

Development and In-Vitro Evaluation of Vildagliptin Fast Dissolving Tablets For Enhanced Oral Bioavailability

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ABSTRACT

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia caused by defects in insulin secretion, insulin action, or both. The global prevalence of type 2 diabetes mellitus continues to rise rapidly, creating a need for effective and patient-friendly drug delivery systems. Vildagliptin, a selective dipeptidyl peptidase-4 (DPP-4) inhibitor, is widely used in the treatment of type 2 diabetes mellitus as it enhances the activity of incretin hormones and improves glycemic control. However, conventional tablet formulations may show delayed disintegration and may not provide rapid onset of action. Therefore, the present study was undertaken to formulate and evaluate fast dissolving tablets (FDTs) of Vildagliptin to enhance dissolution rate, improve patient compliance, and facilitate rapid drug release. Fast dissolving tablets were prepared by the direct compression method using different concentrations of superdisintegrants such as croscarmellose sodium and sodium starch glycolate. Preformulation studies including organoleptic evaluation, solubility testing, melting point determination, physicochemical characterization, UV spectroscopic analysis, and drug-excipient compatibility study using FTIR spectroscopy were carried out to assess the properties of Vildagliptin prior to formulation. The prepared formulations were evaluated for various pre-compression and post-compression parameters. The optimized formulation exhibited satisfactory mechanical strength, rapid disintegration, and improved dissolution characteristics. The results indicated that the developed Vildagliptin fast dissolving tablets provide faster drug release and may offer improved therapeutic effectiveness and better patient convenience compared to conventional oral tablets.

Keywords: Vildagliptin, Fast Dissolving Tablets, Direct Compression, Superdisintegrants, Dissolution Study, Type 2 Diabetes Mellitus.

1. INTRODUCTION

1.1. Diabetes mellitus

Diabetes mellitus is a chronic, multifactorial metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or a combination of both.[1,2] The disease is recognized as one of the most significant non-communicable diseases (NCDs) worldwide and constitutes a major global health challenge due to its rapidly increasing prevalence, chronic nature, lifelong requirement for pharmacotherapy, and strong association with debilitating complications.[3,4] Diabetes not only imposes a substantial clinical burden but also leads to significant socioeconomic consequences, including increased healthcare expenditure, reduced quality of life, loss of productivity, and premature mortality.[5]

1.1.1. Burden Of Diabetes in India

India represents one of the epicenters of the global diabetes epidemic and is often referred to as the “diabetes capital of the world.” According to the International Diabetes Federation (2021), India had approximately 74.2 million adults with diabetes, making it the country with the second highest number of diabetic individuals globally, after China. Projections suggest that this number may increase to 124.9 million by 2045, highlighting the urgent need for effective preventive and therapeutic strategies.[6]

The Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) Study, a large-scale national survey, reported significant regional variation in diabetes prevalence across urban and rural populations. Urban areas exhibit a substantially higher prevalence of diabetes compared to rural regions, largely due to lifestyle factors such as physical inactivity, unhealthy dietary habits, and higher prevalence of obesity. However, recent trends indicate a rapid rise in diabetes prevalence in rural populations as well, suggesting widespread lifestyle transitions.[7]

- India faces unique challenges in diabetes management, including:
- Late diagnosis due to low awareness and limited access to healthcare
- High prevalence of undiagnosed diabetes[8]
- Socioeconomic disparities affecting treatment adherence
- Limited access to advanced therapeutic options in rural and semi-urban areas
- Coexistence of malnutrition and obesity in different population segments[9]

The economic burden of diabetes in India is substantial, with significant out-of-pocket expenditure on medications, diagnostics, and management of complications. Diabetes-related healthcare costs contribute to financial strain on families and increase the overall burden on the healthcare system.[10]

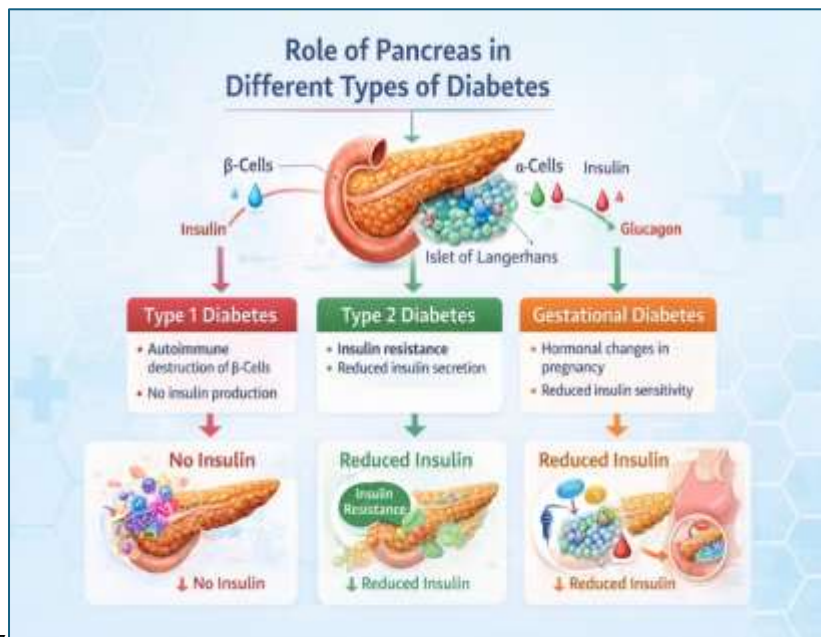


Fig 1: Role of Pancreas in Different Type of Diabetes

1.1.2. Causes

In prediabetes and type 2 diabetes mellitus, peripheral tissues become resistant to the action of insulin, and the pancreas is unable to produce sufficient insulin to overcome this resistance. As a result, glucose accumulates in the bloodstream instead of being taken up by cells for energy. Obesity, genetic predisposition, and environmental factors contribute significantly to the development of type 2 diabetes mellitus. Although excess body weight is strongly associated with type 2 diabetes mellitus, the condition can also occur in individuals who are not overweight.[11]

2. MATERIALS AND METHODS

2.1. Materials

Vildagliptin was obtained as a gift sample from a Bal Pharma Rudhrapur, Uttarkhand India. Microcrystalline cellulose PH 102, mannitol, croscarmellose sodium, sodium starch glycolate, magnesium stearate, and aspartame were used as excipients in the formulation of fast dissolving tablets. All chemicals and reagents used during the study were of analytical grade and procured from N.V.D. Scientific Pvt. Ltd. Lucknow.

2.2. Preformulation Studies

Preformulation studies were carried out to determine the physicochemical and analytical characteristics of Vildagliptin prior to formulation development. These studies provide valuable information regarding the behavior of the drug substance and help in selecting suitable excipients and manufacturing techniques for the development of fast dissolving tablets.[12]

2.2.1 Organoleptic Evaluation

The organoleptic properties of Vildagliptin were examined to determine its basic physical characteristics. The drug sample was visually inspected for its appearance, color, and odor. Organoleptic analysis helps in identifying the drug and detecting any possible impurities or degradation products.[13]

2.2.2 Solubility Study

The solubility of Vildagliptin was investigated in different solvents to evaluate its dissolution characteristics. An excess amount of the drug was introduced into various solvents such as distilled water, methanol, ethanol, and phosphate buffer (pH 6.8). The mixtures were continuously agitated using a mechanical shaker until equilibrium was achieved. After equilibration, the solutions were filtered through filter paper and analyzed to determine the extent of drug solubility. Understanding solubility behavior is essential because it directly affects the dissolution rate and absorption of the drug from oral dosage forms.[14]

2.2.3 Determination of Melting Point

The melting point of Vildagliptin was determined using the capillary tube method in a digital melting point apparatus. A small amount of the drug was filled into a sealed capillary tube and placed in the apparatus. The temperature at which the drug began to melt and the temperature at which it completely liquefied were recorded. The melting point determination provides an indication of the purity and crystalline nature of the drug substance.[15]

2.2.4 Physicochemical Characterization

Physicochemical properties of Vildagliptin powder were evaluated to assess its suitability for tablet formulation and compression.[16]

2.2.4.1 Density Measurement

Density measurements were performed to understand the packing characteristics and compressibility behavior of the drug powder.[17]

a) Bulk Density

Bulk density was determined by transferring a known quantity of Vildagliptin powder into a graduated cylinder without applying external compaction. The volume occupied by the powder was recorded.[17]

$$\text{Bulk Density} = \text{Weight of powder} / \text{Bulk volume}$$

b) Tapped Density

Tapped density was measured by placing the cylinder containing the powder into a tapping apparatus. The cylinder was tapped repeatedly until a constant volume was obtained.[18]

$$\text{Tapped Density} = \text{Weight of powder} / \text{Tapped volume}$$

2.2.4.2 Flow Property

The flow behavior of Vildagliptin powder was assessed to determine its suitability for direct compression during tablet manufacturing.[19]

a) Carr's Index

Carr's Index was calculated from the bulk and tapped density values to evaluate compressibility of the powder.[20]

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

b) Angle of Repose

The angle of repose was determined using the fixed funnel method. The powder was allowed to flow through a funnel to form a conical heap on a flat surface. The height and radius of the pile were measured.[21]

$$\theta = \tan^{-1} (h / r)$$

Where

h = height of powder pile

r = radius of the base

c) Hausner's Ratio

Hausner's ratio was calculated as an additional parameter for evaluating powder flowability.[22]

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

Values close to unity indicate good flow characteristics.

2.2.5 UV Spectroscopic Analysis

UV-Visible spectrophotometry was used for quantitative estimation of Vildagliptin in various analytical procedures such as calibration curve preparation, drug content determination, and dissolution studies.[23]

a) Determination of λ_{max}

A standard solution of Vildagliptin was prepared in an appropriate solvent and scanned in the wavelength range of 200–400 nm using a UV-Visible spectrophotometer. The wavelength at which maximum absorbance was observed was selected for further analysis.[24]

b) Preparation of Calibration Curve

A stock solution of Vildagliptin was prepared by dissolving an accurately weighed quantity of the drug in a suitable solvent. From this stock solution, a series of dilutions with different concentrations were prepared.[25]

The absorbance of each solution was measured. A calibration graph was constructed by plotting concentration versus absorbance. The resulting linear regression equation was used for determining the drug concentration in subsequent analytical studies.[26, 27]

2.2.6 Drug-Excipient Compatibility Study (FTIR Analysis)

Fourier Transform Infrared (FTIR) spectroscopy was carried out to evaluate the compatibility between Vildagliptin and the selected excipients used in the formulation. The FTIR spectra of pure drug and physical mixtures of the drug with excipients were recorded using the KBr pellet method in the spectral range of 4000–400 cm^{-1} . [28]

Characteristic absorption bands corresponding to functional groups of Vildagliptin were analyzed and compared with those present in the drug-excipient mixture. The absence of major peak shifts or disappearance of characteristic peaks indicated that no chemical interaction occurred between the drug and the excipients.[29]

2.3. Formulation Development of Vildagliptin Fast Dissolving Tablets

Fast dissolving tablets of Vildagliptin were prepared by the direct compression method using different concentrations of superdisintegrants such as croscarmellose sodium and sodium starch glycolate. These superdisintegrants were selected to enhance the disintegration rate of the tablets and promote rapid drug release in the oral cavity.[30,31]

Table 1: Formulation of Vildagliptin

Ingredient (mg)	V1	V2	V3	V4	V5	V6
Drug	50	50	50	50	50	50
CCS	5	7	9	-	-	-
SSG	-	-	-	5	7	9
MCC PH 102	40	38	36	40	38	36
Mannitol	50	48	46	50	48	46
Aspartame	2	2	2	2	2	2
Magnesium Stearate	3	3	3	3	3	3
Total Weight (mg)	150	150	150	150	150	150

2.4. Procedure for Preparation of Fast Release Tablets

5.6. All ingredients required for each formulation batch were accurately weighed using an analytical balance according to the formulation design to ensure precision and avoid cross-contamination between batches. The active pharmaceutical ingredient (Vildagliptin), along with superdisintegrants such as croscarmellose sodium and/or sodium starch glycolate, diluents including microcrystalline cellulose PH 102 and mannitol, and the sweetener aspartame, were individually passed through a #60 mesh sieve to remove lumps and obtain a uniform particle size distribution. The sieved drug and excipients, excluding magnesium stearate, were transferred to a clean and dry mortar and blended thoroughly for about 10–15 minutes using the geometric dilution technique to ensure uniform distribution of the drug within the powder mixture and to achieve content uniformity in the final tablets. After uniform mixing, magnesium stearate that had been previously passed through a #60 mesh sieve was added as a lubricant and gently blended with the powder mixture for about 2–3 minutes to prevent over-lubrication, which may affect tablet hardness, disintegration, and dissolution properties. The final lubricated powder blend was then evaluated for pre-compression parameters such as bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio to determine its flow characteristics and suitability for direct compression. Finally, the prepared blend was compressed into tablets using a rotary tablet compression machine fitted with flat-faced punches of suitable diameter, and the compression force was adjusted to obtain tablets with adequate mechanical strength while maintaining rapid disintegration, with in-process checks performed periodically for tablet weight and thickness.[32,33, 34]

Weighing of Ingredients

↓

Sieving of All Ingredients

(#60 Mesh Sieve)

↓

Mixing of Vildagliptin with Diluent and Superdisintegrants
(Geometric dilution for 10–15 minutes)

↓

Addition of Sweetener (Aspartame)

↓

Addition of Lubricant (Magnesium Stearate)
(Gentle mixing for 2–3 minutes)

↓

Pre-compression Evaluation of Powder Blend
(Bulk density, Tapped density, Angle of repose, Carr's index, Hausner's ratio)

↓

Compression of Blend using Rotary Tablet
Compression Machine

↓

Vildagliptin Fast Dissolving Tablets

2.5. Evaluation of Vildagliptin Fast Dissolving Tablets

2.5.1. Weight Variation

The weight variation test was performed to determine the uniformity of tablet weight in each formulation batch. Twenty tablets were randomly selected and weighed individually using a digital analytical balance. The average weight of the tablets was calculated, and the percentage deviation of each tablet from the average weight was determined. According to pharmacopeial standards, not more than two tablets should deviate from the specified percentage limits, and none should deviate by more than twice the permitted limit.[35]

$$\text{Percentage deviation} = \frac{(\text{Tablet Weight} - \text{Average Weight})}{\text{Average Weight}} \times 100$$

2.5.2. Friability

Friability testing was conducted to evaluate the mechanical strength of Vildagliptin tablets and their resistance to abrasion during handling and transportation. The test was performed using a Roche friabilator. A pre-weighed sample of tablets was placed in the rotating drum and subjected to 100 revolutions at 25 rpm. After the test, tablets were removed, dedusted, and reweighed. The percentage weight loss was calculated. A friability value not exceeding 1% is considered acceptable.[36]

$$\% \text{ Friability} = \frac{(W_1 - W_2)}{W_1} \times 100$$

Where:

W_1 = Initial weight of tablets

W_2 = Final weight of tablets after the test

2.5.3. Thickness

Tablet thickness was measured to ensure uniformity in tablet dimensions. Consistent thickness is important for packaging and maintaining dose uniformity. Ten tablets from each batch were randomly selected and their thickness was measured using a Vernier caliper or digital thickness gauge. The mean thickness and standard deviation were calculated.[37]

2.5.4. Hardness

Hardness testing was performed to determine the mechanical strength of Vildagliptin tablets. Adequate hardness is necessary to withstand handling, packaging, and transportation. Five tablets from each formulation batch were tested using a Monsanto hardness tester. The force required to break each tablet was recorded in kg/cm² and the average hardness was calculated.[38]

2.5.5. Disintegration Test

The disintegration test was carried out using a USP disintegration test apparatus. The apparatus consists of six glass tubes fitted with a 10-mesh screen at the bottom. One tablet was placed in

each tube and the basket assembly was immersed in a one-liter beaker containing distilled water maintained at $37 \pm 2^\circ\text{C}$. The basket rack assembly was allowed to move up and down at a frequency of 28–32 cycles per minute. The time required for the tablets to break down completely without leaving residue on the screen was recorded as the disintegration time.[39]

2.5.6. Wetting Time and Water Absorption Ratio

a) Wetting Time

Wetting time indicates the ability of the tablet to absorb moisture and initiate disintegration. A circular tissue paper was placed in a Petri dish containing 10 mL of water with eosin dye. A tablet was placed on the tissue paper and the time required for water to reach the upper surface of the tablet was recorded as the wetting time.[40]

b) Water Absorption Ratio

Water absorption ratio represents the ability of the tablet to absorb water, which influences the disintegration process. A piece of tissue paper folded twice was placed in a Petri dish containing 6 mL of water. A pre-weighed tablet was placed on the paper and allowed to absorb water. After complete wetting, the tablet was removed and weighed again.[41]

$$R = 100 \times \frac{(W_a - W_b)}{W_b}$$

Where:

W_b = Weight of tablet before placing in Petri dish

W_a = Weight of wetted tablet

2.5.7. Dissolution Study

The dissolution test was carried out using six tablets placed individually in dissolution vessels containing 900 mL of 0.1 N HCl maintained at $37 \pm 0.5^\circ\text{C}$. The paddle was rotated at 50 rpm. At predetermined time intervals, samples were withdrawn and replaced with fresh dissolution medium to maintain sink conditions. The samples were filtered and analyzed spectrophotometrically at 211 nm.[42]

2.5.8. Estimation of Drug Content

Drug content analysis was performed to determine the amount of Vildagliptin present in the tablets. Ten tablets were weighed and finely powdered. A quantity of powder equivalent to 100 mg of Vildagliptin was dissolved in 100 mL of 0.1 N HCl, filtered, and suitably diluted. The absorbance of the solution was measured at 211 nm using a UV spectrophotometer. The drug concentration was calculated using the calibration curve.[43]

2.5.9. Uniformity of Dispersion

Uniformity of dispersion was evaluated to determine whether the tablet disperses uniformly without forming lumps. Two tablets were placed in 100 mL of distilled water and stirred gently for 2 minutes. The dispersion was passed through a #22 sieve. Absence of residue on the sieve indicated uniform dispersion.[44]

2.5.10. Drug Content Uniformity

Drug content uniformity ensures that each tablet contains the intended amount of Vildagliptin. Ten tablets were powdered and a quantity equivalent to one tablet dose was dissolved in a suitable solvent. The solution was filtered, diluted, and analyzed spectrophotometrically at 211 nm.[45]

$$\% \text{ Drug Content} = \frac{\text{Measured Drug Content}}{\text{Label Claim}} \times 100$$

2.5.11. In-Vitro Bioavailability Study (Permeability Study)

Bioavailability refers to the proportion of an administered drug that reaches systemic circulation in an unchanged form. For orally administered drugs, bioavailability is influenced by dissolution rate, intestinal permeability, and first-pass metabolism.[46]

The Caco-2 cell model was used to evaluate intestinal permeability of Vildagliptin. Caco-2 cells are derived from human colorectal adenocarcinoma and form a monolayer resembling intestinal epithelial cells when cultured under appropriate conditions.[47]

During the permeability experiment, the drug formulation was applied to the apical side of the Caco-2 monolayer, representing the intestinal lumen. The amount of drug transported to the

basolateral side was measured over time. The permeability of the drug was expressed as the apparent permeability coefficient (P_{app}).[48]

$$P_{app} = \frac{dQ}{dt} \frac{1}{A \times C_0}$$

Where:

P_{app} = Apparent permeability coefficient (cm/s)

dQ/dt = Rate of drug transport across the membrane

A = Surface area of the cell monolayer (cm²)

C₀ = Initial drug concentration in the donor compartment

2.5.12. Stability Studies

Stability studies were conducted to evaluate the ability of the optimized Vildagliptin tablets to maintain their quality, safety, and efficacy during storage.

Procedure:

The optimized formulation was stored under accelerated conditions at 40°C ± 2°C and 75% ± 5% relative humidity for three months. Samples were withdrawn at 0, 1, 2, and 3 months and evaluated for physical appearance, hardness, disintegration time, drug content, and dissolution behavior.[49]

3. Result And Discussion

3.1. Pre formulation Studies

3.1.1. Organoleptic Evaluation

Table 2: Organoleptic Properties of Sitagliptin and Vildagliptin

Drug	Appearance	Color	Odor	Taste
Vildagliptin	Crystalline powder	Off-white	Odorless	Slightly bitter

3.1.2. Physicochemical Characterization

Table 3: Physicochemical Characterization

Parameters	Results
Bulk Density	0.44 ± 0.02 g/ml
Tapped Density	0.51 ± 0.02 g/ml
Carr's Index	13.73
Hausner's Ratio	1.16
Angle of Repose	27.4 ± 1.0

3.1.3. Particle Size Distribution

Table 4: Particle Size Distribution of Final Blends

Sieve No.	% Retained
#20	2.1
#40	7.9
#60	17.6
#80	23.9
#100	22.1
#140	15.4
#200	8.6
Pan	2.4

3.1.4. UV Spectroscopic Analysis

a) Determination of λ_{max}

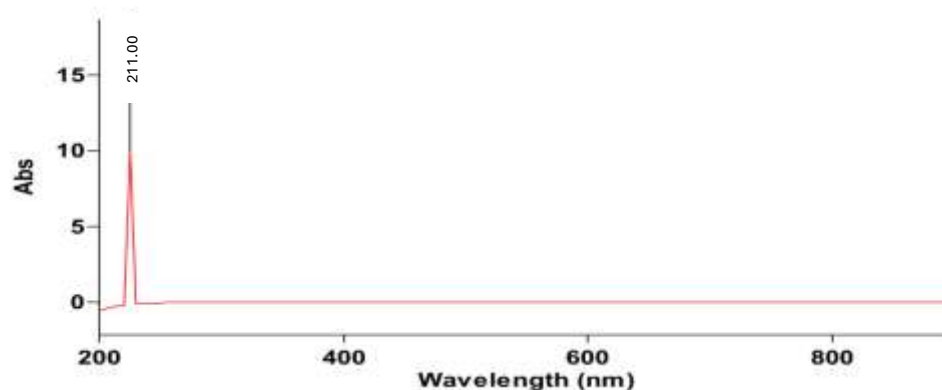


Fig 2: UV Spectra of Vildagliptin

b) Calibration Curve Results

Table 5: Calibration Curve Data for Vildagliptin ($\lambda_{max} = 211 \text{ nm}$)

S. No.	Concentration ($\mu\text{g/mL}$)	Absorbance (Mean \pm SD)
1	0	0.000 \pm 0.000
2	2	0.062 \pm 0.002
3	4	0.124 \pm 0.003
4	6	0.246 \pm 0.004
5	8	0.369 \pm 0.004
6	10	0.492 \pm 0.005

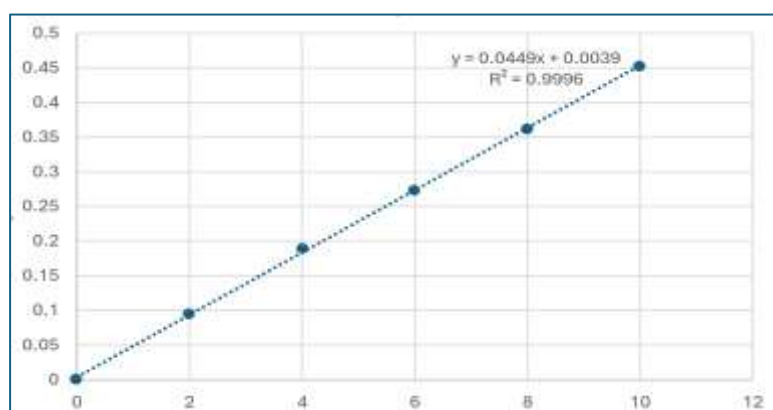


Fig 3: Calibration Curve of Vildagliptin

3.1.5. Drug-Excipient Compatibility (FTIR)

Table 6: FTIR Compatibility Summary

Sample	Characteristic Peaks Observed	Peak Shifts/New Peaks	Compatibility
Pure Vildagliptin	Present	None	Compatible
Drug + Excipients (Mixture)	Retained	None	Compatible

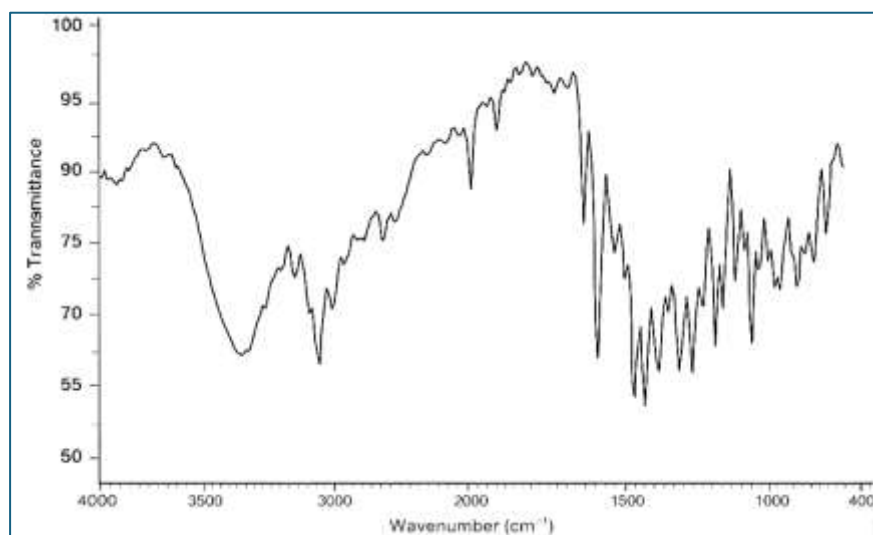


Fig 4: FTIR Spectra of Vildagliptin

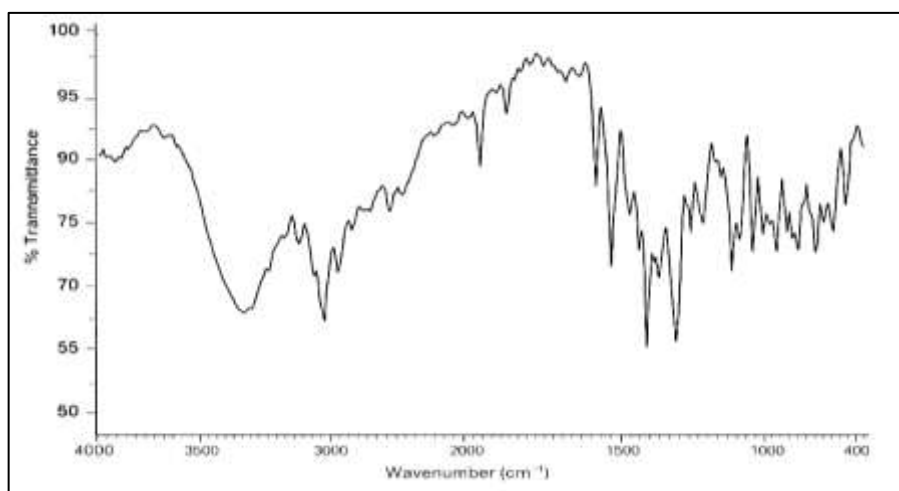


Fig 5: FTIR Spectra of Vildagliptin and Polymer

3.1.6. Solubility Testing

Table 7: Solubility of Vildagliptin

Medium	Vildagliptin
Distilled Water	Freely soluble
0.1 N HCl	Freely soluble
Phosphate Buffer pH 6.8	Soluble
Methanol	Freely soluble
Ethanol	Soluble
Acetone	Slightly soluble
Chloroform	Sparingly soluble
Acetonitrile	Soluble
Dimethyl Sulfoxide (DMSO)	Freely soluble

3.1.7. Melting point:

Table 8: Melting Point

Drug	Trial 1 (°C)	Trial 2 (°C)	Trial 3 (°C)	Average Melting Point (°C)	Reported Range (°C)
Vildagliptin	151	152	153	152	150-155

3.2. Evaluation of Formulation

3.2.1. Physical Appearance of Vildagliptin Tablets

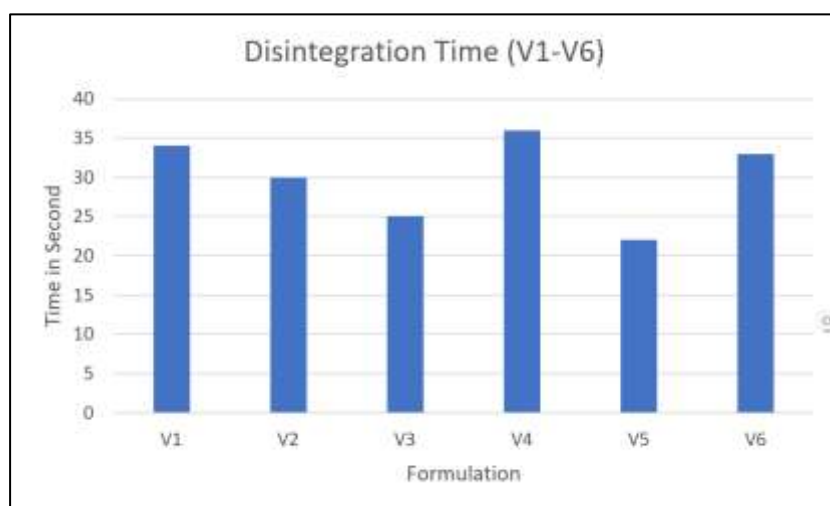
Table 9: Physical Appearance (V1-V6)

Batch	Shape	Color	Surface Texture	Defects (Cracks/Chipping)
V1	Round	Off-white	Smooth	None observed
V2	Round	Off-white	Smooth	None observed
V3	Round	Off-white	Smooth	None observed
V4	Round	Off-white	Smooth	None observed
V5	Round	Off-white	Smooth	None observed
V6	Round	Off-white	Smooth	None observed

3.2.2. Weight Variation, Friability, Hardness Thickness & Disintegration Time of Vildagliptin Tablets

Table 10: Weight Variation, Friability, Hardness Thickness & Disintegration Time

Batch	Weight Variation (%)	Friability (%)	Hardness (kg/cm ²)	Thickness (mm)	Disintegration Time (sec)
V1	1.5	0.57	2.5	3.1	34
V2	1.4	0.54	2.6	3.1	30
V3	1.5	0.56	2.5	3.1	25
V4	1.7	0.60	2.4	3.2	36
V5	1.6	0.52	2.6	3.0	22
V6	1.6	0.55	2.7	3.0	33

**Fig 6: Disintegration Time (V1-V6)**

3.2.3. Water Absorption Ratio Wetting Time and Drug Content of Vildagliptin Tablets

Table 11: Water Absorption Ratio, Wetting Time and Drug Content (V1-V6)

Batch	Water Absorption Ratio (%)	Wetting Time (sec)	Drug Content (%)
V1	76	29	98.1
V2	81	26	99.02
V3	87	21	98.5
V4	74	31	97.6
V5	89	19	99.7
V6	79	28	99.2

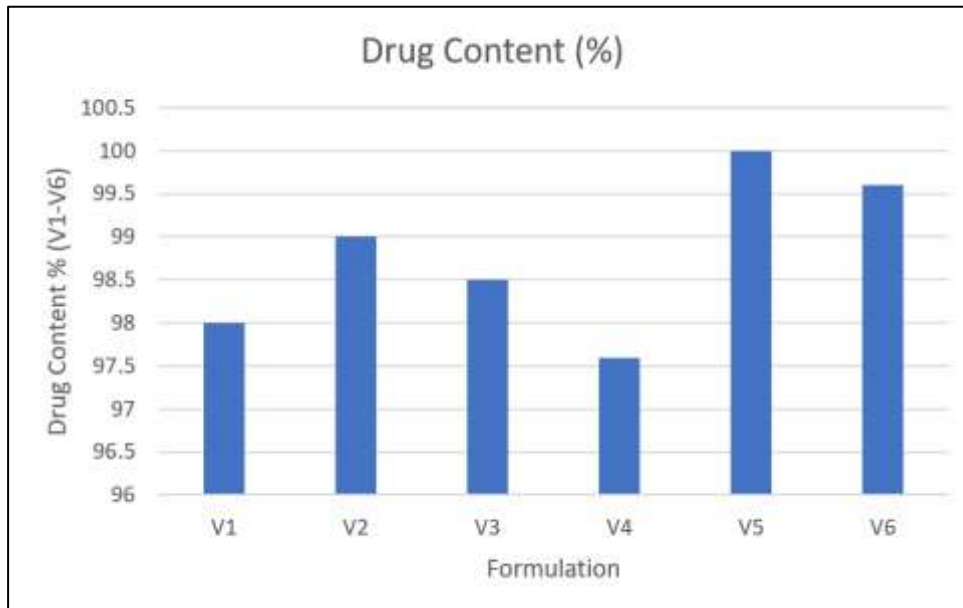


Fig 7: % Drug Content

3.2.4. % Drug Release of Vildagliptin Tablets

Table 12: % Drug Release of Vildagliptin Tablets (V1-V6)

Batch	0 min	1 min	2 min	3 min	4 min	5 min
V1	0	11.8	22.4	35.3	46.7	53.0
V2	0	13.0	24.7	37.9	48.9	56.2
V3	0	12.5	23.1	36.2	47.6	55.0
V4	0	10.2	19.8	30.6	41.5	50.1
V5	0	17.9	30.6	46.2	55.8	63.5
V6	0	15.6	27.5	41.8	51.3	60.4

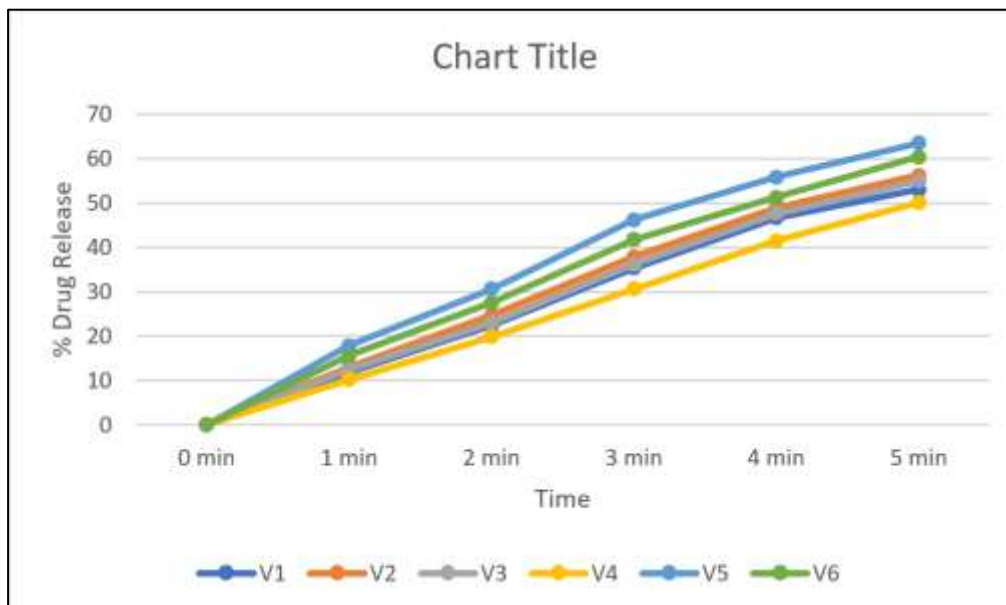


Fig 8: % Drug Release of Vildagliptin Tablets (V1-V6)

3.2.5. Uniformity Of Dispersion of Vildagliptin Tablets

Table 13: Uniformity Of Dispersion of Vildagliptin Tablets

Batch	Observation	Residue on Sieve (#22)
V1	Uniform dispersion observed	No residue
V2	Uniform dispersion observed	No residue

V3	Rapid and uniform dispersion	No residue
V4	Uniform dispersion observed	No residue
V5	Uniform dispersion observed	No residue
V6	Uniform dispersion observed	No residue

3.3. In Vitro Bioavailability Study

Table 14: In Vitro Permeability of Vildagliptin Formulations (Caco-2 Cell Model)

Formulation	Drug	Apparent Permeability Coefficient ($P_{app} \times 10^{-6} \text{ cm/s}$)	Transport Rate (%)
Marketed Tablet	Vildagliptin	2.47 ± 0.11	65.2 ± 1.4
Optimized FDT (V5)	Vildagliptin	3.98 ± 0.14	80.3 ± 1.6

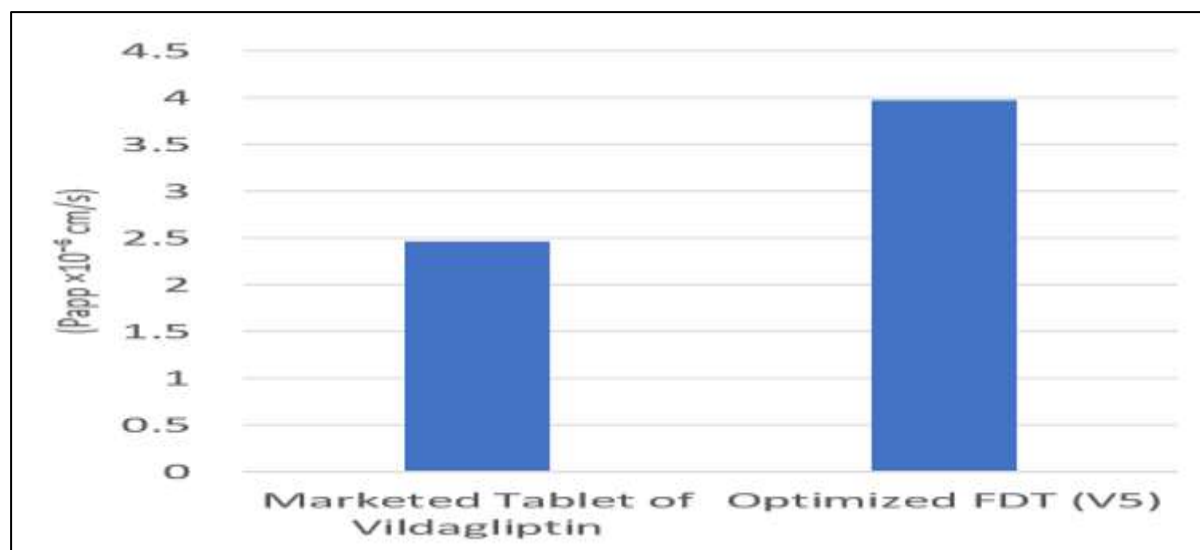


Fig. 9: In Vitro Permeability of Vildagliptin Formulations

Table 15: Cumulative Drug Permeation Across Caco-2 Cell Monolayer

Time (min)	Vildagliptin Marketed (%)	Vildagliptin FDT V5 (%)
15	20.7	32.4
30	36.8	53.7
45	51.6	69.5
60	65.2	80.3

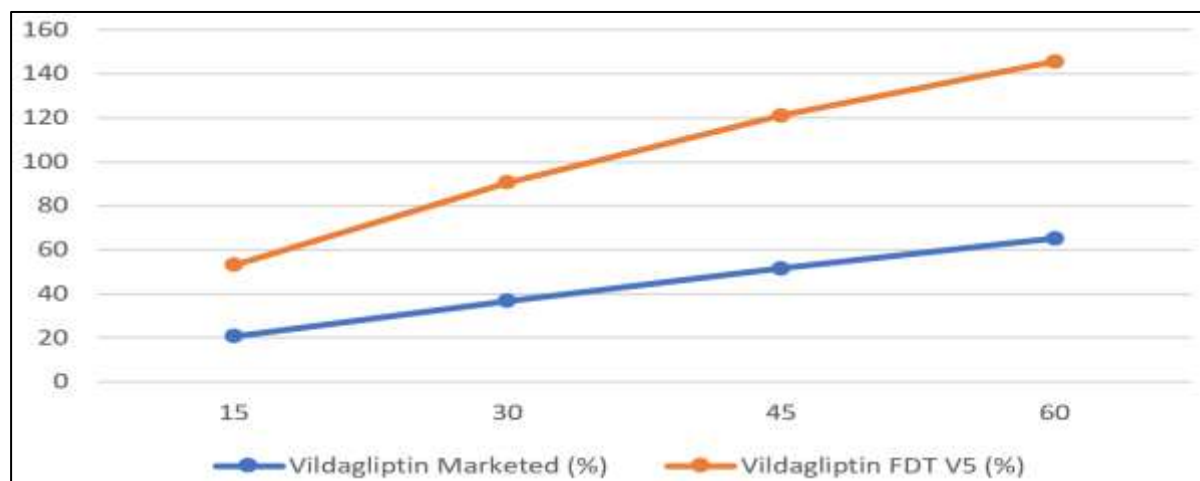


Fig. 10: Cumulative Drug Permeation Across Caco-2 Cell Monolayer

3.4. Stability Study

Table 16: Stability Study of Optimized Vildagliptin Formulation (V5)

Time	Physical Appearance	Drug Content (%)	Disintegration Time (sec)	% Drug Release (5 min)
Initial	Off-white, smooth tablet	99.7	22	63.5
1 Month	No change	99.6	22	63.3
2 Months	No change	99.6	24	63.01
3 Months	No change	99.4	25	62.7

4. CONCLUSION

The present study was carried out to formulate and evaluate fast dissolving tablets of Vildagliptin with the aim of improving drug dissolution and enhancing patient convenience. Preformulation studies were performed to investigate the physicochemical properties of the drug, including organoleptic characteristics, solubility behavior, melting point, flow properties, and drug-excipient compatibility. The results of these studies confirmed that Vildagliptin possesses suitable properties for the development of fast dissolving tablets and showed no significant interaction with the selected excipients.

Fast dissolving tablets were successfully prepared by the direct compression method using superdisintegrants such as croscarmellose sodium and sodium starch glycolate in varying concentrations. The prepared formulations were evaluated for various pre-compression and post-compression parameters including bulk density, tapped density, angle of repose, Carr's index, Hausner's ratio, weight variation, hardness, friability, thickness, disintegration time, wetting time, water absorption ratio, drug content, and in vitro dissolution profile.

The evaluation results demonstrated that the prepared tablets possessed acceptable mechanical strength, uniform weight distribution, and satisfactory drug content. The optimized formulation exhibited rapid disintegration and faster drug release compared with other formulations, indicating the effectiveness of the selected superdisintegrants in promoting quick tablet disintegration. The in vitro dissolution study confirmed that the developed formulation provides enhanced dissolution characteristics, which may contribute to improved drug absorption.

Overall, the study concluded that fast dissolving tablets of Vildagliptin can be successfully formulated using the direct compression technique, offering rapid disintegration, improved dissolution behavior, and better patient compliance. This formulation approach may provide a promising alternative to conventional oral tablets for the effective management of type 2 diabetes mellitus.

5. REFERENCE

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