatric and geriatric populations. The combination of polyherbal extracts with ODF technology offers a promising strategy for rapid drug release, improved bioavailability, ease of administration, and better therapeutic outcomes. This review highlights the pathophysiology of diabetes mellitus, commonly used antidiabetic medicinal plants, formulation methods of polyherbal ODFs, their advantages, and future perspectives. Polyherbal ODFs have the potential to become an effective and patient-friendly alternative for diabetes management by integrating traditional herbal medicine with advanced pharmaceutical drug delivery systems.

Keywords: Diabetes Mellitus, Polyherbal Formulation, Oral Dispersible Film, Herbal Drug Delivery

INTRODUCTION:

Diabetes mellitus is a chronic metabolic disorder characterized by elevated blood glucose levels (hyperglycemia) resulting from defects in insulin secretion, insulin action, or both. It is one of the most common non-communicable diseases worldwide and significantly affects the metabolism of carbohydrates, fats, and proteins. The pancreas plays a vital role by secreting insulin from β-cells and glucagon from α-cells in the islets of Langerhans to regulate blood glucose levels [1].

The pathogenesis of diabetes varies depending on its type. Some forms are primarily associated with insulin resistance, while others result from insulin deficiency or genetic abnormalities affecting insulin production. Long-term uncontrolled diabetes can lead to severe complications, including

nephropathy (kidney damage), neuropathy (nerve damage), retinopathy (eye damage), cardiovascular diseases (CAD), and peripheral vascular disease (PVD).

Common symptoms of diabetes include polyuria (frequent urination), polydipsia (increased thirst), polyphagia (increased hunger), fatigue, blurred vision, weight loss, poor wound healing, and recurrent infections. Diabetes occurs when the body either does not produce enough insulin or cannot effectively utilize it, leading to the accumulation of glucose in the bloodstream. In severe cases, excess glucose may spill into the urine, a condition historically referred to as "sweet urine." [2].

Globally, diabetes prevalence is increasing at an alarming rate. In India, the number of diabetic patients has risen significantly, from 31.7 million in 2000 to over 62 million in 2011, and is projected to reach nearly 70 million by 2025 [3]. This rise is attributed to rapid urbanization, lifestyle changes, and genetic predisposition. Additionally, factors such as increased body fat percentage, upper body adiposity, and insulin resistance further contribute to disease development.

Thus, diabetes mellitus is a progressive metabolic disorder that affects both physical and mental health, emphasizing the need for effective management strategies and innovative drug delivery systems for better patient compliance and therapeutic outcomes [4].

CLASSIFICATION OF DIABETES MELLITUS:

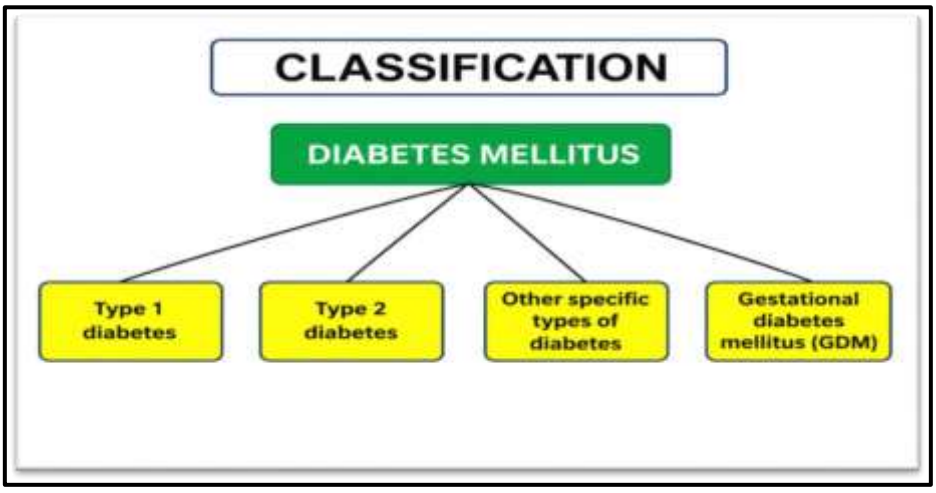


Fig 1: Classification of diabetes mellitus

1. Type 1 Diabetes Mellitus (Insulin-Dependent Diabetes Mellitus – IDDM).

Another name for type 1 diabetes is insulin-dependent diabetes mellitus (IDDM). About 5– 10% of all instances of diabetes are caused by it. This kind is an autoimmune condition when the body's immune system kills the pancreatic β-cells that produce insulin. High blood glucose levels come from the body producing little or no insulin. Although it can happen at any age, children and young adults are typically affected. Insulin replacement therapy is the primary form of treatment because insulin is not generated.

Insulin-dependent diabetes mellitus (IDDM) typically results from the destruction of the βcells of the predominant pancreatic islets of Langerhans, possibly due to an autoimmune process. This leads to an extremely low level of "insulin production" in vivo. Individuals experiencing these biological abnormalities may exhibit noticeable metabolic irregularities, which may eventually result in the development of diabetic β-ketoacidosis along with other acute diabetes symptoms. Insulin is the main therapeutic treatment for Type-I diabetes [5].

2. Type 2 Diabetes Mellitus (Non-Insulin Dependent Diabetes Mellitus – NIDDM).

Type 2 diabetes mellitus is the most common form of diabetes worldwide, accounting for about 90–95% of all cases. It is also known as Non-Insulin Dependent Diabetes Mellitus (NIDDM) or adult-onset diabetes. This condition mainly affects adults above 30 years of age, although it is now increasingly seen in obese children and adolescents.

Type 2 diabetes occurs due to insulin resistance, where the body does not respond properly to insulin, along with a gradual decrease in insulin production. As a result, glucose cannot enter the cells effectively, leading to increased blood sugar levels. The risk of developing this condition increases with age, excess body fat, and lack of physical activity.It is usually managed with oral hypoglycemic drugs that help improve insulin action and increase insulin secretion. If not properly controlled, Type 2 diabetes can lead to long-term complications affecting the blood vessels, kidneys, eyes, and nerves, which are major causes of morbidity and mortality [6].

3. Gestational Diabetes Mellitus (GDM).

High blood sugar levels during pregnancy are a sign of gestational diabetes mellitus (GDM), which is typically discovered in the second or third trimester. Insulin resistance is brought on by hormonal changes. GDM can also be used to identify women who have undiagnosed Type 2 diabetes or who infrequently develop Type 1 diabetes during pregnancy. In order to safeguard mother and child, management primarily consists of food control, appropriate nutrition supervision, and insulin therapy if necessary. GDM often goes away after delivery, but it raises the chance of getting Type 2 diabetes in the future. Due to exposure to elevated glucose levels during pregnancy, babies born to moms with GDM are also more likely to develop obesity and diabetes in the future [7].

4. Other Specific Types of Diabetes.

To put it simply, different varieties of diabetes are not the typical ones. They occur for certain causes, like:[8]

Genetic defects of β-cell function.

- Chromosome 20q, HNF-4α (MODY 1)
- Chromosome 7p, glucokinase (MODY 2)
- Chromosome 12q, HNF-1α (MODY 3)
- Chromosome 13q, insulin promoter factor (MODY 4)
- Chromosome 17q, HNF-1β (MODY 5)
- Chromosome 2q, neurogenic differentiation (MODY 6)
- Mitochondrial DNA

Genetic defects in insulin action.

- Type A insulin resistance
- Leprechaunism
- Rabson–Mendenhall syndrome
- Lipoatrophic diabetes

Diseases of exocrine pancreas.

- Pancreatitis
- Trauma / pancreatectomy
- Neoplasia
- Cystic fibrosis
- Hemochromatosis
- Fibro calculous pancreatopathy

Drug or chemical induced

- Vacor
- Nicotinic acid
- Glucocorticoids
- Thyroid hormone

- Diazoxide
- β-adrenergic agonists

ETYMOLOGY:

The term diabetes was first introduced by Aretaeus of Cappadocia (81–133 CE). It comes from the Greek word diabainein, which means "to pass through" or "siphon," referring to the excessive passage of urine.The word mellitus is derived from the Greek word meaning "sweet." This name was given because people with diabetes produce urine containing high levels of glucose, which made it attractive to insects like flies and ants.In ancient times, Chinese physicians identified diabetes by observing whether ants were drawn to a person's urine[9]. Similarly, in medieval Europe, doctors even tasted urine to detect sweetness. Later, in 1675, Thomas Willis added the term mellitus to describe the sweet nature of the urine and blood in diabetic patients (a feature also noted earlier by ancient Indian physicians).It is important to note that excessive urination can occur in several diseases, especially kidney disorders. Therefore, the term diabetes is used broadly, but the most common types are:

- Diabetes mellitus (sugar-related)
- Diabetes insipidus (not related to sugar

EPIDEMIOLOGY:

Diabetes mellitus is a global disease that affects people all over the world. The risk of developing diabetes is higher in: People with a family history of diabetes, Individuals above 45 years of age,People who are overweight or obese.Studies on identical twins show a very high genetic influence, with more than 94% chance (concordance) of both twins developing NIDDM (Type 2 diabetes)[10].

Additionally, diabetes is more common in:

- Children of diabetic parents.
- Siblings of affected individuals.
- People who are more than 20% above their ideal body weight have a higher risk of developing diabetes.

Other conditions that increase the risk include:

- Impaired glucose tolerance (prediabetes)
- Gestational diabetes
- Hypertension (high BP)
- Hyperlipidemia (high cholesterol levels)

PATHOPHYSIOLOGY

There exists a direct correlation between hyperglycemia and physiological reactions. When the brain detects hyperglycemia, nerve impulses are sent to the pancreas to lessen its effects.

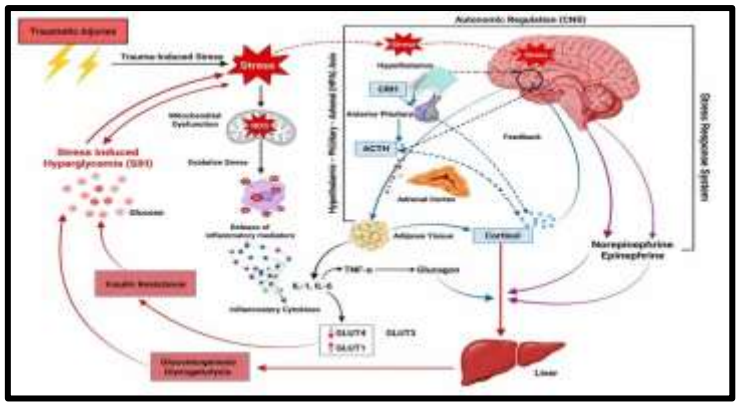


Fig 2: The physiological response to hyperglycemia

TYPE 1 DIABETES MELLITUS

The autoimmune decrease of insulin-producing cells in the pancreas caused by CD4+ and CD8+ T cells and macrophages infiltrating the islets is known as type 1 diabetes mellitus. Type 1 diabetes mellitus is classified as an autoimmune illness based on several characteristics: Pancreatic islets are infiltrated by immune-competent and accessory cells. The human leucocyte antigen and class II genes of the major histocompatibility complex are linked to the disease's susceptibility. There are autoantibodies specific to islets. The observed change in immune-regulation mediated by T cells, particularly in the CD4+ T cell compartment. Monokines and TH1 cells contribute to the illness process by helping to produce interleukins. The disease's reaction to immunotherapy. The afflicted individual frequently has other organ-specific auto-immune diseases. Most islet antibodies are directed against the pancreatic B cells' glutamic acid decarboxylase (GAD). due to a lack of insulin secretion brought on by the autoimmune death of the pancreatic beta cells, which causes metabolic disruption associated with type 1 diabetes mellitus. In addition to the loss of insulin secretion, the primary function of pancreatic alpha cells appears to be aberrant, resulting in an overabundance of glucagon secretion [11].

In healthy individuals, hyperglycemia reduces glucagon secretion; however, in individuals with type 1 diabetes mellitus, hyperglycemia does not inhibit glucagon secretion. As a result, the insulin deficit causes an incorrect increase in glucagon, which worsens metabolic abnormalities. Although insulin insufficiency is thought to be the main cause of type 1 diabetes mellitus, it has also been discovered that insulin administration is flawed. Uncontrolled lipolysis and an increase in free fatty acids in the plasma are the results of insulin insufficiency, which suppresses glucose metabolism, particularly in peripheral tissues like skeletal muscle.

As a result, this primarily hinders the proper utilization of glucose and insulin deficiency, as well as reducing their ability to express a number of genes that are important for responding to insulin normally. One such gene is glucokinase, which is only found in the liver and is primarily responsible for storing glucose as glycogen, which helps phosphorylate glucose to enter glycolysis and obtain more ATP. Additionally, it causes the adipose tissue's GLUT 4 class of glucose transporters to express poorly[12].

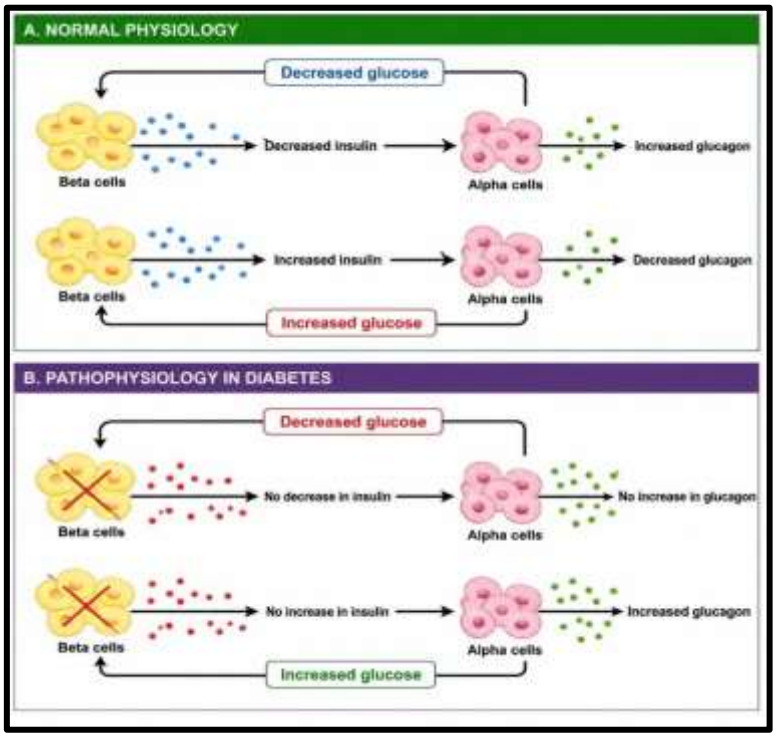


Fig: 3 In Figure 3A it shows the normal physiological effect of reduction in insulin linked with a low glucose concentration which leads to stimulation of alpha cell glucagon secretion. In Figure 3B presents the pathophysiological failure of beta cell, which leads to no decrease in insulin and no increase in alpha-cell glucagon secretion, in spite of the low glucose concentration.

TYPE 2 DIABETES MELLITUS:

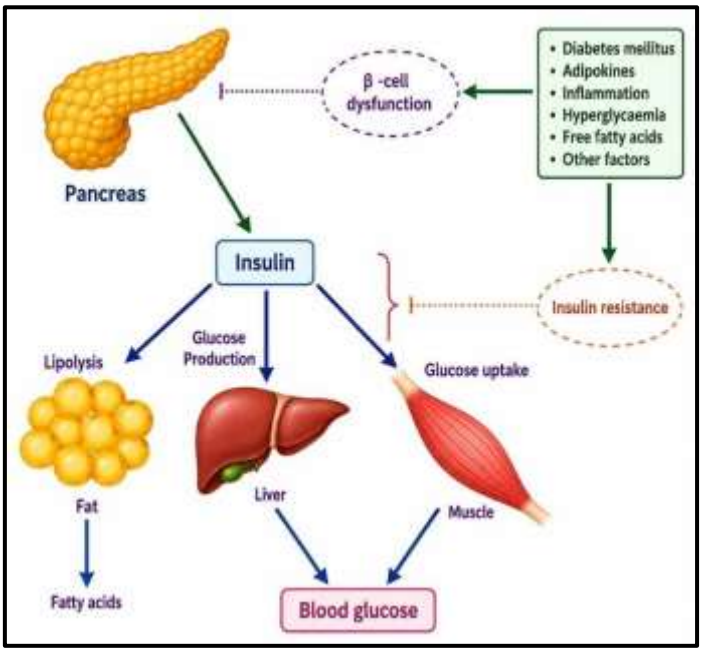


Fig 4: Pathophysiology of hyperglycemia and increased fatty acids in type 2 diabetes

These mechanisms are break down in type 2 diabetes, the main consequences in the pathology of type 2 diabetes are impaired insulin secretion via a dysfunction of the pancreatic beta cells, in addition, impairment of insulin action through insulin resistance. In cases where the insulin resistance dominates, the mass of beta cells been transformed and has the capability to increase the insulin supply, compensation for the excessive and 6 anomalous demand. In other words, the plasma insulin concentration been elevated in both fasting and feeding state[13].

RISK FACTORS:

Non-Modifiable Risk Factors (These cannot be changed)

Age: Getting older increases the risk of type 2 diabetes, especially after 45 years.

Genetics (Family history): If a close family member (parents or siblings) has diabetes, the chances of developing it are higher.

Ethnicity: Some populations such as African Americans, Hispanics, Native Americans, Asian Americans, and Pacific Islanders have a greater risk compared to others.

Gestational Diabetes: Women who had diabetes during pregnancy are more likely to develop type 2 diabetes later in life.

Polycystic Ovary Syndrome (PCOS): Women with PCOS are more prone to insulin resistance, increasing their diabetes risk.[14].

Modifiable Lifestyle Risk Factors (These can be controlled or prevented).

Obesity: Being overweight, especially having excess fat around the abdomen, strongly increases diabetes risk.

Sedentary Lifestyle: Lack of physical activity and long sitting hours reduce insulin sensitivity.

Unhealthy Diet: Eating too much processed food, sugar, and unhealthy fats while consuming fewer fruits, vegetables, and whole grains increases the risk.

Smoking: Smoking raises the chances of developing diabetes and its complications.

Sleep Problems: Poor sleep, short sleep duration, or sleep disorders like sleep apnea can increase diabetes risk [15]

Medical Conditions & Medications.

Cardiovascular Diseases: Conditions like high blood pressure, abnormal cholesterol levels, and heart disease are linked with a higher risk of diabetes.

Hormonal Disorders: Diseases such as Cushing's syndrome and acromegaly can increase blood glucose levels and diabetes risk.

Medications: Some drugs, including corticosteroids, antipsychotics, and certain antiretroviral medicines, may increase the risk of diabetes.a higher chance of getting diabetes. It is crucial to remember that these risk factors frequently interact with one another and might raise the chance of developing diabetes. Furthermore, the presence of certain risk factors and how they interact with genetic predisposition can affect an individual's vulnerability to diabetes. To lower the incidence and impact of diabetes, it is crucial to recognize and comprehend these risk factors in order to put into practice efficient preventive measures, lifestyle modifications, and focused screening initiatives [16].

DIAGNOSIS OF DIABETES MELLITUS:

The main method used to diagnose diabetes is measuring blood glucose levels. This test is also important for long-term monitoring and checking how well treatment is working [17].

Blood glucose can be measured using:

- Venous whole blood.
- Venous plasma.
- Capillary blood (finger prick).

Types of Blood Glucose Tests:

- Fasting Blood Glucose (FBG): Measured after at least 8 hours of fasting.
- Random Blood Glucose (RBG): Measured at any time of the day.
- Postprandial Blood Glucose (PPBG): Measured after meals.
- Oral Glucose Tolerance Test (OGTT): Blood glucose measured after giving 75 g of glucose.

Diagnostic Criteria (Any one confirms diabetes):

- Random plasma glucose ≥ 200 mg/dL (11.1 mmol/L) with symptoms of hyperglycemia.
- Fasting plasma glucose ≥ 126 mg/dL (7.0 mmol/L) on two different occasions.
- OGTT (2 hours) ≥ 200 mg/dL (11.1 mmol/L).
- HbA1c ≥ 6.5% (48 mmol/mol).

Screening for Diabetes:

Screening helps to detect diabetes early, even when no symptoms are present.

- Every 3 years: for individuals above 45 years.
- Every year: for people at high risk (any age).

Screening tests include:

- Fasting blood glucose.
- OGTT.
- HbA1c.

TREATMENT OF DIABETES MELLITUS:

The main goal of diabetes treatment is to improve quality of life and prevent complications.

1. Lifestyle Modification (Initial Step):

- Adoption of a healthy diet.
- Regular moderate physical activity (consistent exercise is important).
- Routine medical monitoring.

Insulin Therapy (Type 1 Diabetes):

Required in Type 1 diabetes due to lack of insulin production.

- Insulin is produced using recombinant DNA technology to match human insulin.
- Includes short-acting and long-acting insulin analogs.

Administered as:

- Multiple daily injections (before meals and at bedtime).
- Continuous delivery using an insulin pump.
- Treatment aims to mimic natural insulin secretion.

3. Oral Antidiabetic Drugs (Type 2 Diabetes):

- Common drug classes: Metformin (Biguanide), Sulfonylurea, Meglitinides Thiazolidinediones, Alpha-glucosidase inhibitors.
- Mechanisms of action: Reduce glucose production in the liver, Improve insulin sensitivity, Stimulate insulin secretion, Delay carbohydrate digestion and absorption.

Additional Benefits of Treatment:

- Helps in weight reduction.
- Improves lipid profile.
- Lowers risk of cardiovascular diseases.
- Reduces progression of diabetic kidney disease.
- Decreases hospitalization due to heart failure (with certain drugs like GLP-1 agonists and SGLT2 inhibitors) [18].

HERBAL TREATMENT:

For doctors, managing diabetes without adverse effects remains a significant issue. 450 of the 800 medicinal plants that are known to help with diabetes have been shown to have antidiabetic qualities. Of these, 109 plants have methods for treating diabetes that are fully understood. Heart disease, cancer, and diabetes are just a few of the conditions that have historically been treated with traditional medicinal plants. Ancient scriptures like the "Charaka Samhita" and "Susruta Samhita" describe diabetes and its symptoms, and there is a long tradition of employing botanicals to treat diabetes in nations like China and India.

Although synthetic medications are frequently used to treat diabetes, they frequently have adverse effects that include nausea, vomiting, digestive problems, dizziness, and even more serious reactions. Stomach problems, light-headedness, and even more serious reactions.

On the other hand, because they have fewer adverse effects, herbal medicines are typically regarded as a safer option. When synthetic medications fail to treat severe illnesses, herbal remedies—which are frequently accessible without a prescription—are utilized. Compared to synthetic medications, they may provide longer-lasting comfort, are natural, and typically have no harmful side effects.

Because herbal formulations contain natural ingredients such fruits, vegetables, and herbs, they are less likely to create damage. Additionally, they are frequently more economical and ecofriendlier than synthetic medications, which are produced chemically [19].

MEDICINAL PLANTS WITH POTENTIAL ANTIDIABETIC EFFECT

Table 1: Plants contain Anti- Diabetic Propertie:[20]

PLANT PROFILE	PLANT DETAILS
 ***Phyllanthus Emblica***	**Scientific Classification** Scientific Name: *Phyllanthus Emblica* Common Names: Amla, Indian Gooseberry Family: Phyllanthaceae **Geographical Distribution** Native to India, Also found in China, Sri Lanka, Southeast Asia and Grows in tropical and subtropical regions **Plant Description** Small to medium-sized deciduous tree: Height: 8–18 meters Leaves: Small, green, closely arranged Fruit: Round, light green/yellow, sour taste **Phytochemical Constituents** Tannins: Emblicanin A & B Phenolic compounds: Gallic acid, Ellagic acid Flavonoids: Quercetin, Kaempferol Vitamin C (Ascorbic acid),Amino acids & minerals **Pharmacological Activities** ➢ Antidiabetic ➢ Antioxidant ➢ Anti-inflammatory ➢ Hepatoprotective ➢ Immunomodulatory **Traditional Uses** ➢ Used in Ayurveda, Siddha, Unani ➢ Treatment of: Diabetes, Digestive disorders, Haircare, Immunity boosting.
	Scientific Classification Scientific Name: *Momordica charantia* Common Names: Bitter gourd, Karela, Bitter melon

<table>
<tr>
<td>

Momordica charantia</td>
<td>Family: Cucurbitaceae
Order: Cucurbitales
Geographical Distribution
Widely grown in India, China, Africa, Southeast Asia. Thrives in tropical and subtropical climates.

Plant Description
Climbing vine with tendrils
Leaves: Deeply lobed, green
Fruit: Elongated, green, bitter taste with rough surface
Seeds: Flat, brownish
Phytochemical Constituents
➢ Charantin
➢ Polypeptide-p (plant insulin)
➢ Vicine
➢ Momordicin
➢ Alkaloids, flavonoids, saponins
Pharmacological Activity
Antidiabetic, antioxidant, anti-inflammatory, antimicrobial, anticancer
Traditional Uses
Diabetes, digestion, skin diseases, liver disorders, wound healing.</td>
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Syzygium cumini</td>
<td>Scientific Classification
Scientific Name: Syzygium cumini
Common Names: Jamun, Indian Blackberry,
Black Plum
Family: Myrtaceae
Order: Myrtales
Geographical Distribution
Native to India and Southeast Asia and Found in Sri Lanka, Nepal, Bangladesh. Grows in tropical and subtropical regions
Plant Description
➢ Large evergreen tree (10–30 meters tall)
➢ Leaves: Opposite, glossy, dark green
➢ Flowers: Small, white to greenish
➢ Fruit: Oval, deep purple to black, sweet and astringent
➢ Seeds: Single, greenish, medicinally active
Phytochemical Constituents
➢ Alkaloids: Jamboline (Jambosine)
➢ Phenolics: Gallic acid, Ellagic acid
➢ Flavonoids</td>
</tr>
</table>

	➢ Anthocyanins (responsible for purple color) ➢ Tannins & Glycosides **Pharmacological Activity** Antidiabetic, antioxidant, antiinflammatory, antimicrobial, hepatoprotective **Traditional Uses** Diabetes, diarrhea, digestion, oral care, wound healing
 ***Trigonella foenum-graecum***	**Scientific Classification** Scientific Name: *Trigonella foenum-graecum* Family: Fabaceae Genus: Trigonella Species: foenum-graecum **Common Names** English: Fenugreek Tamil: Venthayam Hindi: Methi **Morphological Features** Plant Type: Annual herb Height: 30–60 cm Leaves: Trifoliate (three small leaflets), green Flowers: Small, yellowish-white Fruits (Pods): Long, slender pods containing seeds Seeds: Hard, yellowish-brown, aromatic and bitter **Phytochemical Constituents** ➢ Alkaloids: Trigonelline ➢ Amino acid: 4-hydroxyisoleucine ➢ Saponins: Diosgenin ➢ Flavonoids ➢ Fiber and mucilage **Pharmacological Activities** Antidiabetic,Hypocholesterolemic,Antiinflammatory, Antioxidant, Antimicrobial **Traditional Uses** Used for weight management ,Helps in lactation (galactagogue.
	Scientific Classification Scientific Name: *Phaseolus vulgaris* Family: Fabaceae Genus: Phaseolus Species: vulgaris

 ***Phaseolus vulgaris***	**Common Names** English: Common Bean / Green Bean / Kidney Bean Hindi: Rajma / Sem Tamil: Mochai / Beans **Morphological Features** Plant Type: Annual herb (bush or climbing vine) Height: 30 cm – 3 meters (depending on type) Stem: Soft, herbaceous; climbing or erect Leaves: Trifoliate (3 leaflets), green Flowers: Small, white, pink, or purple Fruit: Long pods containing seeds (beans) Seeds: Kidney-shaped, various colors **Phytochemical Constituents** ➢ Proteins ➢ Carbohydrates ➢ Dietary fiber ➢ Flavonoids **Pharmacological Activities** Antioxidant, Antidiabetic, Cholesterol-lowering, Digestive support **Traditional Uses** Widely used as food (vegetable & pulses),Rich source of protein and nutrients, Helps in weight management, Supports heart health
	**Scientific Classification** Scientific Name: *Pterocarpus marsupium* Family: Fabaceae Genus: Pterocarpus Species: marsupium **Common Names** English: Indian Kino Tree / Malabar Kino Hindi: Vijaysar Tamil: Vengai **Morphological Features** Plant Type: Large deciduous tree Height: 15–30 meters Stem: Thick, rough bark with reddish exudate

Pterocarpus marsupium	(kino gum) Leaves: Compound, pinnate leaves Flowers: Yellow, small, in clusters Fruit: Flat, winged pods Wood: Hard, reddish heartwood **Phytochemical Constituents** ➢ Pterostilbene ➢ Flavonoids ➢ Tannins ➢ Saponins ➢ Phenolic compounds **Pharmacological Activities** Antidiabetic, Antioxidant, Anti-inflammatory, Antimicrobial **Traditional Uses** Wood is used to make Vijaysar tumblers for diabetes control. Bark decoction used for blood sugar regulation and Helps in wound healing. Used in Ayurvedic medicine for various disorders
 ***Annona squamosa***	**Scientific Classification** Scientific Name: *Annona squamosa* Family: Annonaceae Genus: Annona Species: squamosa **Common Names** English: Custard Apple / Sugar Apple Hindi: Sitaphal Tamil: Seetha Pazham **Morphological Features** Plant Type: Small deciduous tree / shrub Height: 3–8 meters Stem: Woody, branched Leaves: Simple, thin, green, oblong Flowers: Greenish-yellow, fragrant Fruit: Round, scaly (segmented) with sweet creamy pulp Seeds: Black, shiny, numerous **Phytochemical Constituents** ➢ Alkaloids ➢ Flavonoids ➢ Acetogenins ➢ Glycosides **Pharmacological Activities**

	Antioxidant, Antimicrobial, Antidiabetic, Antiinflammatory **Traditional Uses** ➢ Fruit used as nutritious food rich in sugars and vitamins ➢ Leaves used in wound healing and herbal remedies ➢ Seeds sometimes used as insecticide ➢ (external use only) ➢ Helps in digestive health
 ***Costus igneus***	**Scientific Classification** Scientific Name: *Costus igneus* Family: Costaceae Genus: Costus Species: igneus **Common Names** English: Insulin Plant Tamil: Insulin Cheddi Hindi: Insulin Plant **Morphological Features** Plant Type: Perennial herb Height: 1–2 meters Stem: Spiral, fleshy stem Leaves: Large, green, arranged spirally Flowers: Bright orange, cone-like clusters Roots: Fibrous root system **Phytochemical Constituents** ➢ Flavonoids ➢ Terpenoids ➢ Alkaloids ➢ Glycosides ➢ Phenolic compounds **Pharmacological Activities** Antidiabetic, Antioxidant, Anti-inflammatory, Antimicrobial **Traditional Uses** Leaves are consumed to control blood sugar levels, Used in diabetes management, Helps improve metabolism, Used in herbal remedies

ORAL DISPERSIBEL FLIM :

Orally disintegrating films (ODFs) are one of these that has become very significant. ODFs are applied to the tongue as thin films made of polymers. They absorb saliva fast, dissolve, and release the medication without the need for water.

New drug delivery systems have been created using contemporary technologies to increase patient compliance. Bioadhesive dose forms that adhere to the mucosal surface include pills, gels, and patches [21]. It is simple, safe, non-invasive, and well-liked by patients, the oral route is the most often utilized mode of medication delivery. Children, the elderly, and patients who have trouble swallowing tablets or capsules will find it particularly useful.



Fig 5: Oral Dispersibel Flim

Properties of oral dispersible film

An ideal orodispersible film should possess the following properties:

- Thin, flexible, and uniform in appearance
- Rapid disintegration in the oral cavity
- Good mechanical strength and folding endurance
- Pleasant taste and mouthfeel
- Uniform drug distribution
- Adequate stability during [22]

Types of Oral Dispersible Films:

1. Based on Dissolution:

Fast dissolving films

- Disintegrate within < 30 second
- Used for quick action (e.g., antiemetics)

2. Based on Structure / Layering:

- Monolayer films
- Bilayer films
- Multilayer films

3. Based on Nature of Drug

- Synthetic drug films
- Natural drug films
- Nutraceutical / vitamin films

3. Based on Function / Release (Additional classification)

- Flash release films
- Mucoadhesive melt-away films
- Mucoadhesive sustained release films

METHODS OF ORAL DISPERSIBLE FLIM:

1. Solvent Casting Method for Preparation of Oral Dispersible Films (ODFs):

The solvent casting method is the most widely used and preferred technique for the preparation of oral dispersible films. It involves the preparation of a homogeneous solution of polymer, drug, and excipients, followed by casting and drying to form a thin film. This method is especially suitable for heat-sensitive drugs and is commonly used in laboratory and industrial applications.The method is based on the formation of a uniform solution containing all formulation components. Upon evaporation of the solvent, a thin, flexible, and uniform film is formed. The uniform distribution of drug within the polymer matrix ensures consistent drug delivery [23].

Materials Required

- **Polymer**: HPMC E5 (film-forming agent)
- **Drug/Herbal Extract**: Polyherbal extract (e.g., fenugreek, bitter gourd)
- **Plasticizer**: Glycerol / PEG (improves flexibility)
- **Sweetening agent**: Stevia
- **Flavoring agent**: Peppermint oil
- **Saliva stimulating agent**: Citric acid
- **Solvent**: Distilled water / ethanol

Procedure

1. **Preparation of Polymer Solution**: Accurately weigh the required amount of polymer (HPMC E5).and Dissolve in distilled water with continuous stirring. And Allow it to hydrate completely to form a clear solution.
2. **Preparation of Drug Solution**: Dissolve the drug or herbal extract in a suitable solvent. And Ensure complete dissolution for uniform distribution.
3. **Addition of Excipients**: Add plasticizer (glycerol) to improve flexibility and Add sweetener (stevia) and flavor (peppermint oil) for palatability. And Add citric acid to stimulate saliva and enhance disintegration.
4. **Mixing**: Add drug solution to polymer solution slowly. And Stir continuously to obtain a homogeneous mixture. And Remove air bubbles by keeping the solution undisturbed or by sonication.
5. **Casting of Film**: Pour the prepared solution into a petri dish or glass mold. And Spread uniformly to maintain consistent thickness.
6. **Drying**: Allow the film to dry at room temperature or in a hot air oven (40–50°C). and Ensure slow and uniform drying to avoid cracks [24].
7. **Film Removal and Cutting**: Carefully peel the dried film from the mold. And Cut into uniform strips (e.g., 2×2 cm strips).
8. **Packaging**: Store films in moisture-resistant packaging (aluminum foil pouch).

Advantages

- Simple and cost-effective method
- Uniform drug distribution
- Suitable for heat-sensitive drugs
- Good film clarity and smoothness
- Easy to scale up

Disadvantages

- Time-consuming drying process
- Risk of air bubble formation
- Residual solvent may remain if not dried properly
- Requires controlled environmental conditions

2. Hot Melt Extrusion Method for Preparation of Oral Dispersible Films (ODFs):

Hot melt extrusion (HME) is an advanced and solvent-free technique used in the preparation of oral dispersible films. In this method, the drug is incorporated into a polymer matrix by applying heat and pressure, resulting in a uniform and continuous film. It is widely used in industrial-scale production due to its efficiency and reproducibility. The method is based on melting and mixing of drug and polymer under controlled temperature and pressure. The molten mass is then forced through an extruder to form a thin film. Upon cooling, the film solidifies with uniform drug distribution [25].

Materials Required

- **Polymer**: Thermoplastic polymer (e.g., HPMC, PVA, PEG-based polymers)
- **Drug/Active ingredient**
- **Plasticizer**: PEG, glycerol (reduces brittleness)
- **Flavoring and sweetening agents** (optional)

Equipment

- Hot melt extruder (single screw or twin screw)
- Feeding hopper
- Die (film shaping unit)
- Cooling system

Procedure

1. **Weighing and Mixing**: Accurately weigh drug, polymer, and plasticizer and Mix uniformly in dry form
2. **Feeding into Extruder**: Transfer the mixture into the hopper of the extruder
3. **Melting and Mixing**: Heat is applied (usually 60–150°C depending on polymer) and Material melts and mixes uniformly due to screw rotation
4. **Extrusion**: The molten mass is forced through a flat die and Forms a continuous thin film
5. **Cooling**: Film is cooled using air or cooling rollers and Solidification occurs
6. **Cutting and Packaging**: Film is cut into desired (e.g., 2×2 cm) and Packed in moisture-proof packaging [26].

Advantages

- Solvent-free process (eco-friendly)
- Faster production (no drying step)
- Uniform drug distribution
- Suitable for large-scale manufacturing
- Improved bioavailability (due to solid dispersion formation)

Disadvantages

- Not suitable for heat-sensitive drugs (herbal extracts may degrade)
- High initial equipment cost
- Requires skilled operation

- Limited choice of polymers (must be thermoplastic)

Applications: Used in pharmaceutical industries for:

- Fast dissolving oral films
- Taste masking
- Controlled release formulations
- Improving solubility of poorly soluble drug

3. Semi-Solid Casting Method for Preparation of Oral Dispersible Films (ODFs):

The semi-solid casting method is a technique used for the preparation of oral dispersible films in which a viscous gel or semi-solid mass is formed and then cast into thin films. This method is particularly useful when higher drug loading is required and when improved mechanical strength of the film is needed.This method is based on the preparation of a homogeneous, viscous, gel-like mass by mixing water-soluble and acid-insoluble polymers. The formed semi-solid mass is then cast into films and dried to obtain a thin, flexible film [28].

Materials Required

- Water-soluble polymer: HPMC, PVA
- Acid-insoluble polymer: Cellulose acetate phthalate (CAP), cellulose acetate butyrate
- Plasticizer: PEG, glycerol
- Drug/Active ingredient
- Solvent: Water or suitable solvent

Procedure

1. Preparation of Water-Soluble Polymer Solution: Dissolve water-soluble polymer
2. (e.g., HPMC) in distilled water and Allow proper hydration to form a clear solution
3. Preparation of Acid-Insoluble Polymer Solution: Dissolve acid-insoluble polymer in suitable solvent
4. Mixing of Polymer Solutions: Combine both polymer solutions in a specific ratio and Stir continuously to obtain a uniform mixture
5. Addition of Plasticizer and Drug: Add plasticizer (PEG/glycerol) to improve flexibility and Add drug and mix thoroughly
6. Formation of Semi-Solid Mass: The mixture becomes viscous and gel-like
7. Casting: Spread the semi-solid mass onto a casting surface or mold and Maintain uniform thickness
8. Drying: Dry at controlled temperature (room temperature or oven) and Ensure proper solvent evaporation
9. Cutting and Packaging: Remove dried film carefully and Cut into desired size and store properly.

ORAL DISSOLVING FILM EVALUATION:

Thickness test:

The average mean of a film's thickness determines the digital micrometer. Thickness uniformity is crucial to ascertain that is proportionate to the precision of the film dose when a film's weight fluctuation is tripled by film cutting and weight measurement. The film's medication's portion flawlessness is indicated by thickness A micrometer screw or balanced advanced Vernier caliper is used to compute it at five, not at all like primary areas, and the mean value, which is represented by the final film thickness, is measured. The film's width will range from 5 to 200 µm.Using an adjusted advanced micrometer NIKON Digi-Micro screw measure, precise film thickness estimates were made. The mean normal (n = 3) was then calculated. By cutting the film into 1 x 1 cm pieces, the consistency of film weight is ascertained in triplicate. The

film's thickness is estimated at five points, such as from the center to all four corners. Additionally, the mean thickness is calculated. Determining the consistency [29].

Tensile strength:

More stress when the film breaks is the definition of the tensile function. In essence, films' mechanical strength is experienced. More tension is defined as the strength of the traction when the film is halted. Films' technical prowess is essentially achieved: Tensile resistance 1/4 load at failure = strip thickness × strip width × 100.

Folding endurance:

Another way to gauge a film's mechanical qualities is by its pliability. It is calculated by repeatedly folding the film for the same reason until it breaks. While the film continues, stamina is depleted in a variety of ways. A film's mechanical strength is shown by its greater pliable endurance . Film pliability and mechanical strength are directly correlated. Because plastering concentration controls mechanical strength, it is evident that the plaster focus has an indirect impact on folding strength qualities [30].

Transparency:

A strip's transparency is adjusted using a UV specimen trophotometer. The purpose of this test is to evaluate the formulation's appearance. The film sample is placed within the cell photometer and deals with rectangular shapes. At a wavelength of 600 nm, the film coefficient is displayed. The following is the decisive transparency equation: Transparency ¼ ðlog T600 =b ¼ —.c T600 = coefficient at 600 nm, where b is the film thickness (mm) and c is the concentration.

Disintegration time:

During the crucial phase of film breakdown, the disintegration tools specified in official pharmacopoeias are utilized. Due to the formulation's five to thirty-year duration, the breakdown typically occurs throughout the filmmaking process . This is mainly tested using the USP disintegration systems. For the definitive breakdown of oral fast disintegrating films, there are no clear guidelines available[31]

CONCLUSION

Polyherbal oral dispersible films represent a promising and innovative approach for diabetes management. They combine the pharmacological advantages of medicinal plants with the convenience of a fast-dissolving drug delivery system, improving patient compliance and therapeutic effectiveness. The use of bioactive herbal ingredients may help reduce blood glucose levels while minimizing adverse effects. Although current findings are encouraging, further preclinical and clinical studies are necessary to establish their long-term safety, efficacy, and quality. With continued research, polyherbal ODFs may emerge as an effective alternative or complementary therapy for the management of diabetes mellitus.

DISCUSSION

Polyherbal oral dispersible films combine the therapeutic benefits of medicinal plants with advanced drug delivery technology. The synergistic action of multiple herbal extracts may provide better glycemic control while reducing the risk of adverse effects associated with synthetic antidiabetic drugs. ODFs improve patient compliance because they dissolve rapidly in the oral cavity without water and are easy to administer. Herbal constituents with antioxidant and insulin-sensitizing properties may further enhance therapeutic efficacy. However, challenges such as standardization of herbal extracts, dose uniformity, stability, and large-scale manufacturing must be addressed through further research and clinical evaluation before widespread clinical use.

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