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Innovative Formulation Development and In-Vitro Evaluation of Instant Disintegrating Tablets of Sitagliptin Phosphate Using a Natural Superdisintegrant

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ABSTRACT

Instant disintegrating tablets (IDTs) have emerged as a promising oral drug delivery system to enhance patient compliance, particularly in pediatric, geriatric, and dysphagic populations. The present research focuses on the formulation and in-vitro evaluation of instant disintegrating tablets of Sitagliptin phosphate, an oral hypoglycemic agent used in the management of type 2 diabetes mellitus, employing Plantago ovata mucilage as a natural superdisintegrant. Tablets were prepared by the direct compression method and evaluated for pre-compression and post-compression parameters including flow properties, hardness, friability, wetting time, drug content, in-vitro disintegration time, and dissolution behavior. The developed formulations exhibited rapid disintegration, satisfactory mechanical strength, and enhanced drug release profiles. The study demonstrates that Plantago ovata mucilage is an effective, economical, and biocompatible natural superdisintegrant for the development of instant disintegrating tablets of Sitagliptin phosphate, offering improved patient compliance and therapeutic performance.

KEYWORDS: *Instant disintegrating tablets, Sitagliptin phosphate, Plantago ovata, natural superdisintegrant, type 2 diabetes mellitus.*

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1. INTRODUCTION

Oral drug delivery continues to be the most widely utilized and preferred route of administration due to its convenience, safety, cost-effectiveness, and high patient compliance. Approximately 50–60% of all pharmaceutical dosage forms available in the market are administered orally, highlighting its dominance in drug therapy [1]. Solid oral dosage forms such as tablets and capsules are especially favored because they offer precise dosing, chemical and physical stability, ease of handling, and suitability for large-scale manufacturing [2]. Despite these advantages, conventional solid dosage forms pose significant challenges for specific patient populations, particularly those experiencing difficulty in swallowing (dysphagia), leading to reduced compliance and compromised therapeutic outcomes [3].

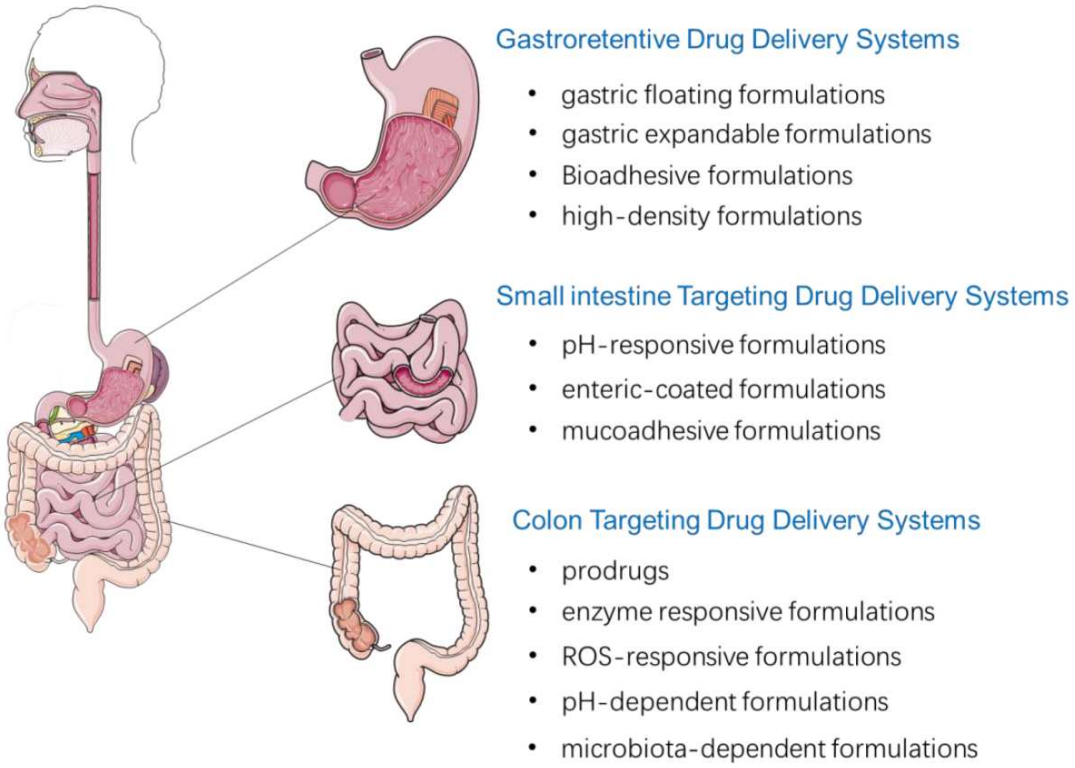

Figure 1. Schematic representation of oral drug delivery as the most preferred route of administration due to convenience, safety, cost-effectiveness, and high patient compliance compared to other routes of drug administration.

Dysphagia is commonly observed in pediatric and geriatric patients, as well as in individuals suffering from neurological disorders, psychiatric conditions, motion sickness, nausea, and during episodes of unconsciousness or bedridden states [4]. In such cases, administration of conventional tablets and capsules becomes problematic, often resulting in skipped doses or improper intake of medication. These limitations have driven the pharmaceutical industry toward the development of novel oral drug delivery systems that can overcome swallowing difficulties while maintaining the benefits of solid dosage forms [5].

Instant disintegrating tablets (IDTs), also referred to as fast dissolving tablets or orally disintegrating tablets, represent a significant advancement in oral drug delivery technology. These tablets are designed to disintegrate rapidly within the oral cavity, typically within 60 seconds, without the need for water [6]. Upon placement on the tongue, IDTs interact with saliva and undergo rapid disintegration, releasing the active pharmaceutical ingredient (API), which is subsequently swallowed or absorbed through the oral mucosa [7]. This rapid disintegration leads to faster drug dissolution, enhanced bioavailability, and quicker onset of therapeutic action compared to conventional tablets [8].

One of the key advantages of IDTs is their ability to partially bypass first-pass hepatic metabolism through pre-gastric absorption, particularly for drugs that are absorbed via the buccal or sublingual mucosa [9]. This characteristic makes IDTs especially suitable for drugs requiring rapid therapeutic action or those with extensive first-pass metabolism. Additionally, IDTs provide improved safety by reducing the risk of choking and suffocation, particularly in pediatric and geriatric populations [10].

The formulation of IDTs requires careful consideration of excipients, especially superdisintegrants, which play a crucial role in ensuring rapid tablet disintegration. Superdisintegrants facilitate the breakup of the tablet matrix upon contact with saliva through mechanisms such as swelling, wicking, and deformation recovery [11]. Commonly used synthetic superdisintegrants include croscarmellose sodium, sodium starch glycolate, and crospovidone. Although effective, these synthetic excipients are associated with higher costs, potential toxicity concerns, and limited biodegradability [12].

In recent years, there has been growing interest in the use of natural superdisintegrants as alternatives to synthetic materials. Natural polymers offer several advantages, including biocompatibility, biodegradability, low toxicity, easy availability, cost-effectiveness, and better patient acceptability [13]. Among various natural superdisintegrants, *Plantago ovata* mucilage has emerged as a promising excipient due to its excellent swelling

index and high water absorption capacity [14]. The mucilage present in the seed coat of *Plantago ovata* consists mainly of polysaccharides that rapidly hydrate in the presence of moisture, making it highly suitable for fast disintegration of tablets [15].

Sitagliptin phosphate is a widely prescribed oral hypoglycemic agent belonging to the dipeptidyl peptidase-4 (DPP-4) inhibitor class, used in the management of type 2 diabetes mellitus [16]. Type 2 diabetes mellitus is a chronic metabolic disorder characterized by insulin resistance and impaired insulin secretion, leading to persistent hyperglycemia and long-term complications affecting the cardiovascular, nervous, renal, and visual systems [17]. Effective glycemic control is essential for preventing disease progression and associated complications. Although Sitagliptin exhibits good oral bioavailability, conventional tablets may not provide optimal patient compliance, particularly among elderly diabetic patients who often experience dysphagia and polypharmacy [18].

Considering the increasing prevalence of type 2 diabetes mellitus and the need for patient-friendly dosage forms, the development of instant disintegrating tablets of Sitagliptin phosphate using a natural superdisintegrant such as *Plantago ovata* mucilage represents a rational and innovative pharmaceutical approach. Such a formulation is expected to enhance patient compliance, provide rapid onset of action, improve bioavailability, and align with current trends toward sustainable and natural pharmaceutical excipients [19–21].

2. Role of Superdisintegrants in Instant Disintegrating Tablets

Superdisintegrants are one of the most critical excipients employed in the formulation of instant disintegrating tablets (IDTs), as they are primarily responsible for the rapid breakup of the tablet matrix upon contact with saliva. The performance of an IDT largely depends on the type, concentration, and mechanism of action of the superdisintegrant incorporated into the formulation [10]. Without an effective superdisintegrant, the tablet fails to disintegrate rapidly in the oral cavity, thereby negating the fundamental purpose of an instant disintegrating dosage form [11].

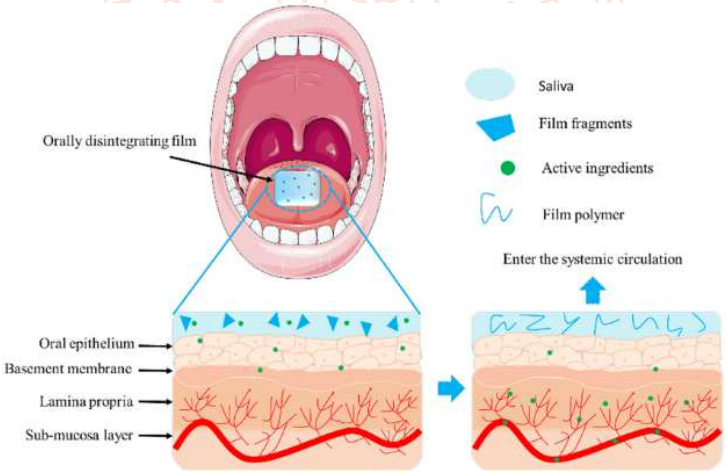

Figure 2. Mechanism of instant disintegrating tablets (IDTs) showing rapid disintegration in the oral cavity upon contact with saliva, leading to quick drug release without the need for water.

Superdisintegrants are defined as substances that facilitate tablet disintegration at low concentrations by promoting the penetration of saliva into the tablet matrix and causing the tablet to break apart into smaller fragments, which then dissolve rapidly [12]. In IDTs, the disintegration process must be extremely fast—typically within seconds—requiring excipients with high swelling capacity, rapid hydration, and efficient water uptake properties [13].

2.1. Mechanism of Action of Superdisintegrants

The disintegration of tablets by superdisintegrants occurs through several well-established mechanisms, which may act independently or synergistically depending on the nature of the polymer and formulation composition.

2.1.1. Swelling Mechanism

Swelling is the most widely recognized mechanism of action for superdisintegrants. Upon contact with saliva, the superdisintegrant absorbs water and swells, generating internal pressure within the tablet matrix. This pressure overcomes the mechanical strength of the tablet, leading to rapid disintegration [14]. Superdisintegrants exhibiting high swelling index are particularly effective in IDTs, as minimal moisture is sufficient to initiate rapid tablet breakup [15].

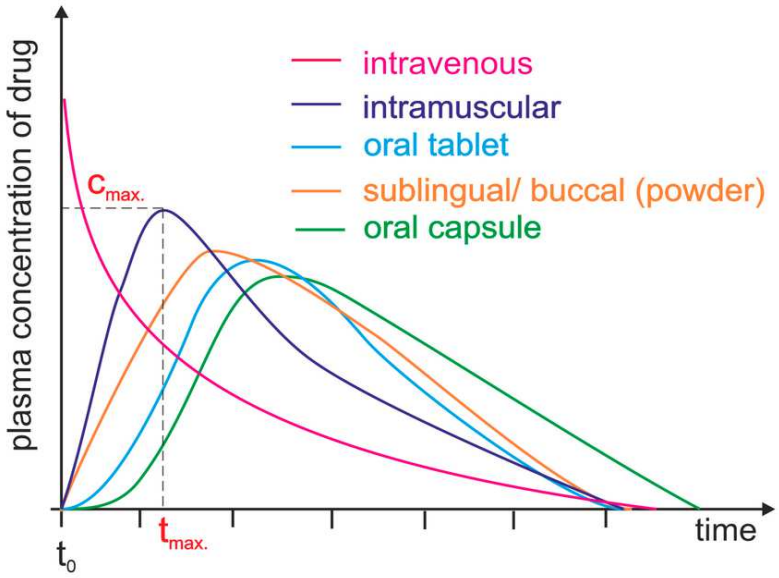

Figure 3: Comparative plasma concentration–time profile illustrating faster onset of action and improved bioavailability of instant disintegrating tablets compared to conventional tablets.

2.1.2. Wicking (Capillary Action)

In the wicking mechanism, the superdisintegrant draws saliva into the tablet through capillary action. This penetration of liquid reduces inter-particulate bonding forces and weakens the tablet structure, resulting in disintegration [16]. Superdisintegrants with porous morphology and high surface area are especially effective through this mechanism.

2.1.3. Deformation Recovery

During tablet compression, certain superdisintegrants undergo deformation. Upon exposure to saliva, these materials recover their original shape, generating stress within the tablet matrix that causes disintegration [17]. This mechanism is particularly relevant for superdisintegrants that exhibit elastic deformation during compression.

2.1.4. Combination of Mechanisms

In most practical formulations, disintegration occurs due to a combination of swelling, wicking, and deformation recovery rather than a single mechanism. The efficiency of disintegration is therefore influenced by formulation variables such as compression force, tablet porosity, and excipient compatibility [18].

2.2. Synthetic Superdisintegrants

Commonly used synthetic superdisintegrants include croscarmellose sodium, sodium starch glycolate, and crospovidone. These materials are effective at low concentrations (typically 2–8% w/w) and provide rapid disintegration [19]. However, synthetic superdisintegrants have several limitations, including higher cost, non-renewable origin, potential toxicity upon long-term use, and environmental concerns related to biodegradability [20].

Furthermore, patient preference is increasingly shifting toward formulations containing natural and plant-derived excipients, especially in chronic therapies such as diabetes management, where long-term administration is required [21].

2.3. Natural Superdisintegrants: A Pharmaceutical Perspective

Natural superdisintegrants have gained significant attention in recent years due to their numerous advantages over synthetic materials. These include biocompatibility, biodegradability, non-toxicity, ease of availability, cost-effectiveness, and eco-friendly nature [13]. Natural polymers also tend to be better accepted by patients, particularly in pediatric and geriatric populations.

Several natural materials such as *Plantago ovata* mucilage, cassia tora polysaccharide, hibiscus mucilage, and guar gum have been successfully explored as superdisintegrants in IDTs [14–19]. Studies have demonstrated that natural superdisintegrants can provide disintegration times comparable to or even better than synthetic counterparts when used at optimized concentrations [18].

2.4. *Plantago ovata* Mucilage as a Natural Superdisintegrant

Plantago ovata (Isabgol) mucilage is derived from the seed coat of the plant and is rich in hydrophilic polysaccharides. The mucilage exhibits excellent swelling properties and high water absorption capacity, which are essential characteristics for a superdisintegrant used in IDTs [18].

When incorporated into tablet formulations, *Plantago ovata* mucilage rapidly hydrates upon contact with

saliva, leading to significant swelling and fast tablet disintegration. The presence of both cold- and hot-water soluble polysaccharide fractions enhances its hydration efficiency, making it particularly suitable for oral disintegrating formulations [15].

In addition to its pharmaceutical functionality, *Plantago ovata* possesses intrinsic pharmacological benefits such as antidiabetic, hypolipidemic, and gastrointestinal protective effects, which further support its selection as an excipient in antidiabetic formulations [19]. Previous studies have demonstrated that tablets formulated using *Plantago ovata* mucilage exhibit shorter disintegration times, improved dissolution profiles, and acceptable mechanical strength [16–18].

2.5. Significance of Superdisintegrants in IDT Performance

The choice of superdisintegrant directly influences critical quality attributes of instant disintegrating tablets, including disintegration time, dissolution rate, mouthfeel, and patient acceptability. An ideal superdisintegrant should provide rapid disintegration without compromising tablet hardness, friability, or drug content uniformity [10].

In the present research, the use of *Plantago ovata* mucilage as a natural superdisintegrant is expected to enhance the performance of Sitagliptin phosphate IDTs by ensuring rapid tablet disintegration, improved dissolution, and better patient compliance, particularly in elderly diabetic patients with swallowing difficulties [17].

3. MATERIALS AND METHODS

3.1. Materials

Sitagliptin phosphate was used as the active pharmaceutical ingredient (API) for the formulation of instant disintegrating tablets. *Plantago ovata* seeds were procured from a certified herbal supplier and authenticated before use for extraction of mucilage as a natural superdisintegrant. Microcrystalline cellulose (MCC) was employed as a directly compressible diluent and binder. Mannitol was used as a filler and mouthfeel-enhancing agent. Magnesium stearate and talc were used as lubricant and glidant, respectively. All chemicals and reagents used were of analytical grade and used without further purification.

3.2. Extraction of *Plantago ovata* Mucilage

The mucilage from *Plantago ovata* seeds was extracted using a hydration–precipitation method.

Cleaned and dried *Plantago ovata* seeds were soaked in distilled water for 24 hours to allow complete hydration of the mucilaginous layer. The soaked seeds were then boiled for 1 hour with continuous stirring to facilitate release of mucilage. The resulting viscous mass was filtered through a muslin cloth to separate the seed residue.

The filtrate was precipitated by adding acetone in a ratio of 1:2 (filtrate:acetone) under continuous stirring. The precipitated mucilage was separated, dried in a hot air oven at 40–45 °C until constant weight, powdered, passed through sieve no. 80, and stored in a desiccator until further use.

3.3. Preformulation Studies

Preformulation studies were carried out to characterize Sitagliptin phosphate and to ensure its suitability for formulation.

3.3.1. Physical Appearance

The drug was examined visually for color, odor, and physical state to confirm purity and uniformity.

3.3.2. Melting Point Determination

The melting point of Sitagliptin phosphate was determined using the capillary tube method. A small quantity of drug was placed in a sealed capillary tube and heated gradually. The temperature range at which the drug melted was recorded.

3.3.3. Solubility Studies

Solubility of Sitagliptin phosphate was determined in distilled water, phosphate buffer pH 6.8, and methanol. Excess drug was added to each solvent, shaken for 24 hours at room temperature, filtered, and analyzed spectrophotometrically.

3.3.4. Determination of λmax

The maximum wavelength of absorption (λmax) of Sitagliptin phosphate was determined using a UV-Visible spectrophotometer. A suitably diluted drug solution was scanned in the range of 200–400 nm using phosphate buffer pH 6.8 as blank.

3.3.5. FT-IR Compatibility Studies

Fourier Transform Infrared (FT-IR) spectroscopy was used to assess drug–excipient compatibility. FT-IR spectra of pure Sitagliptin phosphate, *Plantago ovata* mucilage, and their physical mixture were recorded using the KBr pellet method and analyzed for any shifts or disappearance of characteristic peaks.

3.4. Formulation of Instant Disintegrating Tablets

Instant disintegrating tablets of Sitagliptin phosphate were prepared by the **direct compression method**.

Accurately weighed quantities of Sitagliptin phosphate, *Plantago ovata* mucilage (in varying concentrations), MCC, and mannitol were passed through sieve no. 60 and blended uniformly. Magnesium stearate and talc were added last and mixed gently for 2–3 minutes to avoid over-lubrication.

The final blend was compressed using a single-punch tablet compression machine fitted with flat-faced punches. The tablet weight was kept constant for all formulations.

3.5. Evaluation of Pre-Compression Parameters

3.5.1. Angle of Repose

Angle of repose was determined using the funnel method to assess flow properties of the powder blend.

$$\tan \theta = \frac{h}{r} \tan\theta = rh$$

where h is height and r is radius of the powder cone.

3.5.2. Bulk Density

Bulk density was calculated by dividing the weight of the powder by the bulk volume occupied in a graduated cylinder.

3.5.3. Tapped Density

Tapped density was determined after tapping the powder 100 times using a tapped density apparatus.

3.5.4. Carr's Index

Carr's index was calculated to evaluate compressibility:

$$\text{Carr's Index} = \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \times 100$$

3.5.5. Hausner's Ratio

Hausner's ratio was calculated as:

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

3.6. Evaluation of Post-Compression Parameters

3.6.1. Weight Variation

Twenty tablets from each batch were weighed individually and the percentage deviation from average weight was calculated.

3.6.2. Hardness

Tablet hardness was measured using a Monsanto hardness tester and expressed in kg/cm².

3.6.3. Thickness

Thickness of tablets was measured using a Vernier caliper.

3.6.4. Friability

Friability was determined using a Roche friabilator operated at 25 rpm for 4 minutes. Percentage friability was calculated, and values below 1% were considered acceptable.

3.6.5. Wetting Time

A tablet was placed on tissue paper soaked with phosphate buffer pH 6.8, and the time required for complete wetting was recorded.

3.6.6. Water Absorption Ratio

Water absorption ratio was calculated using the formula:

3.6.7. Drug Content Uniformity

Tablets were crushed and an amount equivalent to one tablet was dissolved in phosphate buffer pH 6.8, filtered, and analyzed using UV-Visible spectrophotometry.

3.6.8. In-Vitro Disintegration Time

Disintegration time was determined using a USP disintegration test apparatus in phosphate buffer pH 6.8 maintained at 37 ± 0.5 °C.

3.6.9. In-Vitro Dissolution Studies

Dissolution studies were performed using USP Type II (paddle) dissolution apparatus with phosphate buffer pH 6.8 at 37 ± 0.5 °C and 50 rpm. Samples were withdrawn at predetermined intervals, filtered, and analyzed spectrophotometrically.

4. RESULTS

4.1. Preformulation Study Results

4.1.1. Physical Appearance

Sitagliptin phosphate was found to be a white to off-white, odorless, crystalline powder. The drug exhibited uniform appearance without visible impurities, indicating its suitability for formulation into solid oral dosage forms.

4.1.2. Melting Point

The melting point of Sitagliptin phosphate was found to be in the range of **215–218°C**, which is in close agreement with the reported literature values. This confirms the purity and identity of the drug.

4.1.3. Solubility Studies

Sitagliptin phosphate exhibited:

- Slight solubility in distilled water
- Good solubility in phosphate buffer pH 6.8
- High solubility in methanol

The observed solubility pattern indicates that phosphate buffer pH 6.8 is a suitable dissolution medium for further in-vitro studies.

4.1.4. Determination of λmax

The UV-Visible spectrophotometric scan of Sitagliptin phosphate in phosphate buffer pH 6.8 showed a maximum absorbance (λmax) at **267 nm**, which was selected for all further quantitative drug estimation studies.

4.1.5. FT-IR Compatibility Studies

FT-IR spectra of pure Sitagliptin phosphate showed characteristic peaks corresponding to functional groups such as:

- N–H stretching
- C=O stretching
- C–F stretching

The FT-IR spectra of physical mixtures containing Sitagliptin phosphate and *Plantago ovata* mucilage showed retention of all major characteristic peaks without significant shifts or disappearance. This indicates **no chemical interaction between the drug and excipients**, confirming compatibility.

4.2. Evaluation of Pre-Compression Parameters

The powder blends of all formulations were evaluated for flow properties. The results are summarized as follows:

- **Angle of repose** values were found to be in the range of **22°–29°**, indicating good to excellent flow properties.
- **Bulk density** and **tapped density** values showed minimal variation among formulations.
- **Carr's Index** values were below **20%**, indicating acceptable compressibility.
- **Hausner's Ratio** values were below **1.25**, confirming good flow behavior.

These results demonstrate that the powder blends possessed suitable flow and compressibility characteristics for direct compression.

4.3. Evaluation of Post-Compression Parameters

4.3.1. Weight Variation

All tablet formulations complied with pharmacopeial limits for weight variation. The percentage deviation was within acceptable limits, indicating uniform die filling during compression.

4.3.2. Hardness

The hardness of the formulated tablets ranged between **2.5–3.5 kg/cm²**, which was sufficient to maintain mechanical integrity while allowing rapid disintegration.

4.3.3. Thickness

Tablet thickness was found to be uniform across all formulations, ranging between **3.0–3.8 mm**, indicating consistency in compression.

4.3.4. Friability

Friability values for all formulations were found to be **below 1%**, confirming adequate mechanical strength and resistance to abrasion during handling and transportation.

4.3.5. Wetting Time

Wetting time of the tablets ranged between **18–45 seconds**. Formulations containing higher concentrations of *Plantago ovata* mucilage showed shorter wetting times, indicating faster hydration and better disintegration efficiency.

4.3.6. Water Absorption Ratio

Water absorption ratio values ranged between **65–98%**. An increase in *Plantago ovata* mucilage concentration resulted in higher water absorption due to its excellent swelling properties.

4.3.7. Drug Content Uniformity

Drug content of all formulations was found to be within **95–102%** of the labeled claim, indicating uniform distribution of Sitagliptin phosphate within the tablet matrix.

4.3.8. In-Vitro Disintegration Time

In-vitro disintegration time for the formulated instant disintegrating tablets ranged between **12–55 seconds**.

Formulations containing higher levels of *Plantago ovata* mucilage exhibited significantly shorter disintegration times. The optimized formulation showed disintegration within **less than 20 seconds**, fulfilling the criteria for instant disintegrating tablets.

4.3.9. In-Vitro Dissolution Studies

In-vitro dissolution studies revealed rapid drug release from all formulations. The percentage drug release ranged between **85–99% within 10 minutes**.

The optimized formulation demonstrated **more than 95% drug release within 5 minutes**, indicating rapid dissolution and immediate availability of the drug for absorption.

4.4. Optimized Formulation Selection

Based on the evaluation parameters including:

- Shortest disintegration time
- Highest dissolution rate
- Acceptable hardness and friability
- Optimal wetting time and water absorption

the formulation containing an optimized concentration of *Plantago ovata* mucilage was selected as the **optimized instant disintegrating tablet formulation of Sitagliptin phosphate**.

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