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FORMULATION AND EVALUATION OF GLIBENCLAMIDE ORAL DISPERSIBLE TABLET BY SOLID DISPERSION TECHNIQUE

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Keywords:

Oral dispersible tablet, Solid dispersion technique, Direct compression method, Potential Drug Delivery Technology, Fusion methods, Disintegrating tablets

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ABSTRACT: Glibenclamide belongs to a group of medicines called sulfonylureas. Glibenclamide is used to manage diabetes. Glibenclamide, also known as glyburide, is an antidiabetic medication used to treat type 2 diabetes. The purpose of the present study was to formulate an Oral dispersible tablet of Glibenclamide using the Solid dispersion technique through using polyethylene glycol ratio as a water-soluble carrier. The solid dispersion of Glibenclamide was prepared by using fusion methods. The characterization of Glibeclamide solid dispersion powder was done by using several parameters like bulk density, tapped density, Carr's Index, Hausners's ratio, drug content, solubility and *in-vitro* dissolution study. While the oral dispersible tablet was prepared by using direct compression method. The prepared tablets were evaluated for disintegration time, moisture content, friability, and wetting time. From this study, it can be concluded that fast disintegrating tablets could be a potential drug delivery technology for managing diabetic patients.

INTRODUCTION: There are several types of routes of drug administration available, including oral, rectal, parenteral, nasal, topical, eye and ear routes of drug delivery. However, before choosing the right dosage form, special attention must be made to relating the drug substance to the clinical complication and factors governing the correct choice of drug administration, such as bioavailability and solubility, which must be taken into consideration.

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Amongst the route of administration, oral drug delivery remains the main and most appropriate and commonly employed route of administration due to its safety with the lowest microbial-related restrictions during the manufacturing process and high patient compliance due to ease of administration. It is mostly intended for systemic effect resulting in drug absorption in the gastrointestinal tract (GIT).

The drug gets dissolved in the fluid of the mouth or stomach and then gets absorbed into the systemic circulation. However, drawbacks are correlated with the highly desired route of administration due to the slow onset of action and gastrointestinal enzyme secretion, which can affect the absorption of the drug into the bloodstream. In the field of

pharmacy or pharmaceutics, a route of drug administration is the path by which a drug is taken into the human body. Additionally, a pure chemical substance must be formulated into an appropriate dosage form to be taken by the patient in the chosen route of administration. The main purpose of dosage form design is to reach and achieve a desired therapeutic outcome while maintaining reproducibility and high-quality control in the large batch production for the pharmaceutical industry. Glibenclamide is highly lipophilic and minimally soluble in aqueous media. According to the Biopharmaceutical Classification, Glibenclamide can be classified as a Class II hypoglycemic drug, poorly soluble but able to permeate gastrointestinal mucosa. The work aims to develop a stable, fast dissolving oral dispersible tablet of Glibenclamide for anti-diabetic effect.

MATERIALS & METHOD:

TABLE 1: LIST OF MATERIALS USED FOR TABLET PREPARATION

Sr. no.	Name of Material	Grade	Name of Supplier
1	Glibenclamide	AR	Aurochem Lab. Ltd., Mumbai
2	PEG 1500	AR	Loba Chemie Pvt. Ltd., Mumbai
3	PEG 4000	AR	Loba Chemie Pvt. Ltd., Mumbai
4	Talc	AR	Loba Chemie Pvt. Ltd., Mumbai
5	Magnesium Stearate	AR	Loba Chemie Pvt. Ltd., Mumbai
6	Lactose Monohydrate	AR	Loba Chemie Pvt. Ltd., Mumbai

TABLE 2: LIST OF EQUIPMENT USED FOR TABLET PREPARATION

Sr. no.	Equipment/Instrument	Make & Model
1	Analytical weighing balance	AUX220 Shimadzu, Japan
2	FT-IR spectrophotometer	Jasco, FT/IR-4100, Japan
3	UV-visible spectrophotometer	UV-1800 Shimadzu, Japan
4	Melting point apparatus	Veego, VMP, India
5	USP Dissolution test apparatus	Electrolab, TDL-08L, India
6	Hot Air Oven	Biotechnics& BTI-20D, India
7	Motic digital microscope	Motic Inco. Pvt.Ltd., B1-223ASC
8	Ultra-Centrifuge	REMI R-8C, India
9	Tapped density Apparatus	Electrolab ETD-1020, India

METHODS (EXPERIMENTAL WORK):

Preformulation Study:

Methods Preparation of Calibration Curve: Stock solution A was prepared by dissolving 10 mg of pure drug (Glibenclamide) in 100 mL volumetric flask and volume was made up to mark with phosphate buffer pH 7.4 1 ml of the stock solution A was taken in another volumetric flask and volume was made upto 100 ml with phosphate buffer pH 7.4 (stock solution B). Aliquots of 0.2 mL, 0.4 ml, 0.6 mL, and 0.8 mL were taken from Stock Solution B and diluted upto 10ml in order to get the concentration range from 2-10 µg/mL, and absorbance was noted at 237 nm using UV- VIS spectrophotometer (UV-1601 Shimadzu).

Melting Point Determination: The melting point is determined by a capillary method using melting point apparatus (vego VMP1). A very fine powder of drug is filled in the capillary, then sealed at one end. Due care was taken to maintain the uniform heating of the silicon bath, in which the capillary containing drug is placed. The temperature at which the column of the substance is collapsed and recorded as a melting point of the substance under test is compared with values given in standard value [9].

FTIR (Fourier Transform Infrared Spectroscopy): The IR spectrum of Glibenclamide was recorded using Fourier transform infrared spectrophotometer (FTIR-4100 (Jasco Japan)). Sample preparation done by mixing the drug with potassium bromide (KBr), and triturating it in a glass mortar. Add a spatula full of KBr into an agate mortar, take a small amount of powder sample (Glibenclamide) of 0.1-2% KBr and grind it to a fine powder. Finally, the sample is placed in the holder and scanned over a frequency range of 4000-400cm^{-1}. The spectrum obtained is compared with that reported in standard spectra [10].

Preparation of Solid Dispersion of Glibenclamide: Solid dispersions were prepared

by physical mixing and fusion method. **Table 3** describes the composition of various solid dispersions.

TABLE 3: COMPOSITION OF SOLID DISPERSION

Formulation Code	Drug (mg)	Polyethylene Glycol 1500 (mg)	Polyethylene Glycol 4000 (mg)
F1	15	25	25
F2	15	0	50
F3	15	05	45
F4	15	10	40
F5	15	15	35
F6	15	20	30
F7	15	30	20
F8	15	35	15
F9	15	40	10
F10	15	45	05
F11	15	50	0

Preparation of Glibenclamide-Peg Physical Mixture: Physical mixture of Glibenclamide with the combination of PEG 4000 and PEG 1500 in different ratios obtained by mixing the accurately weighed quantity of drug and carrier in a glass mortar and pestle for 5 minutes.

Preparation of Glibenclamide - Peg Solid Dispersion by Fusion Method: The physical mixture was melted in a water bath with gradually increasing temperature up to the value necessary for the complete melting. The molten mass was rapidly cooled with constant stirring using a glass rod. The resulting solid dispersions were stored in desiccator for 24 hrs, then grounded in mortar for 2 min. and passed through a 0.25 mm sieve (# 60).

Evaluation of Tablet: Flow properties of powder.

i) Angle of Repose: The angle of repose was determined by the funnel method. The funnel was adjusted to a height of 10 cm. After the powder blend was passed through 224 µm sieve. Accurately weighed 30g blend was allowed to flow through the funnel onto the surface freely. The diameter of the powder cone and height of the powder heap were measured, and the angle of repose was calculated according to Equation 1.

$$\theta = \tan^{-1}(h/r) \quad \text{Eq. 1}$$

Where, h is height, r is the radius of the powder cone, and θ is the angle of repose.

ii) Bulk Density (BD): Accurately weighed and sieved 30g of the blend was transferred to 250 ml graduated cylinder, carefully leveled without compacting, and the apparent bulk volume was read. Bulk density in g/ml was calculated using Equation 2.

$$\text{Bulk density} = \text{weight of powder} / \text{Bulk volume} \quad \text{Eq. 2}$$

iii) Tapped Density (TD): Accurately weighed and sieved 30 g of the blend was transferred to 250 ml graduated cylinder. Then, the cylinder was tapped using a tap densitometer at a fixed tap of 14 ± 2 mm and at a nominal rate of 300 taps per min, until no further change in the volume was noted (500 times), and the tapped volume was read. Finally, the tapped density in g /ml was calculated using Equation 3.

$$\text{Tapped density} = \text{Weight of powder} / \text{Tapped volume} \quad \text{Eq.3}$$

iv) Compressibility Index: The compressibility index has been proposed as an indirect measure of the size, shape, surface area, and cohesiveness of material. Carr's compressibility index determined the compressibility index of the powders according to Equation 4.

$$\text{Carr's index (\%)} = [(TD-BD) / TD \times 100] \quad \text{Eq. 4}$$

v) Hausner's Ratio: Hausner's ratio is a number correlated with the powders' flowability using TD and BD in Equation 5 [18].

$$\text{Hausner's Ratio} = TD / BD \quad \text{Eq. 5}$$

TABLE 4: STANDARD RANGE OF FLOW PROPERTIES

Flow character	Angle of repose (º)	Hausner's ratio	Carr's index (%)
Excellent	25-30	1.0-1.11	11-15
Good	31-35	1.1-1.18	16-20
Passable	36-40	1.19-1.25	21-25
Poor	41-50	1.26-1.34	26-30
Very Poor	51-55	1.35-1.45	31-30

Solubility Studies: The solubility of Glibenclamide was determined in different solvents systems (particularly phosphate buffer pH 7.4 and distilled water). An excess quantity of the drug was mixed with 10mL of each solvent in conical flasks and kept on a shaker for 24 h at room temperature. The further mixture is centrifuged at 3000 rpm for 15 min, followed by filtration. The filtrates were diluted with methanol, and the solutions were analyzed spectrophotometrically at λmax 237 nm.

Drug Content: An accurately weighed quantity of solid dispersions, equivalent to 10 mg of Glibenclamide, was transferred to a 100 mL volumetric flask containing ethanol and filtered. 5 mL of filtered solution was transferred to a 50 mL volumetric flask, diluted with pH 7.4 phosphate buffer, and analyzed (in triplicate) for drug content of Glibenclamide.

***In-vitro* Dissolution Studies:** *In-vitro* dissolution study was performed using USP dissolution apparatus II (DS 8000, Lab India); sample of the tablet were placed in 900 ml of phosphate buffer (pH 7.4) as a dissolution medium at 37±0.5ºC and stirred at 100 rpm. 5 ml each were collected at specified time intervals and replaced with an equal volume of fresh medium. The withdrawn aliquots were filtered and analyzed for drug content using a UV double beam visible spectrophotometer (2202, Systronics, India) at λmax 237 nm. The study was done in triplicate. Drug concentration was calculated and expressed as the cumulative percent of the drug released.

Release Kinetics: The drug release kinetic is directed by one or more mechanisms that depend on the matrix's composition, geometry, preparation method, and dissolution media of drug release. Mathematical models can explain this in accordance with the model's desired or required predictive ability and accuracy. Release kinetics is an integral part of developing a dosage form because if the kinetics of drug release is known, one can also establish an *in-vitro in-vivo* (IVIVC) correlation. The mathematical approach is one of the scientific methods to optimize and evaluate the error in terms of deviation in the release profiles of formulated products during the formulation development stage. The dissolution profile of the optimized batch was fitted to the different kinetic models [16, 17].

Preparation and Evaluation of Oral Dispersible Tablet:

Development of Tablet by Direct Compression Method: Materials used as dry binders should possess adequate cohesive or compressibility properties to form satisfactory, acceptable hardness and friability tablets. They should possess adequate flow ability and bulk density to ensure the die cavities are uniformly filled.

Dry ingredients like lactose, starch, magnesium stearate, and talc are thoroughly mixed in geometric proportions bellowed with solid dispersion of drug and carrier and then fill into the hopper, adjust the weight and then compressed into tablets using single side rotary tablet press machine with 8 mm diameter punch and the maximum operating force of this machine is 5-6 .5 tone [18, 19].

TABLE 5: FORMULA FOR TABLET PREPARATION

Solid dispersion of Glibenclamide with Excipients	Quantity taken (mg)	Quantity taken (%)	Role of Ingredients
Glibenclamide Solid Dispersion	65 mg	32.5	API with polymer
Lactose	106 mg	53	Diluent
Talc	10 mg	5	Adsorbent
Magnesium Sterate	9 mg	4.5	Flow agent
Starch	10 mg	5	Disintegrant
Total Weight of Tablet	200 mg	100	

Evaluation of Tablet [20]:

Drug Content: The crushed tablet was transferred to 100 mL volumetric flask containing ethanol and filtered. 5 mL of filtered solution was transferred to a 50 mL volumetric flask, diluted with pH 7.4 phosphate buffer, and analyzed (in triplicate) for drug content of Glibenclamide.

Dissolution Study: *In-vitro* dissolution study was performed using USP dissolution apparatus II (DS 8000, Lab India) sample of the tablet were placed in 900 ml of phosphate buffer (pH 7.4) as a dissolution medium at 37±0.5ºC and stirred at 100 rpm. 5 ml each were collected at specified time intervals and replaced with an equal volume of fresh medium.

The withdrawn aliquots were filtered and analyzed for drug content using a UV double beam visible spectrophotometer (2202, Systronics, India) at λmax 237 nm. The study was done in triplicate. Drug concentration was calculated and expressed as the cumulative presence of the drug released [21].

Hardness: The average hardness of 10 randomly selected tablets was determined using (labotech) hardness tester.

Friability: This test utilized a friability tester (model-317, LALCO). The weight of 10 tablets was recorded before and after being subjected to 100 rotations. The percentage loss was calculated and taken as a measure for the friability with the tablets being accepted if the friability did not exceed 1%.

Disintegration Test: The *in-vitro* disintegration test was carried out using 6 tablets using the disintegration apparatus (Labotech). Distilled water warmed to 37°C was used as a disintegration medium.

Moisture Uptake Study: 2 g optimized composites were spread homogeneously on a Petri dish (5 cm diameter), and the dish was then stored in a stability chamber (Newtronic, India) at 40 °C and 75% relative humidity. The percent gain in weight was observed after 24 h.

Water Absorption Ratio: A piece of multi-folded tissue paper was placed into a small Petri dish comprising distilled water (10 ml). A tablet was placed on the center of the paper, and the time required for complete wetting was noted. The water absorption ratio (R) was calculated using the following equation.

Water Absorption Ratio = wa-wb / wb x 100

Stability Study:

Collection of Sample: For each new product sample collected for stability study under accelerated study and humidity conditions for all products, at least one optimized batch is kept under long-term stability testing.

Storage of Sample: The optimized batch was stored at 25°C ±2°C with 40% relative humidity for 60 days as per ICH (International Conference on Harmonization) guidelines for Stability Testing [21].

RESULTS AND DISCUSSION:

Calibration curve of Glibenclamide: The linearity of response of the drug was obtained at 2 to10 µg/ml concentrations. The calibration curve was obtained by plotting the absorbance versus the concentration data and was treated by linear regression analysis as shown in **Fig. 1**. Graph of linearity obey Beer's lambert law in the concentration range of 2-10µg/ml in distill water.

TABLE 6: CALIBRATION CURVE OF GLIBEN-CLAMIDE

Parameters	Results
Absorption maxima nm	237nm
Linearity Range	2-10 µg/ml
Standard Regression	Y=0.02x + 0.002
Correlation Coefficients	R^2 = 0.995

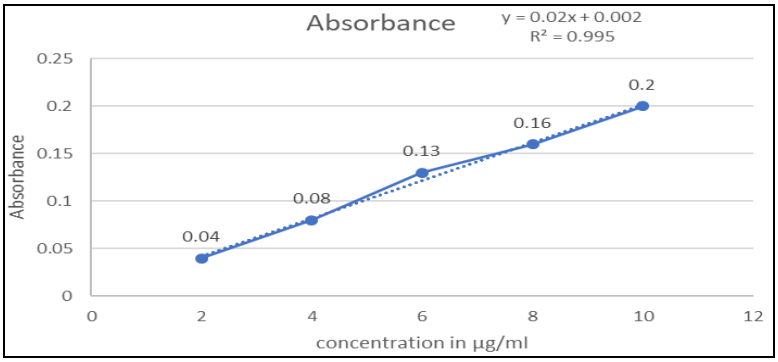

FIG. 1: CALIBRATION CURVE OF GLIBENCLAMIDE

Physicochemical Properties:

TABLE 7: PHYSICOCHEMICAL PROPERTIES OF DRUG AND EXCIPIENT

Organoleptic properties	Glibenclamide		Polyethylene glycol 4000		Polyethylene glycol 1500	
	Standard	Observation	Standard	Observation	Standard	Observation
Colour	White	White	White	White	White	White
Odour	Characteristic	Characteristic	Odorless	Odorless	Odorless	Odorless
Appearance	Amorphous	Amorphous	Crystalline	Crystalline	Crystalline	Crystalline
Melting point	169-170ºC	168-170ºC	53-54ºC	53-54ºC	46-48º	48-50ºC

Fourier Transform Infra-Red Spectroscopy (FTIR): FTIR spectrum reveals characteristic absorption band of Glibenclamide observed 1479 C=C Stretch, 3365.78 N-H Bending, 1591.27 N-H Bending, 2854.65 C-H Stretch, 2929.87 C-H Stretch. The peak corresponding to the mention frequencies confirms the identity of the Glibenclamide as per standard spectra.

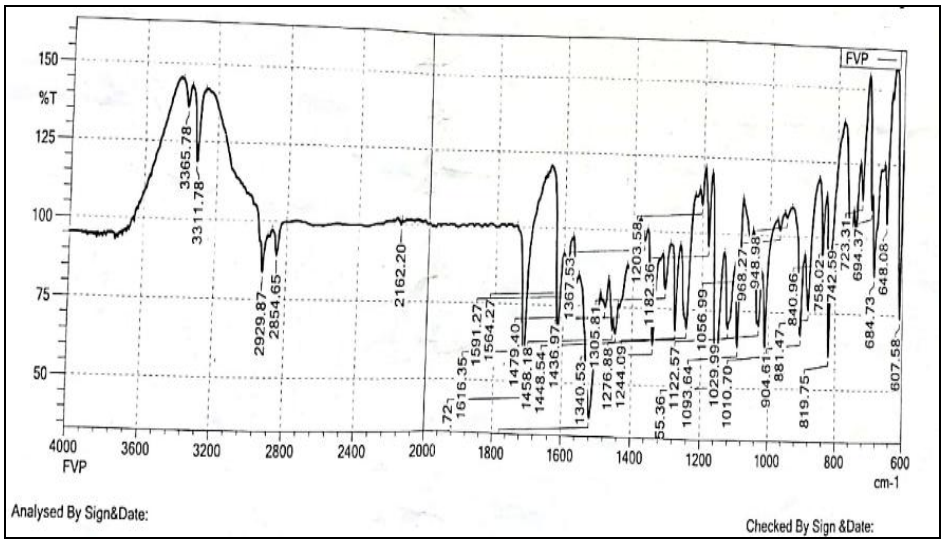

FIG. 2: FTIR SPECTRA OF GLIBENCLAMIDE

TABLE 8: VALUE OF FTIR

Functional group	Observed range	Standard range
C=C	1479	1400-1600
N-H (Stretch)	3365	3300-3500
N-H(Bending)	1616	1600
C-H(Stretch)	2854	2800-3000
C-H(Bending)	2929.87	1350-1480

Characterization of Solid Dispersions:

Flow Properties of Solid Dispersion: Solid dispersion of Glibenclamide was characterized by bulk density, tapped density, angle of repose. The result of the compressibility index, Hausner's ratio, and angle of repose show that all materials have sufficient compressibility and flow properties and are shown in **Table 9**.

TABLE 9: VALUE OF FLOW PROPERTIES

Formulation Code	Bulk Density g/ml	Tapped Density	Hauser's Ratio	Compressibility Index	Angle of Repose
F1	0.541±0.03	0.621±0.03	1.15±0.04	12.88±0.6	19.6±1.3
F2	0.621±0.05	0.731±0.08	1.18±0.07	17.71±5.5	18.4±0.1
F3	0.470±0.1	0.521±0.13	1.11±0	9.78±2.24	20.66±0.4
F4	0.74±0.17	0.89±0.24	1.12±0.1	16.85±4.6	21.87±3.6
F5	0.591±0.02	0.629±0.03	1.16±0.05	6.04±6.1	18.75±0.5
F6	0.623±0.05	0.741±0.09	0.87±0.24	15.92±3.7	14.02±3.9
F7	0.505±0.07	0.548±0.11	1.09±0.02	7.8±4.4	21.88±3.6
F8	0.723±0.15	0.820±0.17	1.13±0.02	11.8± 0.4	23.3±5.0
F9	0.557±0.02	0.631±0.02	1.13±0.02	11.72±0.4	17.75±0.4
F10	0.407±0.17	0.458±0.2	1.13±0.02	11.13±1.0	13.2±5.0
F11	0.552±0.02	0.632±0.02	1.14±0.03	12.65±0.4	12.98±5.2

Solubility Studies: The solubility data revealed that the drug's solubility increased in these carriers' presence.

The solubility of the drug markedly increased in the presence of both polymers and was found to be more in pH 7.4 phosphate buffer as compared to distilled water **Fig. 3**. The solubility of (F3) Tablet in water was found to be 40µg/ml. In comparison, in phosphate buffer it was 59µg/ml hence, F3 showed best results as compared to others.

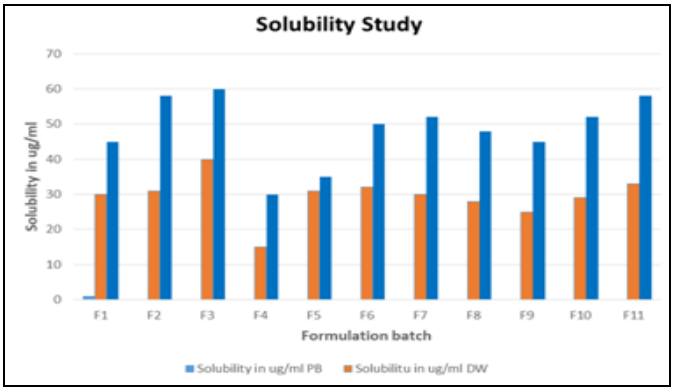

FIG. 3: SOLUBILITY STUDIES OF SOLID DISPERSION OF GLIBENCLAMIDE

TABLE 10: SOLUBILITY VALUE OF SOLID DISPERSION IN WATER AND BUFFER SOLUTION (7.4)

Batch Number	Water Solubility mg/ml	Buffer Solubility mg/ml
F1	30±0.2	45±3.2
F2	32±2.2	57±8.8
F3	40±10.2	59±10.8
F4	17±12	30±18.2
F5	31±1.2	34±14
F6	32±2.2	50±1.8
F7	30±0.2	52±3.8
F8	28±1.8	48±0.2
F9	25±4.8	46±2.2
F10	29±0.8	52±3.2
F11	34±4.2	58±9.8

Drug Content: The drug content in each solid dispersion was determined by UV spectroscopy. The maximum percent drug content for all formulations was found to be 99.1% percent, and the minimum percent drug content from all formulations was found to be 93.5%. The ratio of polymers in batch F3 gives better results than others. As shown in **Table 11.**

TABLE 11: DRUG CONTENT OF GLIBENCLAMIDE SOLID DISPERSION

Formulation code	Drug content
F1	96.1± 0.9
F2	96.5 ± 0.10
F3	98.2 ± 0.11
F4	94.3± 0.12
F5	96.8 ± 0.13
F6	95.4 ± 0.14
F7	96.2± 0.15
F8	96.5 ± 0.16
F9	94.8 ± 0.17
F10	93.5 ± 0.18
F11	96.3 ± 0.19

***In-vitro* Dissolution Studies:** The release of Glibenclamide from all formulations was plotted as cumulative percent drug release vs. time in minutes, as shown in **Fig. 4**.

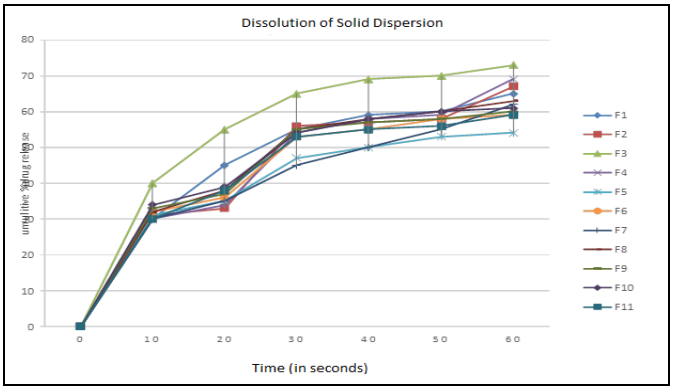

FIG. 4: GRAPH OF DISSOLUTION VALUE OF SOLID DISPERSION

TABLE 12*: IN-VITRO* DISSOLUTION STUDIES GLIBENCLAMIDE

Time(min)	0	10	20	30	40	50	60
F1	0	30±0.3	45±2.1	55±2.1	59±7	60±3	65±2
F2	0	32±1.3	34±9.2	56±1.2	57.8±2.4	62±2	67±5
F3	0	40±9	55±9.9	65±1.2	69±3	70.3±5	72.8±4
F4	0	30±0.3	34±8	54±2.2	58±6	60±9	69.2±0.2
F5	0	31±1.3	35±9	50±2.2	52±12	52.8±12	54±0.5
F6	0	32±2.3	36±10	52±0.2	54±10	56.5±10	59.4±5
F7	0	30±0.3	35±9	59±8	62.8±4	61±5	63.2±9
F8	0	32±2.3	38.9±9.8	58.8±7.1	61±5	62±4	63±9.1
F9	0	33±3.3	37±5	55±2	57±8	58±8	60±7
F10	0	34±4.4	39±3	54±3	58±7	60±6	61.3±8
F11	0	33.5±3.5	38±4	59±5	55±4.3	57±5.2	59.8±2.1

As shown in the figures, more than 50% of the drug was dissolved out of solid dispersion in 10 min. F3 and F4 showed 72.5% and 69%, respectively, show slightly better dissolution properties as compared to the rest of the formulations, which may be due to solubilizing effect of PEG 4000 in both cases, its prevention of aggregation and agglomeration effect, and its improvement of wettability and dispersibility of drug from Solid Dispersion which can result in increasing the dissolution rate of Glibenclamide.

Release Kinetics: There is a number of kinetic models which describe the overall release of drug from the dosage forms, the qualitative and quantitative changes in a formulation may alter drug release profile and *in-vivo* performance. The correlation coefficient (R^2) was determined for kinetic models (Zero order, First order, Higuchi, and Peppas model) as shown in the graph and compared with each other; the model showing the greatest Correlation coefficient (≈1) (Korsmeyer-Peppas model) was taken as best fit model.

TABLE 12: *IN-VITRO* DISSOLUTION STUDIES GLIBENCLAMIDE

Time (Min)	cumulative % drug released	% drug remaining	Square root time	log Cumu % drug remaining	log time	log Cumu % drug released	% drug released	Cube Root of % drug Remaining(Wt)	Wo-Wt
0	0	100	0.000	2.000	0.000	0.000	100	4.642	0.000
10	50.04	49.96	3.162	1.699	1.000	1.699	50.04	3.683	0.959
20	75.56	24.44	4.472	1.388	1.301	1.878	25.52	2.902	1.740
30	81.00	19	5.477	1.279	1.477	1.908	5.44	2.668	1.974
40	89.90	10.1	6.325	1.004	1.602	1.954	8.9	2.162	2.480
50	95.55	4.45	7.071	0.648	1.699	1.980	5.65	1.645	2.997
60	99.91	0.09	7.746	1.046	1.778	2.000	4.36	0.448	4.194

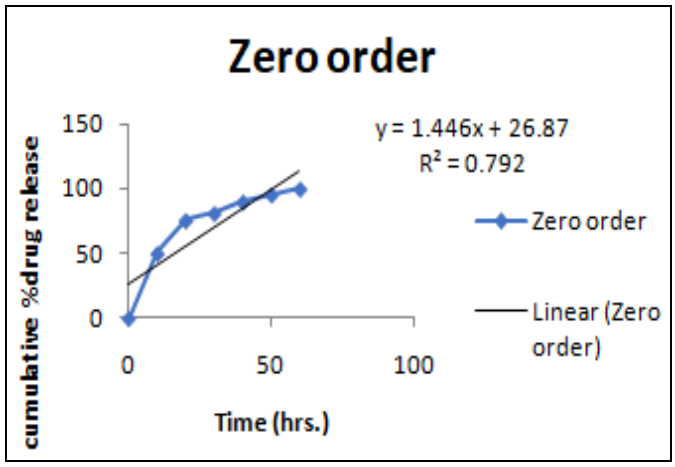

FIG. 5: GRAPH OF ZERO ORDER RELEASE OF DRUG FROM SOLID DISPERSION

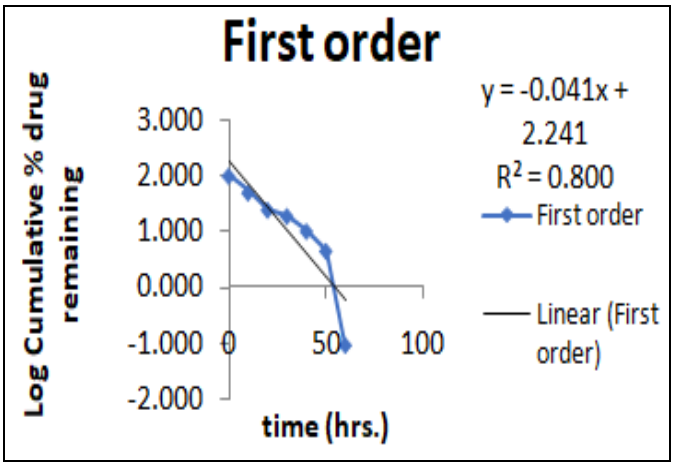

FIG. 6: GRAPH OF FIRST ORDER RELEASE OF DRUG FROM SOLID DISPERSION

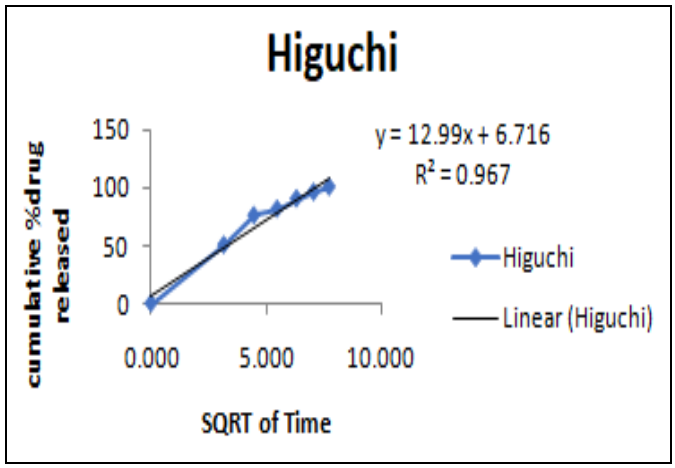

FIG. 7: GRAPH OF HIGUCHI RELEASE MODEL OF DRUG FROM SOLID DISPERSION

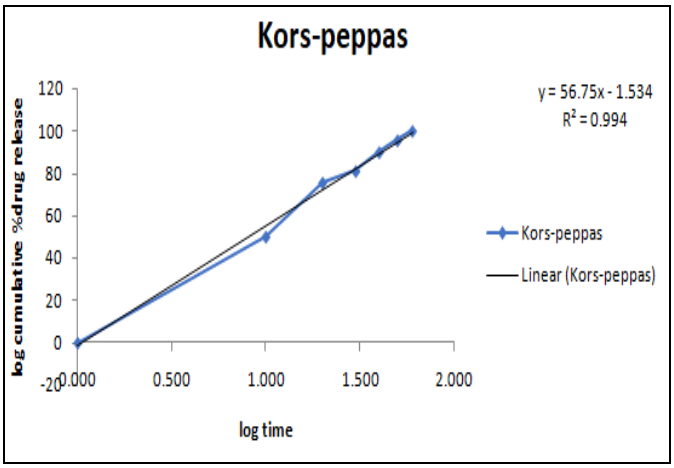

FIG. 8: GRAPH OF KORS-PEPPAS RELEASE OF DRUG FROM SOLID DISPERSION

Evaluation of Oral Dispersible Tablet: Determination of hardness, disintegration time, water absorption ratio, friability, and moisture content. The mean hardness, disintegration time, wettability, friability, and moisture content were 2.2mpa, 21.2 sec, 29%, 28%, and 5.10, respectively.

TABLE 14: VALUE OF TABLET PARAMETER

Formulation code(F3)	Tensile Strength (Mpa)	Disintegration Time (Seconds)	Moisture Content
1	2.2±0	19±2	5.12±0.2
2	2.4±0.2	25±4	5.19±0.9
3	2.1±0.3	20±1	5.01±0.9
Mean	2.2	21.2	5.10
Water Absorption ratio (%)	**Friability (%)**	**Weight Variation (mg)**	**Moisture Content**
29.02±0.3	0.24±0.4	200±0.7	5.12±0.2
32.31±3	0.29±0.1	199.2±0.01	5.19±0.9
26.56±4	0.32±0.4	198.9±0.4	5.01±0.9
29.5	0.28	199.3	5.10

Dissolution Study of Optimize Batch of Tablet: Dissolution of formulated oral dispersible tablet was fond to be73%, and Dissolution of the marketed product was found to be Preparation of Glibenclamide oral dispersible tablet by fusion method of solid dispersion shows significantly higher dissolution rate compared to the unprocessed one.

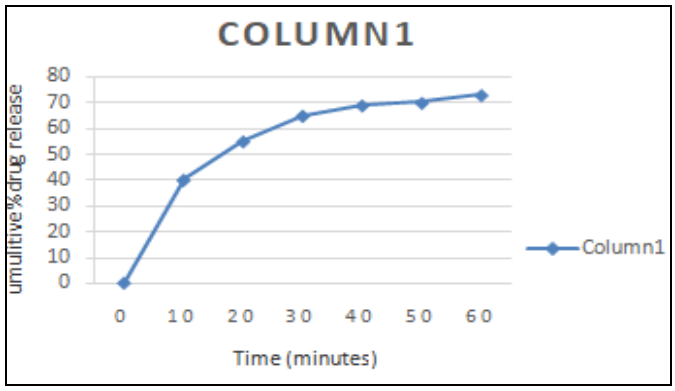

FIG. 9: DISSOLUTION GRAPH OF TABLET (OPTIMIZE BATCH)

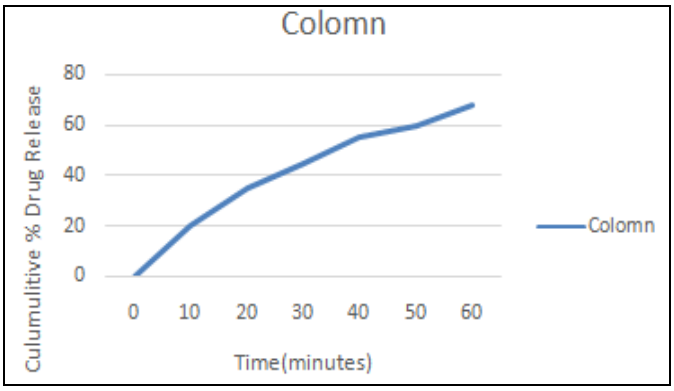

FIG. 10: DISSOLUTION GRAPH OF MARKETED TABLET

Stability Studies: Stability data of optimum batch (F3) tablet at 25ºC and 40% relative humidity. (RH) After removal of samples were analyzed for the content and *in-vitro* release study and results were compared with the original data. No significant ($P < 0.05$) variations were found in the results. It is indicated that the prepared tablet was stable under accelerated storage conditions.

TABLE 15: VALUE OF DRUG CONTENT AND DRUG RELEASE

Days	Appearance	% Drug content	%Drug release
1	White	98±2.8	72.87±3
7	White	97.3±1.2	72.80±3
14	White	97±1	77.82±2.2
21	White	96.8±0	77.77±2.3
28	White	96.2±0.6	77.65±2.3

CONCLUSION: Solid dispersion was prepared by the Fusion method using Glibenclamide as the drug and PEG as the carriers and was then incorporated into a tablet. The solubility of the tablet in water was found to be 39µg/ml, while in phosphate buffer, it was 59µg/ml. The goal of this study was to maximize the drug release rate. The maximum percent of drug content was found to be 98.2%. *In-vitro* dissolution test of tablets showed a higher *in-vitro* drug release rate than the pure drug itself. It was found to be 73.2% for optimized tablets. The Disintegration time and wetting time were found to be 21.2 sec and 29.56%; respectively, On the basis of this, we consider (F3) batch has a good result.

The stability study of the prepared formulation was stable because there was no significant loss (≤5%) at that condition. As shown in the graph of the kinetic release model, the Korsmeyer Peppas model was taken as best fit model for this formulation. Tablet of solid dispersion batch (F3) had a faster dissolution rate and was optimized than others.

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