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DESIGN DEVELOPMENT AND CHARACTERIZATION OF FAST DISINTEGRATING TABLET OF GLIPIZIDE BY SOLID DISPERSION TECHNIQUE

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Keywords:

Glipizide, Sodium caprylate, Super disintegrants, Fast-disintegrating tablets, FTIR studies

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ABSTRACT: Glipizide, a second-generation sulfonylurea, is extensively employed in the management of Type 2 diabetes mellitus due to its insulin secretagogue activity. However, its limited aqueous solubility, as classified under the Biopharmaceutics Classification System (BCS) Class II, results in dissolution rate-limited absorption and suboptimal oral bioavailability. The present investigation was aimed at enhancing the solubility and dissolution profile of Glipizide through the formulation of solid dispersions, followed by the development of fast-disintegrating tablets (FDTs) to improve therapeutic efficacy and patient compliance. Solid dispersions of Glipizide were prepared using sodium caprylate as a hydrophilic carrier in varying drug-to-carrier ratios (1:1 to 1:5) employing the solvent evaporation technique. The optimized ratio (1:3) was selected based on preliminary solubility enhancement studies. Fast-disintegrating tablets were subsequently formulated by direct compression utilizing superdisintegrants such as croscarmellose sodium, sodium starch glycolate, and locust bean gum at different concentrations. The prepared formulations were evaluated for micromeritic properties, tablet hardness, friability, content uniformity, disintegration time, and in vitro dissolution behavior. The results demonstrated that all formulations exhibited acceptable physicomechanical properties. Among them, formulation F6 containing 6.5 mg of locust bean gum exhibited superior performance, achieving rapid disintegration and 99.5% cumulative drug release within 30 minutes. Fourier-transform infrared (FTIR) spectroscopy confirmed the absence of significant drug–excipient interactions. The study concludes that the integration of solid dispersion technology with fast-disintegrating tablet formulation significantly enhances the dissolution characteristics of Glipizide, thereby potentially improving its bioavailability and clinical performance.

INTRODUCTION: Diabetes mellitus is a multifactorial metabolic disorder characterized by chronic hyperglycemia resulting from defects in insulin secretion, insulin action, or a combination of both. Type 2 diabetes mellitus, the most prevalent form, necessitates sustained pharmacological intervention for effective glycemic control.

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Glipizide, a second-generation sulfonylurea, exerts its pharmacological action by inhibiting ATP-sensitive potassium channels in pancreatic β-cells, thereby stimulating insulin release.

Despite its clinical efficacy, Glipizide exhibits poor aqueous solubility, which significantly limits its dissolution rate and contributes to variable oral bioavailability. According to the Biopharmaceutics Classification System, it is categorized as a Class II drug, wherein dissolution is the rate-limiting step in systemic absorption. Consequently, enhancing its solubility is imperative to optimize therapeutic outcomes.

Solid dispersion technology has emerged as a robust strategy for improving the dissolution characteristics of poorly water-soluble drugs. This approach involves the molecular dispersion of the drug within a hydrophilic carrier matrix, leading to enhanced wettability, reduced particle size, and potential amorphization, thereby facilitating improved dissolution kinetics. In parallel, fast-disintegrating tablets represent an advanced oral drug delivery system characterized by rapid disintegration in the oral cavity without the requirement for water. This dosage form offers advantages such as improved patient compliance, particularly in geriatric and dysphagic populations, and a faster onset of action. Therefore, the present study aims to integrate solid dispersion technology with fast-disintegrating tablet formulation to enhance the dissolution rate and overall biopharmaceutical performance of Glipizide.

MATERIALS AND METHODS:

Materials: Glipizide was procured from the central store of Smriti College of Pharmaceutical Education, Indore. Sodium caprylate was utilized as a hydrophilic carrier. Superdisintegrants including croscarmellose sodium, sodium starch glycolate, and locust bean gum were employed. Microcrystalline cellulose served as a diluent, while talc and magnesium stearate were used as glidant and lubricant, respectively. All materials were of analytical grade.

Methods:

Organoleptic Characterization: The drug sample of Glipizide was subjected to organoleptic evaluation to assess its physical characteristics, including color, odor, and general appearance. The sample was visually inspected under normal lighting conditions to confirm uniformity and absence of any visible impurities or degradation. These parameters serve as preliminary indicators of drug identity and purity.

Determination of Melting Point: The melting point of Glipizide was determined using the capillary fusion method to assess its purity and crystalline nature. A small quantity of the drug was filled into a sealed capillary tube and placed in a digital melting point apparatus. The temperature at which the drug sample completely melted was recorded. A sharp and narrow melting range indicates the purity of the compound, whereas deviations may suggest the presence of impurities or polymorphic variations.

Solubility Analysis: The solubility profile of Glipizide was evaluated in various solvents, including distilled water, phosphate buffer (pH 6.8), ethanol, and methanol, using the saturation solubility method. An excess amount of drug was added to a known volume of each solvent and subjected to continuous agitation at controlled temperature until equilibrium was achieved. The resulting solutions were filtered, appropriately diluted, and analyzed using a UV-visible spectrophotometer. The solubility data provided critical insight into the drug's dissolution behavior and guided the selection of suitable formulation strategies.

Determination of Absorption Maximum (λmax):
Preparation of Standard Stock Solution: An accurately weighed quantity (10 mg) of Glipizide was transferred into a 100 ml volumetric flask. The drug was dissolved in a small volume of phosphate buffer (pH 6.8), and the final volume was adjusted to 100 ml with the same buffer to obtain a standard stock solution with a concentration of 100 µg/ml.

Spectral Scanning: An aliquot of 1 ml was withdrawn from the stock solution and further diluted to 10 ml with phosphate buffer (pH 6.8) to obtain a working concentration of 10 µg/ml. The solution was scanned over a wavelength range of 200–400 nm using a UV-visible spectrophotometer. The absorption spectrum exhibited a prominent peak at 224 nm, which was identified as the maximum absorption wavelength (λmax) for Glipizide. This wavelength was subsequently employed for all quantitative analytical estimation

TABLE 1: MATERIALS AND METHODS

S. no.	Material	Uses
1	Glipizide	Antidiabetic activity
2	Sodium Caprylate	Used as carrier in solid dispersion
3	Croscarmellose Sodium	Super disintegrant
4	Sodium starch glycolate	Super disintegrant
5	Locust bean gum powder	Super disintegrant
6	Microcrystalline cellulose	Used as binder
7	Talc	Used as glidant
8	Magnesium stearate	Used as lubricant

Calibration Curve of Glipizide: The calibration curve of Glipizide was developed by preparing standard solutions in the concentration range of 10–30 µg/ml from a pre-standardized stock solution prepared in phosphate buffer (pH 6.8). The absorbance of each dilution was recorded at 224 nm using a UV-visible spectrophotometer (UV-1800). The absorbance values were plotted against the corresponding concentrations to obtain a linear calibration curve, which was subsequently utilized for quantitative estimation in formulation analysis.

Preparation of Solid Dispersion: Solid dispersions of Glipizide were prepared by the solvent evaporation technique using sodium caprylate as a hydrophilic carrier. The drug and carrier were accurately weighed in different weight ratios (1:1, 1:2, 1:3, 1:4, and 1:5). The components were dissolved in a minimum quantity of ethanol under continuous magnetic stirring to obtain a clear and homogenous solution. The solvent was completely removed using a rotary vacuum evaporator under reduced pressure at controlled temperature conditions. The resulting solid mass was dried to eliminate residual solvent, then pulverized and passed through a 60-mesh sieve to ensure uniform particle size distribution. The prepared solid dispersions were stored in a desiccator until further use.

FTIR Spectral Analysis: FTIR studies were performed to investigate possible physicochemical interactions between Glipizide and excipients in the solid dispersion system. Spectra were recorded using a Thermo IR-200 FTIR spectrophotometer. Samples were prepared by the potassium bromide (KBr) pellet technique, wherein approximately 2 mg of sample was mixed with 100 mg of dry KBr and compressed under hydraulic pressure of 5–6 tons to form a transparent pellet. The pellets were scanned over a spectral range of 4000–400 cm^{-1} with a resolution of 4 cm^{-1} and 32 scans per sample to improve signal-to-noise ratio.

The obtained spectra of pure drug and solid dispersion were compared for shifts in characteristic peaks, disappearance of peaks, or changes in intensity to assess compatibility and confirm absence of chemical interaction.

Preparation of Fast-Disintegrating Tablets: Fast-disintegrating tablets of Glipizide were prepared using the direct compression technique. The solid dispersion equivalent to the required drug dose was accurately weighed along with excipients including superdisintegrants, microcrystalline cellulose, talc, and magnesium stearate.

All ingredients were passed through a 60-mesh sieve to ensure uniform particle size distribution. The powders were blended in a stainless-steel mortar using geometric dilution for 15 minutes to achieve uniform mixing.

The final blend was compressed using a single-punch tablet compression machine equipped with 8 mm flat-faced punches. Compression force was maintained between 5–7 kN to obtain tablets of desired hardness and rapid disintegration characteristics.

TABLE 2: FORMULATION TABLE ALL INGREDIENTS WERE TAKEN IN MG

Ingredients	F1	F2	F3	F4	F5	F6
10 mg equivalent of Glipizide in complex	40	40	40	40	40	40
Croscarmellose sodium	3.5	6.5	-	-	-	-
Sodium starch glycolate	-	-	3.5	6.5	-	-
Locust bean Gum	-	-	-	-	3.5	6.5
Microcrystalline cellulose	54.5	51.5	54.5	51.5	54.5	51.5
Talc	1	1	1	1	1	1
Magnesium stearate	1	1	1	1	1	1
Total quantity	100	100	100	100	100	100

Evaluation of Solid Dispersion:

Pre-compression Parameters:

Determination of Flow Properties:

Angle of Repose: The angle of incidence of the powder mixture was determined using the funnel method. The sample was taken & passed through funnel slowly to form a heap. The height of heap was measured. The circumference formed draw with the help of pencil on graph paper. Radius was observed and the angle of repose was determined.

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

Bulk density and Tapped Density: In bulk density sample of known mass was poured into graduated cylinder &the volume occupied was measured.

BD = weight of powder / volume of container

In tapped density sample of known mass was poured into graduated cylinder & the volume occupied of shaken container was measured.

TD = weight of powder / volume of shaken container.

Compressibility Index: The Carr's compressibility index (or Carr index) determined the compressibility index of the powder mixture.

Carr's index (%) = [(TBD – LBD) × 100] /TBD

Hausner's Ratio = Tapped Density / Bulk Density.

Tablet Preparation: Fast-disintegrating tablets were formulated using the direct compression method. All ingredients were weighed and sieved through a 60-mesh sieve, followed by mixing and compression into tablets.

Tablet Evaluation: The compressed tablets underwent examination under a tablet shape lens.

Diameter and Thickness: The diameter & the thickness of the tablet was measured with the help of vernier caliper & it was expressed in mm.

Friability: The friability of sample of 20 tablets was measured using Roche friabilator. Friability below 1% was acceptable.

%F = Initial Weight - Final weight / Initial weight × 100

Post compression Parameters:

Disintegration Test: The time taken by the dosage form to complete and break into fragments is called disintegration test.

***In-vitro* Dissolution Studies:** Dissolution studies were performed using USP Type II (paddle apparatus). Tablets equivalent to one dose of Glipizide were placed in 900 ml of phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C.

The paddle speed was set at 50 rpm. At predetermined time intervals (5, 10, 15, 20, 25, and 30 minutes), 5 ml aliquots were withdrawn and immediately replaced with fresh dissolution medium to maintain sink conditions.

Samples were filtered through Whatman filter paper and analyzed at 224 nm using UV-1800 spectrophotometer. All experiments were performed in triplicate, and results were expressed as mean ± standard deviation.

Drug Content: A randomly selected tablet was crushed in a glass mortar and pestle, and the powdered tablet was suspended in 100 ml of phosphate buffer (pH 6.8) with stirring on a magnetic stirrer. After 24 hours, the solution was filtered and the filtrate was analyzed by UV-1800 spectrophotometer at 224 nm.

RESULTS AND DISCUSSIONS:

Physical and Preformulation Studies: The drug was observed to be whitish in appearance and odorless, which is consistent with its standard organoleptic characteristics.

TABLE 3: PHYSICAL APPEARANCE OF GLIPIZIDE

S. no.	Parameters	Standard	Observed
1.	Color	Whitish Powder	Whitish Powder
2.	Odor	Odorless	Odorless

TABLE 4: MELTING POINT OF GLIPIZIDE

Drug	Reported Melting Point	Observed Melting Point
Glipizide	206-208 °C	208.1±0.16°C

TABLE 5: THE SOLUBILITY OF GLIPIZIDE IN VARIOUS SOLVENTS WAS ASSESSED

Solvent	Solubility mg/ml
Water	Poorly soluble
pH 6.8 buffer (0.2M)	Soluble
Ethanol	Freely soluble
Methanol	Very soluble

Evaluation of Precompression Parameters: Based on the obtained results, the values of the angle of repose, bulk density, shaking density, Carr's index, and Hausner's ratio indicate good flow properties for the formulation.

FTIR Studies: FTIR spectra of pure drug and solid dispersion showed no significant disappearance or major shifting of characteristic peaks, confirming compatibility between drug and excipients.

Minor shifts in functional groups (C=O, N–H, and S=O) were observed, indicating possible hydrogen bonding but no chemical interaction. This confirms stability of drug in formulation.

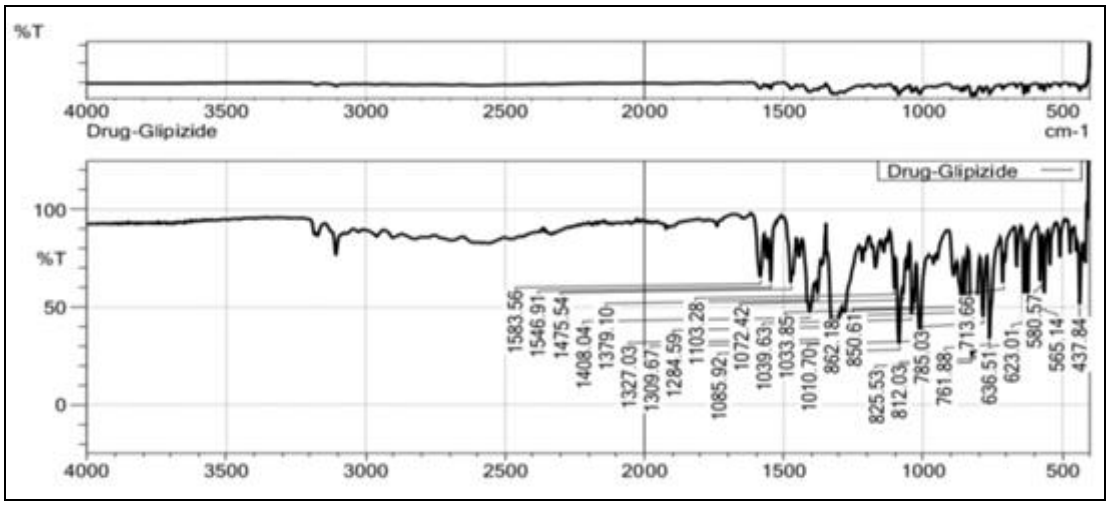

FIG. 1: FTIR GRAPH OF GLIPIZIDE

TABLE 6: INTERPRETATION TABLE FOR FT-IR OF GLIPIZIDE

S. no.	Functional group	Standard range	Interference
1	C=O	1670-1820 cm^{-1}	1687cm^{-1}
2	C=C	1400-1600 cm^{-1}	1444 cm^{-1}
3	S=O	1000-1410 cm^{-1}	1033 cm^{-1}
4	C-N	1325-1250 cm^{-1}	1160 cm^{-1}
5	N-H	1550-1640 cm^{-1}	1540 cm^{-1}

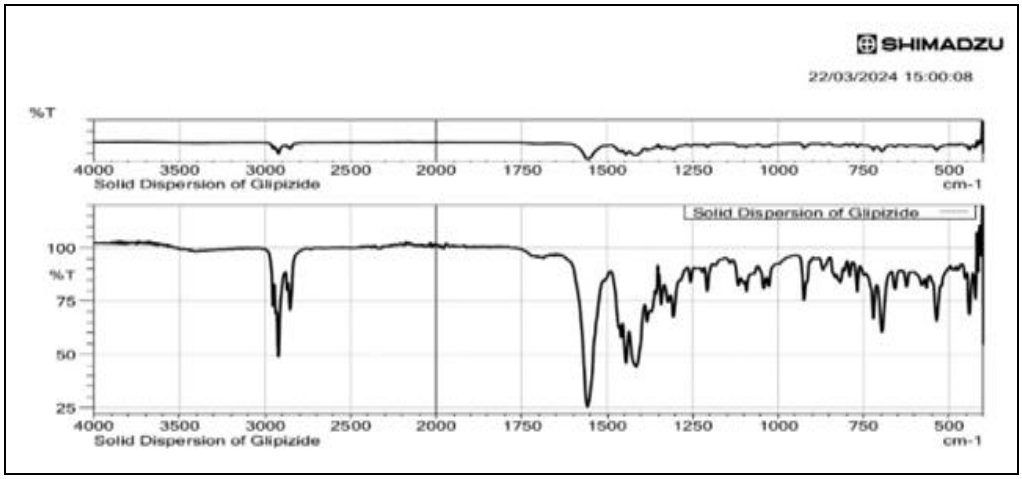

FIG. 2: FTIR GRAPH OF SOLID DISPERSION

TABLE 7: INTERPRETATION TABLE FOR FT-IR OF GLIPIZIDE (SOLID DISPERSION)

S. no.	Functional group	Standard range	Interference
1	C=O	1670-1820 cm^{-1}	1695cm^{-1}
2	C=C	1400-1600 cm^{-1}	1444 cm^{-1}
3	S=O	1000-1410 cm^{-1}	1026cm^{-1}
4	C-N	1325-1250 cm^{-1}	1207 cm^{-1}
5	N-H	1550-1640 cm^{-1}	1556 cm^{-1}

Absorption Maxima of Glipizide:

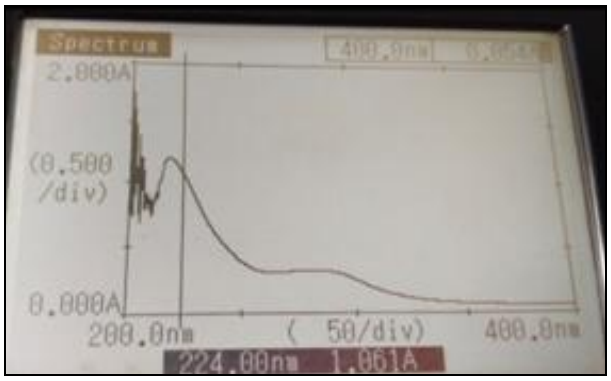

FIG. 3: DETERMINATION OF ABSORPTION MAXIMA OF GLIPIZIDE

Calibration Curve: The calibration curve showed linearity in the range of 10–30 µg/ml at 224 nm with a high correlation coefficient ($R^2 \approx 0.99$), confirming suitability of Beer–Lambert's law for quantitative analysis. Calibration curve of glipizide at 224 nm.

TABLE 8: CALIBRATION CURVE OF GLIPIZIDE IN PBS BUFFER (6.8)

S. no.	Concentration (µg/ml)	Absorbance
1	10	0.241
2	15	0.412
3	20	0.652
4	25	0.812
5	30	0.941

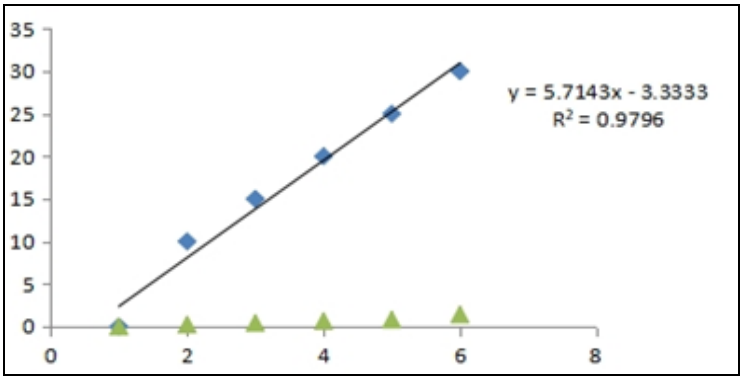

FIG. 4: CALIBRATION CURVE OF GLIPIZIDE

TABLE 9: THE *IN-VITRO* DISSOLUTION TEST PROFILE OF CROSCARMELLOSE SODIUM BY USING SOLID DISPERSION METHOD

S. no.	Time in min	Amount of drug dissolved	
		3.5 (F1)	6.5 (F2)
1	0	0	0
2	5	25.8	26.4
3	10	40.9	35.8
4	15	47.7	51.3
5	20	64.1	69.6
6	25	70.1	92.6
7	30	80.6	95.3

TABLE 10: THE *IN-VITRO* DISSOLUTION RATE TEST PROFILE OF SODIUM STARCH GLYCOLATE BY USING SOLID DISPERSION METHOD

S. no.	Time in min	Amount of drug dissolved	
		1.5 (F3)	6.5 (F4)
1	0	0	0
2	5	20.9	26.2
3	10	26.1	38.5
4	15	39.4	52.1
5	20	50.2	67.5
6	25	68.4	78.5
7	30	77.5	92.2

TABLE 11: THE *IN-VITRO* DISSOLUTION TEST PROFILE OF LOCUST BEAN GUM POWDER USING THE SOLID DISPERSION METHOD

S. no.	Time in min	Amount of drug dissolved	
		3.5 (F5)	6.5 (F6)
1	0	0	0

2	5	19.5	35.5
3	10	22.4	48.4
4	15	36.5	65.5
5	20	48.8	80.6
6	25	70.4	89.4
7	30	80.5	99.5

***In-vitro* Dissolution Study:**

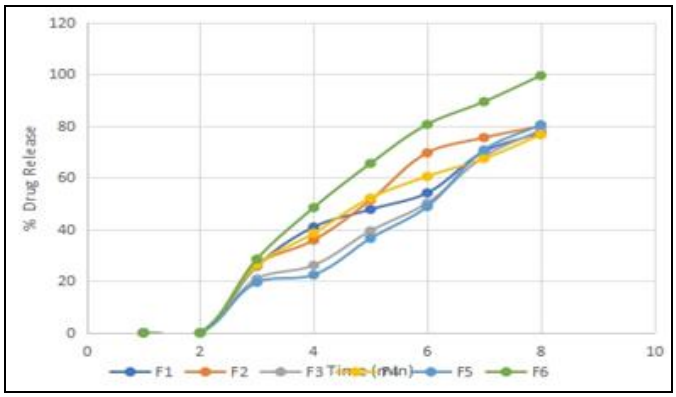

FIG. 5: GRAPH OF *IN-VITRO* DISSOLUTION STUDY

CONCLUSION: Glipizide, a BCS Class II antidiabetic agent, exhibits dissolution-rate–limited oral absorption due to its inherently poor aqueous solubility, resulting in reduced and variable bioavailability. In the present investigation, a solid dispersion approach using sodium caprylate as a hydrophilic carrier was successfully employed via the solvent evaporation technique to enhance solubility and wettability. The optimized drug–carrier ratio (1:3) demonstrated improved dispersion efficiency and likely partial amorphization, leading to enhanced dissolution characteristics. These dispersions were further engineered into fast-disintegrating tablets using direct compression with selected superdisintegrants, namely croscarmellose sodium, sodium starch glycolate, and locust bean gum, to achieve rapid tablet breakup and accelerated drug release kinetics.

Among all formulations, F6 containing locust bean gum exhibited superior performance with significantly reduced disintegration time and maximum cumulative drug release of 99.5% within 30 minutes. This enhanced performance is attributed to the high swelling index, rapid wicking action, and capillary water uptake of locust bean gum, which facilitated rapid tablet disintegration and efficient drug diffusion from the matrix. Overall, the synergistic application of solid dispersion technology and optimized superdisintegrant selection markedly improved the dissolution profile of Glipizide, thereby offering a promising strategy for enhancing its oral bioavailability and therapeutic efficacy in diabetes management.

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CONFLICTS OF INTEREST: Nil

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