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# FORMULATION, OPTIMIZATION AND EVALUATION OF SITAGLIPTIN ORODISPERSIBLE FILM FOR ENHANCED PATIENT COMPLIANCE IN THE MANAGEMENT OF TYPE 2 DIABETES MELLITUS

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**Keywords:**

Sitagliptin, Orodispersible Film, Solvent Casting, Type 2 Diabetes Mellitus, Patient Compliance

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## ABSTRACT

Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder requiring long-term pharmacotherapy, where patient compliance plays a crucial role in achieving optimal therapeutic outcomes. Conventional tablet formulations of sitagliptin may present swallowing difficulties, particularly among geriatric and dysphagic patients, resulting in poor adherence to treatment. The present study was undertaken to formulate, optimize, and evaluate an orodispersible film (ODF) of sitagliptin using the solvent casting method to improve convenience, rapid drug release, and patient acceptability. Hydroxypropyl methylcellulose (HPMC) and polyvinylpyrrolidone (PVP) were employed as film-forming polymers, while polyethylene glycol 400 served as the plasticizer. Suitable sweeteners, saliva-stimulating agents, and flavoring agents were incorporated to enhance palatability and facilitate rapid disintegration. Various formulations were prepared by varying polymer concentrations and were evaluated for physical appearance, thickness, weight variation, folding endurance, tensile strength, surface pH, moisture content, drug content uniformity, disintegration time, and in vitro drug release. Fourier Transform Infrared Spectroscopy (FTIR) confirmed the compatibility of sitagliptin with the selected excipients, while the optimized formulation demonstrated satisfactory mechanical properties, uniform drug distribution, rapid disintegration, and efficient drug release. Stability studies conducted under ICH recommended conditions indicated that the optimized formulation remained physically and chemically stable throughout the study period. The developed sitagliptin ODF offers several advantages over conventional tablets, including ease of administration without water, improved patient compliance, reduced risk of choking, and rapid onset of drug release. Therefore, the developed formulation represents a promising patient-centric dosage form for the effective management of Type 2 Diabetes Mellitus and provides potential for future commercialization.

**INTRODUCTION**

Type 2 Diabetes Mellitus (T2DM) is one of the most common chronic metabolic disorders worldwide and represents a major public health challenge due to its rapidly increasing prevalence [1]. It is characterized by insulin resistance, progressive pancreatic β-cell dysfunction, and impaired insulin secretion, resulting in persistent hyperglycemia. Long-term uncontrolled blood glucose levels lead to serious microvascular and macrovascular complications, including diabetic nephropathy, retinopathy, neuropathy, cardiovascular diseases, and stroke, significantly affecting patients' quality of life and increasing healthcare costs [2]. Effective management of T2DM requires lifelong pharmacotherapy, lifestyle modification, dietary regulation, and regular monitoring of blood glucose levels [3]. Among these factors, patient adherence to medication plays a pivotal role in achieving optimal glycemic control and preventing disease-related complications [4]. However, poor compliance remains a significant obstacle in diabetes management, particularly among elderly patients who often receive multiple medications for various comorbidities [5].Conventional oral dosage forms such as tablets and capsules remain the most widely prescribed formulations for antidiabetic therapy due to their convenience, stability, and cost-effectiveness [6]. Nevertheless, these dosage forms possess several limitations that may reduce treatment adherence [7]. A considerable proportion of geriatric, pediatric, and dysphagic patients experience difficulty swallowing solid oral dosage forms, a condition known as dysphagia [8]. This may result in missed doses, incomplete medication intake, or the need to crush tablets, which can adversely affect drug efficacy and safety. Furthermore, conventional tablets require water for administration, making them less convenient during travel, emergencies, or in situations where drinking water is unavailable [9-11]. These limitations have stimulated extensive research into patient-friendly drug delivery systems capable of improving convenience, compliance, and therapeutic effectiveness [12-13].Orodispersible films (ODFs) have emerged as an innovative and patient-centric oral drug delivery system that addresses many of the shortcomings associated with conventional tablets [14-15]. ODFs are thin, flexible polymeric strips that rapidly disintegrate when placed on the tongue, usually within a few seconds, without requiring water [16-17]. The films are formulated using hydrophilic polymers, plasticizers, sweeteners, saliva-stimulating agents, and flavoring agents to provide rapid hydration, excellent mechanical strength, and improved palatability [18]. Their large surface area facilitates quick wetting and rapid drug dissolution, resulting in faster onset of action. Additionally, certain drugs may undergo partial absorption through the buccal or sublingual mucosa, thereby reducing hepatic first-pass metabolism and potentially enhancing bioavailability [19]. ODFs also minimize the risk of choking, provide accurate unit dosing, improve portability, and enhance patient acceptance, making them particularly suitable for pediatric, geriatric, psychiatric, and dysphagic populations.Sitagliptin is a highly selective dipeptidyl peptidase-4 (DPP-4) inhibitor widely prescribed as first-line or combination therapy for the management of Type 2 Diabetes Mellitus. It exerts its antihyperglycemic effect by preventing the degradation of endogenous incretin hormones, thereby enhancing glucose-dependent insulin secretion and suppressing glucagon release without causing significant hypoglycemia. Sitagliptin possesses favorable physicochemical properties, including a relatively low therapeutic dose, good aqueous solubility, chemical stability, and acceptable taste profile, making it an ideal candidate for incorporation into an orodispersible film dosage form. Formulating sitagliptin as an ODF may improve patient compliance, facilitate rapid drug availability, and offer greater convenience for chronic diabetic therapy [20].The present study was therefore undertaken to formulate, optimize, and evaluate sitagliptin-loaded orodispersible films prepared by the solvent casting technique using suitable hydrophilic polymers and pharmaceutical excipients. Various formulations were developed by optimizing polymer composition to obtain films with desirable mechanical strength,

flexibility, rapid disintegration, and uniform drug distribution [21]. The prepared films were comprehensively evaluated for physicochemical properties, thickness, weight variation, folding endurance, surface pH, tensile strength, drug content uniformity, in vitro disintegration time, dissolution characteristics, and stability under ICH-recommended conditions. The ultimate objective of this research was to develop a stable, patient-friendly, rapidly disintegrating oral dosage form capable of enhancing therapeutic efficacy, improving medication adherence, and providing a more convenient alternative to conventional sitagliptin tablets for the long-term management of Type 2 Diabetes Mellitus.

## MATERIAL AND METHODS

Sitagliptin was used as the model drug for the preparation of orodispersible films. Hydroxypropyl methylcellulose (HPMC) and polyvinylpyrrolidone (PVP) were employed as film-forming polymers, while polyethylene glycol 400 (PEG 400) served as the plasticizer. Citric acid, sucralose, and peppermint flavor were incorporated as the saliva-stimulating agent, sweetener, and flavoring agent, respectively, and all other chemicals and reagents used were of analytical grade.

### *Determination of Melting Point*

The melting point of sitagliptin was determined as a preformulation study to assess its purity, identity, and crystalline nature. A small quantity of finely powdered drug was filled into a sealed capillary tube and placed in a digital melting point apparatus. The temperature was increased gradually, and the temperatures at which the drug started and completed melting were recorded. A sharp melting point range indicated the purity and suitability of the drug for formulation development [22].

### *Solubility*

The solubility of sitagliptin was evaluated as a preformulation study to determine its dissolution characteristics and suitability for formulation development. An excess quantity of the drug was added to different solvents, including distilled water and selected organic solvents, in sealed containers and shaken continuously until equilibrium was attained. The solutions were then observed for drug solubility, and the results were used to select a suitable solvent system for the formulation of orodispersible films [23].

### *UV Spectroscopy*

UV spectroscopic analysis was carried out to determine the wavelength of maximum absorption (λmax) and to develop a suitable analytical method for the estimation of sitagliptin. A standard stock solution (1000 µg/mL) was prepared by dissolving 100 mg of sitagliptin in phosphate buffer (pH 6.8) and making the volume up to 100 mL. The solution was scanned over the wavelength range of 200–400 nm using a UV–Visible spectrophotometer, and the λmax was found to be 267 nm. The stock solution was serially diluted with phosphate buffer (pH 6.8) to obtain concentrations ranging from 5–35 µg/mL. The absorbance of each solution was measured at 267 nm against phosphate buffer as the blank. A calibration curve was constructed [24].

### Drug Excipients Compatibility Studies

Drug–excipient compatibility was evaluated using Fourier Transform Infrared (FTIR) spectroscopy to identify any possible interactions between sitagliptin and the selected excipients. FTIR spectra of the pure drug and the physical mixture were recorded using a Shimadzu FTIR spectrophotometer (Japan). Samples were prepared by the KBr pellet method using a 1:100 (sample:KBr) ratio. The obtained spectra were compared for characteristic functional group peaks to confirm the compatibility of the drug with the formulation excipients [25].

### Formulation of Sitagliptin Orodispersible Films

Sitagliptin orodispersible films were prepared by the solvent casting method. Sitagliptin was dissolved in purified water, while HPMC E5 and PVP K30 were separately hydrated to prepare a homogeneous polymeric solution. The drug solution was added to the polymer dispersion, followed by the incorporation of sucralose, citric acid, glycerol, and flavoring agent with continuous stirring to obtain a clear, bubble-free casting solution. The final solution was poured into a 9 cm diameter Petri dish and dried in a hot air oven at 60°C for 24 h. The dried film was carefully peeled off and cut into 2 × 2 cm (4 $cm^2$) strips. Based

on the Petri dish area (63.58 $cm^2$), approximately 15 films were obtained from each batch, with each strip containing 50 mg of Sitagliptin. The prepared films were wrapped in aluminum foil and stored in a desiccator until further evaluation [26].

**Table: Composition of Orodispersible Film of Sitagliptin Phosphate**

| Ingredient | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 |
|---|---|---|---|---|---|---|---|---|
| Sitagliptin Phosphate (mg) | 750 | | | | | | | |
| HPMC E5 (mg) | 200 | 250 | 300 | 350 | 200 | 250 | 300 | 350 |
| PVP K30 (mg) | 50 | 50 | 50 | 50 | 100 | 100 | 100 | 100 |
| Crosscarmellose Sodium (mg) | 2 | | | | | | | |
| Glycerol (ml) | 0.5 | | | | | | | |
| Sucralose (mg) | 10 | | | | | | | |
| Citric acid (mg) | 5 | | | | | | | |
| Flavor | q.s. | | | | | | | |
| Purified Water (ml) | q.s. to10 mL | | | | | | | |

**Evaluation of orodispersible films**

***Weight Uniformity of Films***

Weight uniformity is a critical quality control parameter for orodispersible films, as it directly reflects dose uniformity, consistency in formulation, and reproducibility of the manufacturing process. Uniform weight ensures that each film contains an accurate and consistent amount of the drug, which is essential for therapeutic efficacy and patient safety. In the present study, weight uniformity was evaluated by individually weighing randomly selected films from each formulation batch using a calibrated digital balance. The average weight and standard deviation were calculated to assess uniformity. Minimal variation in film weight indicated homogeneous distribution of drug and excipients throughout the polymeric matrix, confirming efficient mixing, uniform casting of the solution, and consistent solvent evaporation during film formation. Good weight uniformity demonstrates the reliability of the solvent casting method and ensures dose accuracy in the final dosage form [27].

***Thickness of Film***

Film thickness is an important physical parameter that influences drug loading, mechanical strength, disintegration behavior, and drug release characteristics of orodispersible films. Uniform thickness is necessary to maintain consistency in drug content and performance between individual film units. In this study, the thickness of films was measured at multiple points using a digital Vernier caliper to ensure accuracy and uniformity. The mean thickness values and standard deviations were calculated. Uniform thickness across the films indicated proper spreading of the casting solution, uniform polymer distribution, and controlled drying conditions. Thickness also plays a significant role in hydration rate and disintegration time, as thinner films hydrate faster, leading to quicker disintegration in the oral cavity. Therefore, thickness evaluation served as an essential quality attribute to ensure reproducible performance of the formulated orodispersible films. [28]

***Folding Endurance of Films***

Folding endurance is another procedure to estimate the mechanical properties of a film. It is measured by repeatedly folding a film at the same point until it breaks. Folding endurance value is number of times the film is folded without breaking. Higher folding endurance value depicts the more mechanical strength of a film. A direct relation exists between mechanical strength and folding endurance of films. As mechanical strength is governed by plasticizer concentration so it is clearly evident that plasticizer concentration also indirectly affects folding endurance value. The folding endurance was measured manually for the prepared films. Folding endurance of the films was determined by repeatedly folding a film at the same place till it broke. The number of times films could be folded at the same place, without breaking gives the value of folding endurance. [29]

***Surface pH of Films***

Surface pH is a crucial parameter for orodispersible films, as it determines their compatibility with the oral mucosa and patient comfort. Films with highly acidic or alkaline surface pH may cause irritation, discomfort, or damage to the oral mucosal tissues. Therefore, maintaining a surface pH close to neutral or salivary pH is essential for patient acceptability. In the present study, the surface pH of the films was determined

by placing the film in contact with distilled water and measuring the pH using a calibrated pH meter after equilibration. The results showed that the surface pH of the films was within the physiological range, indicating that the formulations are non-irritant and safe for oral administration. This confirms the suitability of the excipients and formulation composition for oral mucosal application and supports the safety profile of the developed orodispersible films [29].

***Drug Content Uniformity Study***

The films were tested for drug content uniformity by U.V-Spectrophotometric method. Films of 2×2 cm2 were each film was placed in 10 ml volumetric flask and diluted with phosphate buffer pH 6.8 up to 10 ml. The absorbance of the solution was measured at 267 nm using U.V visible spectrophotometer after suitable dilution. The percentage drug content was determined [29].

**In-Vitro *Disintegration Time***

The *in-vitro* disintegration time of the orodispersible films was determined by the Petri dish method. Each film was placed at the center of a Petri dish containing 10 mL of distilled water, and the time required for complete disintegration was recorded. The test was performed in triplicate, and the average disintegration time was calculated [29].

***In Vitro* Dissolution Study**

*In-vitro* dissolution of Sitagliptin phosphate orodispersible films was studied using USP Type 2 dissolution test apparatus, 900 ml phosphate buffer solution pH 6.8 was used as dissolution medium. The stirrer was adjusted to rotate at 50 rpm. The temperature of dissolution medium was maintained at 37±0.5ºC throughout the experiment. Samples of dissolution medium (5ml) were withdrawn by mea8ns of syringe. Solution was filtered with Whatman filter Paper. Sample were withdrawn after 1,2,4,6,8 and 10-minute time intervals. The sample ware analyzed for drug release by measuring the absorbance at 267 nm. The volume withdrawn at each time interval was replaced with fresh quantity of dissolution medium. Cumulative percent released of drug was calculated and plotted against time [29].

***Stability Study***

Accelerated stability studies were performed on the optimized orodispersible film formulation according to ICH guidelines. The films were packed in aluminum foil strips and stored at 40 ± 2°C and 75 ± 5% RH for 3 months. Before and after the storage period, the films were evaluated for appearance, folding endurance, disintegration time, drug content, and in vitro drug release to assess their stability [29].

**RESULTS AND DISCUSSION**

***Determination of Melting Point***

The melting point of Sitagliptin phosphate was determined by capillary method, melting point of Sitagliptin was found to be in the 205°C to 206°C. Melting point compared with Pharmacopoeial standards that confirmed the purity of drug sample.

***Solubility***

The solubility of the drug was determined in different solvents and media. The solubility of Sitagliptin phosphate was found as follows. The results are shown in table 1.

**Table 1: Solubility Profile of Sitagliptin Phosphate in Different Solvents**

| Solvents | Solubility |
|---|---|
| Water | Soluble |
| Methanol | Slightly Soluble |
| Ethanol | Slightly Soluble |
| DMSO | Soluble |
| Dimethyl Formamide | Soluble |
| Phosphate Buffer Solution pH 6.8 | Soluble |
| Acetone | Slightly Soluble |

***UV-Spectroscopy***

**Table 2: Standard Calibration Curve of Sitagliptin Phosphate in PBS pH 6.8**

| Concentration (µg/ml) | Absorbance |
|---|---|
| 0 | 0 |
| 5 | 0.144 |
| 10 | 0.289 |
| 15 | 0.448 |

| | |
|---|---|
| 20 | 0.571 |
| 25 | 0.702 |
| 30 | 0.868 |
| 35 | 0.986 |

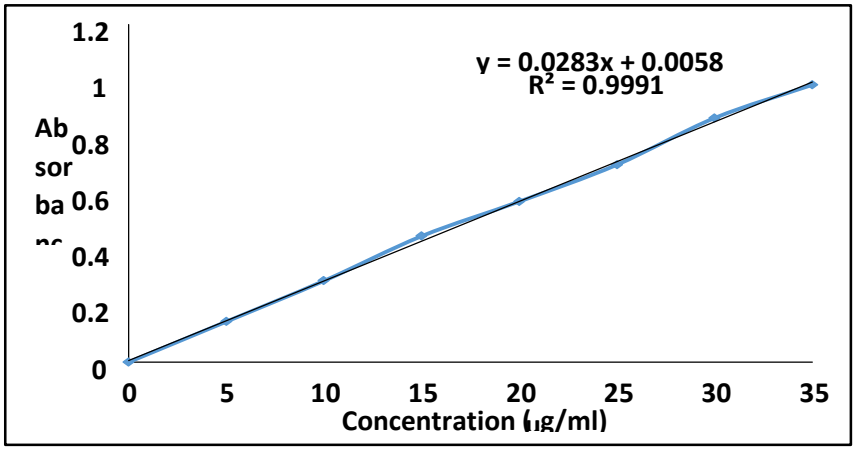


**Figure 1: Standard Calibration Curve of Sitagliptin Phosphate in Phosphate Buffer pH 6.8**

A standard calibration curve of sitagliptin was prepared in phosphate buffer (pH 6.8) by measuring the absorbance of standard solutions (5–35 µg/mL) at 267 nm, and plotting absorbance against concentration to establish a linear relationship for quantitative drug estimation (Table 2 & Figure 1).

***Compatibility Studies (FT-IR)***

The FTIR spectrum of Sitagliptin Phosphate (figure 2) shows characteristic absorption peaks corresponding to its functional groups, confirming the identity and purity of the drug. A broad peak observed in the region of ~3200–3500 $cm^{-1}$ is attributed to N–H stretching vibrations of amine groups along with possible O–H stretching due to moisture or phosphate association. The peaks around 2976 $cm^{-1}$ and 2887 $cm^{-1}$ correspond to C–H stretching vibrations of aliphatic groups. A prominent peak at ~1631 $cm^{-1}$ indicates C=O stretching (amide group), which is a key functional group in sitagliptin structure. The peak around ~1705 $cm^{-1}$ may also suggest contribution from carbonyl stretching vibrations. The absorption bands in the region of 1476 $cm^{-1}$ and 1391 $cm^{-1}$ are attributed to C–N stretching and CH bending vibrations, confirming the presence of amine functionalities. Further, peaks observed between 1257 $cm^{-1}$ to 1088 $cm^{-1}$ are characteristic of C–N stretching and P=O stretching vibrations, indicating the presence of the phosphate group. The peaks in the region of 1000–1150 $cm^{-1}$ also support P–O stretching vibrations, confirming the phosphate salt form of the drug. Overall, the FTIR spectrum shows all the characteristic peaks of Sitagliptin Phosphate.

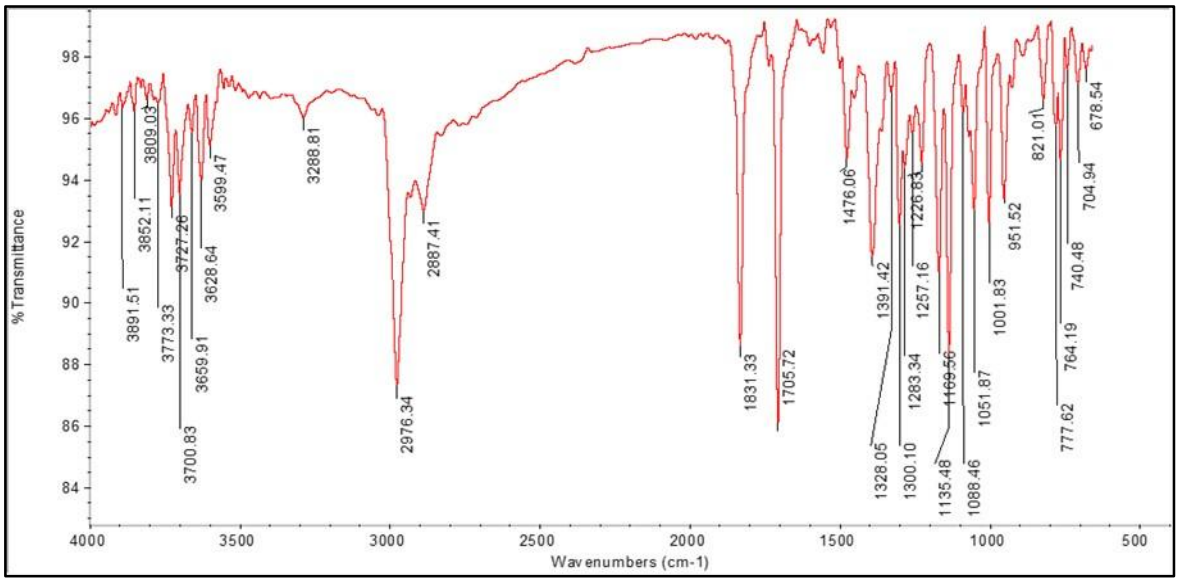


**Figure 2: IR spectra of pure drug Sitagliptin Phosphate**

The FTIR spectrum of Sitagliptin Phosphate with Hydroxypropyl Methylcellulose and PVP (figure 3) shows the presence of all the characteristic peaks of the drug without any significant shift, disappearance, or formation of new peaks. The main functional group peaks are seen to be retained in the combined spectrum. The absence of major changes in peak positions indicates that there is no chemical interaction between the drug and polymer. Therefore, the FTIR study confirms that Sitagliptin Phosphate is compatible with HPMC and PVP and the polymer can be safely used in the formulation without affecting the stability or integrity of the drug.

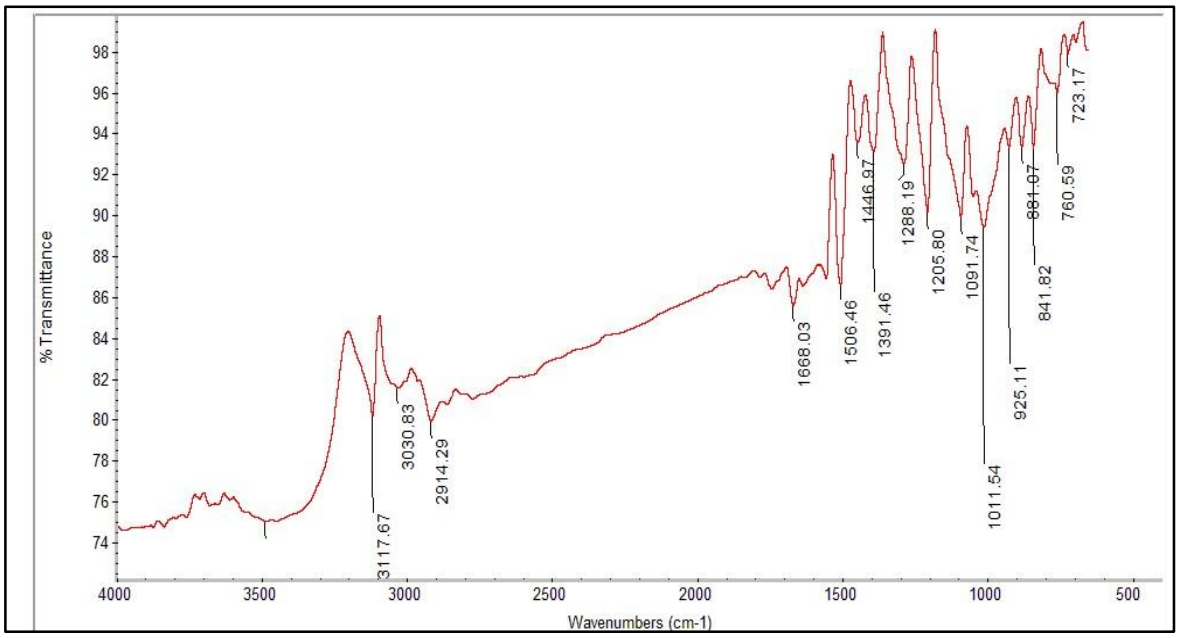


**Figure 3: IR Spectra of Sitagliptin Phosphate Orodispersible Film**

**Evaluation of sitagliptin phosphate orodispersible films**

**Physical appearance**

All the prepared orodispersible films were found to be transparent, smooth, flexible, and free from air bubbles or cracks, indicating uniform film formation by the solvent casting method. The films could be

easily peeled from the casting surface without damage, suggesting adequate plasticization and polymer distribution.

**Weight Uniformity of Films**

The weight variation of the films ranged from 118.24 ± 2.15 mg to 141.28 ± 2.58 mg. It was observed that the weight of the films increased progressively from F1 to F4 and F5 to F8 with increasing concentration of HPMC E5 and PVP K30. This increase in weight may be attributed to the higher solid content of polymers present in the formulation. The relatively low standard deviation values indicate uniform distribution of the casting solution and reproducibility of the formulation method. All batches showed acceptable weight uniformity, confirming consistency in film preparation. Result was shown in table 3.

**Thickness of Films**

The thickness of the films was found to be in the range of 0.18 ± 0.01 mm to 0.25 ± 0.02 mm. Similar to weight variation, thickness increased with increasing polymer concentration. Formulations containing higher amounts of HPMC E5 (F4 and F8) exhibited maximum thickness, whereas F1 showed the lowest thickness. The uniform thickness across all batches indicates even spreading of the casting solution in the Petri dish, which is essential for dose uniformity and consistent drug release. Results of thickness are shown in table 3.

***Table 3: Evaluation of Appearance, Thickness and Weight variation of Sitagliptin Phosphate Orodispersible Film (F1 to F8)***

| Batch No. | Appearance | Thickness (mm) | Weight Variation (mg) |
|---|---|---|---|
| **F1** | Transparent | 118.24 ± 2.15 | 0.18 ± 0.01 |
| **F2** | Transparent | 124.56 ± 2.36 | 0.20 ± 0.01 |
| **F3** | Transparent | 131.42 ± 2.48 | 0.22 ± 0.02 |
| **F4** | Transparent | 138.36 ± 2.62 | 0.24 ± 0.02 |
| **F5** | Transparent | 120.84 ± 2.21 | 0.19 ± 0.01 |
| **F6** | Transparent | 127.76 ± 2.33 | 0.21 ± 0.01 |
| **F7** | Transparent | 134.92 ± 2.44 | 0.23 ± 0.01 |
| **F8** | Transparent | 141.28 ± 2.58 | 0.25 ± 0.02 |

***Folding Endurance of Films***

The folding endurance of the films was determined by repeatedly folding a small strip of the films at the same place till it broke and the average folding endurance of all films was given in table 4 & figure 4. Folding endurance values ranged from 210 ± 8.32 to 285 ± 12.16, indicating good mechanical strength of the films. The folding endurance increased with increasing concentration of polymers, particularly PVP K30, which acts as a film-forming and strengthening agent. Formulation F7 showed the highest folding endurance (285 ± 12.16), suggesting excellent flexibility and resistance to breaking upon repeated folding. This may be due to the optimal combination of HPMC E5 and higher concentration of PVP K30, along with the presence of glycerol as a plasticizer.

***Table 4: Folding Endurance of Sitagliptin Orodispersible Film (F1 to F8)***

| Batch No. | Folding Endurance |
|---|---|
| **F1** | 210 ± 8.32 |
| **F2** | 228 ± 9.14 |
| **F3** | 245 ± 10.26 |
| **F4** | 262 ± 11.38 |
| **F5** | 238 ± 9.45 |

| | |
|---|---|
| **F6** | 258 ± 10.84 |
| **F7** | 285 ± 12.16 |
| **F8** | 270 ± 11.52 |

All the values are expressed as mean ± SD, n=3.

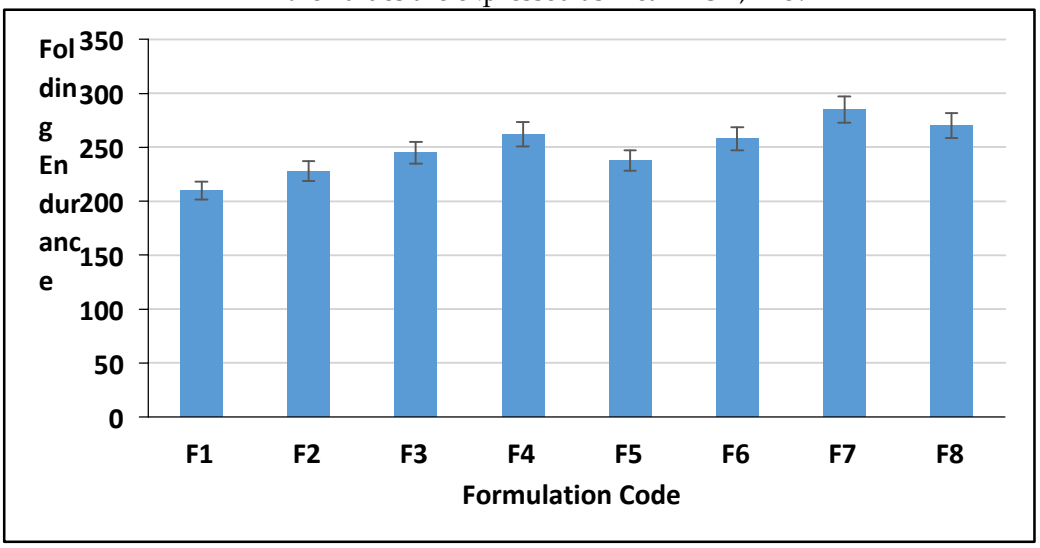


**Figure 4: Folding Endurance of Orodispersible Film (F1 to F8)**

**In Vitro *Disintegration Time of Films***

The disintegration time of the films ranged from 38.26 ± 1.84 seconds to 24.36 ± 1.41 seconds. It was observed that the disintegration time decreased with an increase in PVP K30 concentration and the presence of superdisintegrant (croscarmellose sodium). Formulation F7 showed the fastest disintegration time (24.36 ± 1.41 seconds). This rapid disintegration can be attributed to higher concentration of PVP K30, which enhances water uptake, presence of croscarmellose sodium, which promotes rapid swelling and optimal polymer balance allowing quick penetration of saliva.In other hand formulations with higher HPMC concentration alone (such as F4) showed relatively slower disintegration due to the formation of a viscous gel barrier upon hydration. The average disintegration time of different formulation was shown in table 5 and figure 5.

***Table 5:* In Vitro *Disintegration Time of Films Sitagliptin Orodispersible Film***

| Batch No. | Disintegration Time (Sec) |
|---|---|
| **F1** | 38.26 ± 1.84 |
| **F2** | 34.18 ± 1.76 |
| **F3** | 31.74 ± 1.65 |
| **F4** | 29.56 ± 1.58 |
| **F5** | 32.64 ± 1.69 |
| **F6** | 28.42 ± 1.52 |
| **F7** | 24.36 ± 1.41 |
| **F8** | 27.18 ± 1.47 |

All the values are expressed as mean ± SD, n=3.

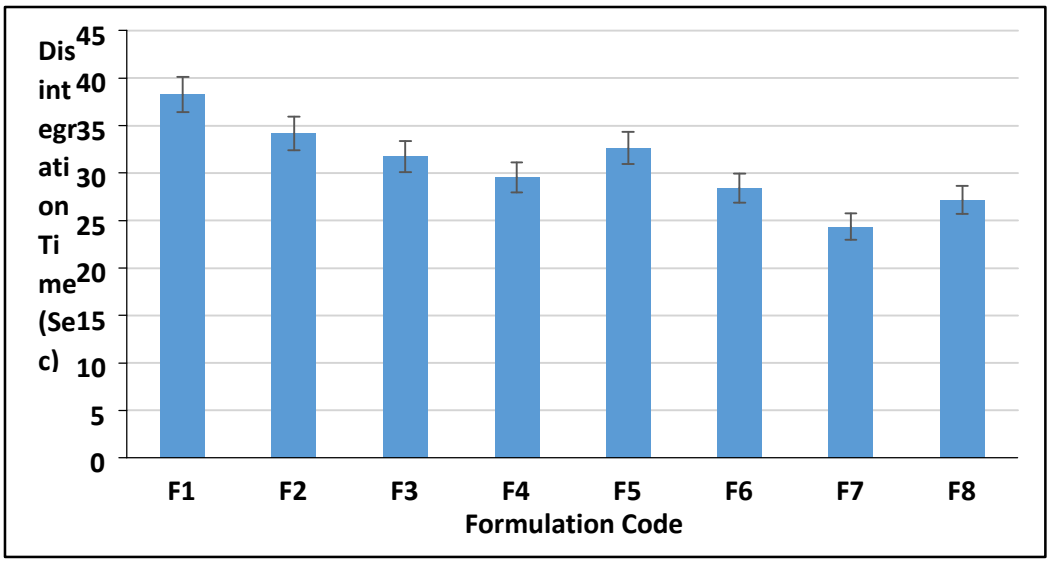


*Figure 5: Disintegration Time of Orodispersible Film (F1 to F8)*

**Surface pH of Films**

The surface pH of all formulations was found to be in the range of 6.45 ± 0.12 to 6.71 ± 0.12, which is close to the neutral pH of saliva. This indicates that the films are non-irritating and suitable for oral administration. No significant variation in surface pH was observed among the batches, suggesting that the excipients used in the formulation did not alter the pH to an extent that could cause mucosal irritation. The result was showed in table 6.

**Drug Content Uniformity Study**

The drug content of the films ranged from 95.84 ± 1.42 % to 99.24 ± 1.18 %, indicating uniform distribution of Sitagliptin Phosphate within the films. Formulation F7 showed the highest drug content (99.24 ± 1.18 %), while F1 showed slightly lower drug content. The increase in drug content uniformity in higher polymer batches may be attributed to better entrapment and uniform dispersion of the drug within the polymeric matrix. The low standard deviation values further confirm the reproducibility and reliability of the preparation method.

The results clearly indicate that polymer concentration and ratio significantly influence the properties of orodispersible films. HPMC E5 primarily contributed to film formation, thickness, and mechanical strength. Increasing its concentration resulted in thicker films with improved folding endurance but slightly delayed disintegration due to gel formation. PVP K30 enhanced film flexibility, drug dispersion, and disintegration rate. Higher levels of PVP K30 improved water penetration into the film, leading to faster disintegration. The combination of both polymers provided a balanced effect, where HPMC ensured structural integrity and PVP facilitated rapid disintegration.

Among all the formulations, F7 was found to be the optimized batch, exhibiting acceptable weight and thickness, highest folding endurance (285 ± 12.16), near-neutral surface pH (6.68 ± 0.10), maximum drug content (99.24 ± 1.18 %) and fastest disintegration time (24.36 ± 1.41 sec). The superior performance of F7 can be attributed to the optimal ratio of HPMC E5 and PVP K30, which provided a balance between mechanical strength and rapid disintegration.

**Table 6: Evaluation Orodispersiblefilm of Sitagliptin Phosphate**

| Formulation | Weight Variation (mg) | Thickness (mm) | Folding Endurance | Surface pH | Drug Content (%) | Disintegration Time (sec) |
|---|---|---|---|---|---|---|
| **F1** | 118.24 ± 2.15 | 0.18 ± 0.01 | 210 ± 8.32 | 6.45 ± 0.12 | 95.84 ± 1.42 | 38.26 ± 1.84 |
| **F2** | 124.56 ± 2.36 | 0.20 ± 0.01 | 228 ± 9.14 | 6.52 ± 0.10 | 96.92 ± 1.36 | 34.18 ± 1.76 |
| **F3** | 131.42 ± 2.48 | 0.22 ± 0.02 | 245 ± 10.26 | 6.58 ± 0.11 | 97.64 ± 1.28 | 31.74 ± 1.65 |
| **F4** | 138.36 ± 2.62 | 0.24 ± 0.02 | 262 ± 11.38 | 6.63 ± 0.13 | 98.12 ± 1.22 | 29.56 ± 1.58 |
| **F5** | 120.84 ± 2.21 | 0.19 ± 0.01 | 238 ± 9.45 | 6.49 ± 0.11 | 97.18 ± 1.34 | 32.64 ± 1.69 |
| **F6** | 127.76 ± 2.33 | 0.21 ± 0.01 | 258 ± 10.84 | 6.56 ± 0.12 | 98.36 ± 1.26 | 28.42 ± 1.52 |
| **F7** | 134.92 ± 2.44 | 0.23 ± 0.01 | 285 ± 12.16 | 6.68 ± 0.10 | 99.24 ± 1.18 | 24.36 ± 1.41 |
| **F8** | 141.28 ± 2.58 | 0.25 ± 0.02 | 270 ± 11.52 | 6.71 ± 0.12 | 98.86 ± 1.20 | 27.18 ± 1.47 |

*All the values are expressed as mean ± SD, n=3.

***In Vitro* Dissolution Studies**

The *in-vitro* dissolution study of the prepared orodispersible films of Sitagliptin Phosphate (F1–F8) was carried out for a period of 10 minutes, and the cumulative percentage drug release was determined at predetermined time intervals (1, 2, 4, 6, 8, and 10 minutes). The results indicated that all formulations exhibited rapid drug release. The cumulative drug release at the end of 10 minutes was found to be in the

range of 94.72 ± 3.06 % to 99.42 ± 3.36 %, demonstrating efficient drug availability from the films. An initial rapid release was observed in all formulations within the first 1–2 minutes, which may be attributed to the fast hydration and disintegration of the film matrix upon contact with dissolution medium, leading to immediate drug dissolution. This behavior confirms the suitability of the solvent casting method in producing films with uniform drug dispersion and rapid wettability. As time progressed, the drug release increased steadily and reached near complete release within 10 minutes for all batches.

Among the formulations, F7 exhibited the highest drug release (99.42 ± 3.36 % at 10 minutes), followed closely by F8 and F6. The superior performance of F7 can be attributed to the optimal ratio of film-forming polymer and hydrophilic excipients, which facilitated rapid water uptake, efficient disintegration, and enhanced drug diffusion. In contrast, formulation F1 showed comparatively slower drug release (94.72 ± 3.06 %), which may be due to lower polymer optimization and comparatively reduced wettability.

The drug release behavior of the films was significantly influenced by the type and concentration of polymers used, particularly Hydroxypropyl Methylcellulose and PVP. HPMC E5, being a hydrophilic film-forming polymer, plays a major role in providing structural integrity to the film. However, at higher concentrations (F3, F4, and F8), HPMC tends to form a viscous gel layer upon hydration, which can act as a diffusion barrier and slightly retard drug release.

On the other hand, PVP K30 is a highly water-soluble polymer that enhances the wettability and porosity of the film matrix. Formulations containing higher concentrations of PVP K30 (F5–F8) demonstrated faster drug release profiles compared to those with lower PVP content (F1–F4). This is because PVP K30 promotes rapid penetration of dissolution medium into the film, resulting in quicker drug dissolution.

The combined effect of HPMC E5 and PVP K30 was found to be synergistic. While HPMC provided mechanical strength and film integrity, PVP K30 facilitated rapid hydration and drug release. Formulation F7, which contains a balanced concentration of both polymers, exhibited rapid and maximum drug release, indicating that the polymer ratio was ideal for immediate release. Additionally, the presence of croscarmellose sodium as a superdisintegrant further enhanced the drug release by promoting rapid swelling and disintegration of the film, thereby increasing the surface area available for dissolution.

The *in-vitro* dissolution study confirmed that all prepared orodispersible films exhibited rapid and efficient drug release within 10 minutes, making them suitable for immediate drug delivery. Among all formulations, F7 was identified as the optimized batch, showing maximum drug release with rapid onset, which can be attributed to the optimal polymer ratio and effective formulation design. Data for in vitro drug release of orodispersible film was shown in table 7 and figure 6.

***Table 7:* In-Vitro *Drug Release Data of Sitagliptin Phosphate Orodispersible Film***

| Time (min) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 |
|---|---|---|---|---|---|---|---|---|
| 1 | 32.48 ± 1.24 | 35.62 ± 1.36 | 38.74 ± 1.42 | 40.18 ± 1.51 | 36.82 ± 1.33 | 42.56 ± 1.58 | 45.84 ± 1.66 | 43.92 ± 1.60 |
| 2 | 48.36 ± 1.58 | 52.74 ± 1.72 | 56.28 ± 1.86 | 58.92 ± 1.94 | 54.36 ± 1.80 | 60.84 ± 2.02 | 64.72 ± 2.14 | 62.48 ± 2.06 |
| 4 | 65.84 ± 2.06 | 70.42 ± 2.18 | 74.36 ± 2.32 | 76.58 ± 2.44 | 72.48 ± 2.26 | 78.92 ± 2.58 | 82.64 ± 2.72 | 80.36 ± 2.64 |
| 6 | 78.26 ± 2.48 | 82.18 ± 2.62 | 85.94 ± 2.76 | 87.62 ± 2.84 | 83.74 ± 2.70 | 89.36 ± 2.92 | 92.48 ± 3.06 | 90.84 ± 2.98 |
| 8 | 88.14 ± 2.82 | 91.36 ± 2.94 | 93.72 ± 3.06 | 94.86 ± 3.12 | 92.48 ± 3.00 | 95.72 ± 3.18 | 97.86 ± 3.26 | 96.48 ± 3.20 |
| 10 | 94.72 ± 3.06 | 96.84 ± 3.18 | 97.96 ± 3.24 | 98.42 ± 3.28 | 97.18 ± 3.22 | 98.86 ± 3.30 | 99.42 ± 3.36 | 99.08 ± 3.32 |

All the values are expressed as mean ± SD, (n=3)

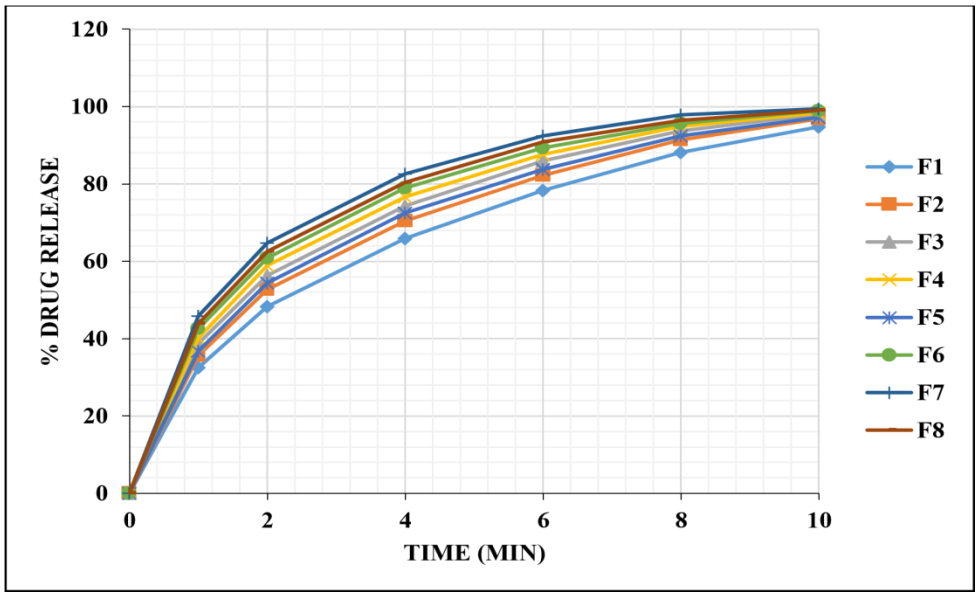


*Figure 6: Comparative Dissolution Profile of Sitagliptin Phosphate Orodispersible Film (F1 to F8)*

**Stability Study**

The stability study of the optimized orodispersible film formulation (F7) of Sitagliptin Phosphate was carried out for a period of 3 months under specified storage conditions. The formulation was evaluated for critical parameters such as folding endurance, drug content, disintegration time, and percentage drug release before storage (0 month) and after storage (3 months). The results indicated that the formulation remained physically and chemically stable throughout the study period.

The folding endurance of the formulation was found to be 285 ± 12.16 before storage and 286 ± 8.58 after 3 months, showing no significant change. This indicates that the mechanical strength and flexibility of the films were well maintained during storage. The slight variation observed is within acceptable limits and may be attributed to minor environmental variations. The results confirm that the polymeric matrix, particularly Hydroxypropyl Methylcellulose and Povidone, retained its structural integrity over time.

The drug content showed a very slight decrease from 99.24 ± 1.18 % to 98.68 ± 1.14 %, indicating minimal drug degradation during the storage period. The values remained within acceptable pharmacopeial limits (generally 95–105%), confirming the chemical stability of Sitagliptin Phosphate in the film formulation. The absence of significant drug loss suggests that there was no major interaction between the drug and excipients.

The disintegration time of the films increased marginally from 24.36 ± 1.41 seconds to 25.34 ± 0.86 seconds after storage. This slight increase may be attributed to minor changes in the moisture content of the films or slight hardening of the polymer matrix over time. However, the disintegration time remained well within the acceptable range for orodispersible films, indicating that the formulation retained its rapid disintegration property.

Similarly, the percentage drug release showed a negligible decrease from 99.42 ± 3.36 % to 98.72 ± 2.26 % after 3 months. This indicates that the drug release profile of the formulation was not significantly affected by storage conditions. The sustained rapid release behavior confirms that the polymeric network maintained its hydration and dissolution characteristics, ensuring consistent drug delivery.

In conclusion, the stability study demonstrates that the optimized formulation F7 is stable over the tested period, with no significant changes in mechanical properties, drug content, disintegration time, or drug release. The minor variations observed in the parameters are within acceptable limits and do not affect the performance of the formulation. Therefore, it

can be concluded that the optimized orodispersible film formulation possesses good stability and can be considered suitable for further development and potential commercialization. The results of stability data were shown in table 8.

*Table 8: Stability Data of Optimized Formulation Sitagliptin Phosphate Orodispersible Film (F7)*

| Formulation Code | Parameter | Before storage(0 month) | After storage(3 month) |
|---|---|---|---|
| F7 | **Folding Endurance** | 285 ± 12.16 | 286±8.58 |
| | **Drug Content (%)** | 99.24 ± 1.18 | 98.68±1.14 |
| | **Disintegration Time (sec)** | 24.36 ± 1.41 | 25.34±0.86 |
| | **% Drug Release** | 99.42 ± 3.36 | 98.72±2.26 |

## CONCLUSION

The present investigation successfully demonstrated the formulation and evaluation of a sitagliptin-loaded orodispersible film as a novel oral drug delivery system for the management of Type 2 Diabetes Mellitus. The solvent casting method proved to be a simple, reproducible, and economical technique for preparing thin, flexible, and uniform films with desirable physicochemical and mechanical characteristics. Appropriate selection of film-forming polymers, plasticizer, sweetening agents, and saliva stimulants contributed to the development of films possessing excellent flexibility, acceptable tensile strength, rapid disintegration, and uniform drug distribution.

The optimized formulation exhibited satisfactory thickness, weight uniformity, folding endurance, surface pH, moisture content, and drug content, indicating consistency in manufacturing. FTIR analysis confirmed the absence of significant drug-excipient interactions, demonstrating formulation compatibility. In vitro drug release studies revealed rapid and efficient release of sitagliptin, suggesting the potential for faster therapeutic availability compared with conventional tablets. Furthermore, stability studies performed according to ICH recommendations confirmed that the optimized formulation maintained its physical integrity, drug content, and dissolution characteristics throughout the storage period.

Overall, the developed sitagliptin orodispersible film offers significant advantages, including administration without water, improved patient compliance, enhanced convenience, rapid onset of drug release, and reduced risk of choking, making it particularly suitable for geriatric and dysphagic diabetic patients. This patient-friendly dosage form has considerable potential as an alternative to conventional tablets and may contribute to improved adherence and better glycemic control. Future studies involving pharmacokinetic evaluation, in vivo bioavailability, and large-scale manufacturing optimization may further establish its clinical utility and commercial feasibility.

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