



Formulation, Development and In-Vitro Evaluation of Immediate Release Tablet of Glibenclamide

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Method,
% Drug Release.

ABSTRACT:

Introduction: Diabetes is treated with Glibenclamide, an oral antidiabetic medication that encourages the pancreatic beta cells to release insulin. Glibenclamide belongs to the class of sulphonyl urea class; an oral antidiabetic drug. It causes the pancreatic beta cells to release more insulin, thereby which maintains the blood sugar level. By lowering the hepatic clearance of the hormone, Glibenclamide raises the level of insulin in the blood.

Objectives: According to the biopharmaceutical classification system, Glibenclamide is a member of class II (drugs with poor solubility and high permeability). The major goal of the current investigation was to use the wet granulation method to develop pharmaceutically active, stable, and bioequivalent immediate release (IR) tablets of Glibenclamide.

Methods: Wet granulation method

Results: Utilizing several physical parameters, tools, a dissolution study, and a drug release profile, the formulated formulations were assessed. In order to prepare Glibenclamide IR tablets, superdisintegrants such as Crosscarmallose sodium and maize starch were mostly used. These substances offer immediate disintegration after ingestion. For the purpose of assessing drug release, in-vitro dissolution testing study was carried out for 1 hours using 0.1N HCl in a dissolution apparatus. Batch F4 performs better and was found to be 100% released in just 30 minutes, according to the dissolution profile.

1. Introduction

The oral route is the most preferred for systemic effect owing to its simplicity, lack of discomfort, avoidance, adaptability, and most crucially, patient compliance. Since they don't need special processing and are therefore less expensive to manufacture, solid oral delivery systems (particularly tablets) are preferred among all drug administration systems.¹

Additionally, immediate release tablets are more popular than any other tablets. Any dose regimen that instantly achieves the necessary therapeutic concentration of drug in plasma (or at the site of action) and maintains it constant for the length of treatment is excellent for treating any condition / illness with medication.^{2,3} The majority of pharmaceuticals intended for oral administration that are currently sold on the prescription and over-the-counter markets are of the

instant release variety, which are intended for immediate drug release for quick absorption.⁴

Tablets can be divided into three categories based on how they release their medications: immediate release, extended release, and delayed release.²

In case of immediate release tablets, the drug is either dissolved or given as a solution or is intended to be released quickly after ingestion. This is the most typical kind of tablet, which also includes buccal, sublingual, effervescent, chewable, and dissolving tablets. Without any specific rate-controlling features, immediate release tablets are formulated to dissolve and release their medicament.^{4, 5} Rapidly delivering instant medication levels is the goal of immediate release drug delivery devices. A variety of pharmaceutical research has been carried out recently to formulate new dosage forms that take quality of life into account; the majority of these



efforts have been concentrated on medication convenience.⁵ A manufacturer can extend market exclusivity while providing patients with an easy-to-use dose form or regimen with an immediate release dosage form. Because they are simple to use, have a rapid onset of action, are economical, and improves patient compliance, immediate release tablets have recently begun to acquire popularity and acceptability as a drug delivery strategy.⁶ Superdisintegrants are the excipients of choice that are frequently employed in the formulation of immediate release tablets because they efficiently cause the medicine to immediately disintegrate, release, and be absorbed after delivery into the body. Crosscarmellose sodium which is commonly known as Ac-di- sol is cross linked Carboxyl Methyl Cellulose Sodium and Sodium Starch Glycolate (SSG) is a carboxyl methyl starch and both of which are stable through hygroscopic material.⁷

Diabetes and a decrease in insulin levels necessitate the immediate release of the medication for a quicker start to action. In light of this, intended to formulate Glibenclamide tablets with an immediate release that can deliver efficient drug release right away after ingestion. Antidiabetic medications are mostly used for type II diabetes mellitus. The most used combination is Glibenclamide and Metformin HCl. However, Metformin HCl has a high dose requirement (1.5–2.0g/day), limited bioavailability (40–60%), and a short half-life (0.9–2.6hr), necessitating frequent high dose administration to maintain the effective plasma concentration and ultimately posing the risk of GIT adverse effects.⁸

Formulated Glibenclamide immediate release tablets achieve effective medication release right away upon administration with a minimal dose, thereby reducing adverse effects and boosting bioavailability.

2. MATERIALS AND METHOD:

Wockhardt Ltd. provided a gift sample of the Glibenclamide. The Mumbai Fine Chem. Industry Research Lab provided the crosscarmellose sodium. All other chemicals required were of the analytical variety.

Method of preparation of Immediate Release tablets:^{9,10}

Glibenclamide, Microcrystalline cellulose, lactose, mannitol, and superdisintegrant (Crosscarmellose

sodium) were sifted through a 40# sieve. Sifted material was extensively combined with maize starch in water as a binder solution for 15 minutes in a porcelain mortar before being ground into granules. Granules were dried for 30 minutes in a hot air oven at 50 OC after passing through a 20# screen. Aerosol has already passed through 60# and magnesium stearate was used to lubricate the prepared granules. In order to compress the prepared granules into tablets with an average weight of 200 mg, a round-shaped concave punch (7 no.) employed.

Table 1: Formulation of immediate release tablet by wet granulation method

Sr. No.	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Glibenclamide	5	5	5	5	5	5	5	5	5
2	Crosscarmalose sodium	12	10	8	12	10	8	12	10	8
3	Maize starch	10	10	10	10	10	10	10	10	10
4	Microcrystalline cellulose	69	69	69	67	67	67	65	65	65
5	Mannitol	50	50	50	50	50	50	50	50	50
6	Lactose	48	50	52	50	52	54	52	54	56
7	Aerosil	2	2	2	2	2	2	2	2	2
8	Magnesium stearate	4	4	4	4	4	4	4	4	4

3. EVALUATION PARAMETERS:¹¹⁻¹⁶

Preformulation Study:

The following Preformulation studies were carried out for Glibenclamide and polymers;

1. Determination of melting point of Glibenclamide
2. UV-Spectrum
3. Solubility
4. Drug–excipients compatibility studies.

Determination of melting point:¹¹⁻¹⁶

By placing a little amount of Glibenclamide in a capillary tube that was closed at one end, the drug's melting point was ascertained. The melting point of the Glibenclamide was measured by inserting the capillary tube into an electrically powered melting point instrument. This was done three times, and the average value was recorded.

UV Spectra:¹¹⁻¹⁶

Using the Shimadzu UV-1800, the UV spectrum of Glibenclamide was determined. A stock solution (1000 µg/ml) was prepared by dissolving an accurately weighed 10 mg of the drug in enough ethanol to make 100 ml. To achieve a concentration of 10 µg/ml, an aliquot of 1 ml was taken out and volume was made upto 10 ml with water. The spectra of the resulting solution were scanned between 200 and 400 nm. Max value for λ_{max} absorption is 301 nm.

Solubility:¹¹⁻¹⁶



The compound's solubility in ethanol, water, and methanol was assessed. In 5 ml of solvent, the excess medication was dissolved. After that, the solution was ultrasonically processed for 30 minutes. After that, it was left to stand for 24 hours at room temperature in firmly covered vials in order to reach saturation equilibrium. The solution was run through Whatman filter paper No. 41 after 24 hours. It was then appropriately diluted with the solvent before being examined by a UV Spectrophotometer at 301 nm.

Drug-excipients compatibility studies:¹¹⁻¹⁶

Drug instability may result from interactions between the drug and polymer, which are in close proximity during the manufacture of tablet formulation. Therefore, choosing the right polymers requires careful consideration of preformulation research on the interaction between drugs and polymers. The compatibility of Glibenclamide with the chosen polymers was determined using FT-IR spectroscopy.

FTIR Study:¹¹⁻¹⁶

Using the KBr pellet approach, the IR spectra of the drug sample were recorded. In a porcelain mortar and pestle, the drug was triturated in a ratio with dry potassium bromide (1:100). The pellets were prepared in a KBr press using an 8-ton pressure setting. The pellet was scanned on between 4000 and 400 cm^{-1} and the resulting spectra are reported.

DSC study:¹¹⁻¹⁶

Differential scanning calorimeters (DSC) detect heat loss or gain as a function of temperature arising from physical or chemical changes within a sample. Numerous aspects of preformulation studies such as purity, polymorphism, solvation, degradation, and excipient compatibility, can benefit from quantitative evaluation of these processes. Drugs and mixtures of drugs and polymers were subjected to differential scanning Calorimetry (DSC).

The trituration of the drug and the polymers (1:1) in a dried mortar for 5 minutes was used to prepare the physical mixtures of the drugs and polymers for compatibility studies. The samples were measured, weighed, and sealed in aluminium pans (1:1) mixture of medication and polymers). The sealed aluminium pan was heated between 100 and 200 $^{\circ}\text{C}$ at a scanning rate of 10 $^{\circ}\text{C}/\text{min}$.

Evaluation of preliminary batches¹¹⁻¹⁶

Micromeritic Properties:

1. Angle of repose
2. Bulk density
3. Tap density
4. Carr's index
5. Hausner's ratio

Angle of repose (θ):

The angle of repose is a useful tool for calculating the frictional force in loose powder or granules. The maximum angle that can be formed between a pile of powder's surface and a horizontal plane is known as the angle of repose.

Tan $\theta = h/r$

Where

θ = Angle of repose, h = Height of pile, r = Radius of base.

Bulk density and Tapped Density:

Bulk density is defined as the mass of a powder divided by the bulk volume. The bulk density of a powder depends primarily on particle size distribution, particle shape, and the tendency of the particles to adhere to one another.

Method:

The tapped bulk density (TBD) and the loose bulk density (LBD) were both calculated. Each formula's powder (bulk) was precisely weighed and then added to a 25 ml measuring cylinder after being shaken to break up any agglomerates. After the initial volume was measured, the cylinder was allowed to drop from a height of 2.5 cm to a hard surface at intervals of 2 seconds.

The taping was continued until no further change in volume was noted.

$$\text{Bulk density (gm/ml)} = \frac{\text{Weight of sample in gm}}{\text{Volume occupied by sample in ml}}$$

$$\text{Tapped density (gm/ml)} = \frac{\text{Weight of sample in gm}}{\text{Volume occupied by sample in ml}}$$

Carr's compressibility index:

The compressibility index of the granules was determined by Carr's compressibility index.

$$\text{Compressibility Index} = \frac{\text{Bulk density} - \text{Tapped density}}{\text{Tapped density}} \times 100$$

Hausner's ratio:

Hausner's ratio is an index of ease of powder flow; it is calculated by following formula.

$$\text{Hausner Ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Evaluation of immediate release tablet of Glibenclamide:¹⁷⁻²²

1. Thickness.
2. Hardness
3. Friability
4. Weight variation
5. Disintegration Time
6. Wetting Time
7. Water absorption Ratio
8. Drug content
9. In vitro Dissolution Study

Shape and Color of Tablet (Appearance):

Prepared tablets were viewed using a lens to determine their color and shape while being kept in light.

Thickness:¹⁷⁻²²

A Vernier Caliper was used to measure the thickness of the tablet. From each formulation, six tablets were chosen at



random, and the mean and standard deviation values were computed.

Hardness Test: ¹⁷⁻²²

A hardness tester was employed to evaluate the tablet hardness. The unit of measurement is kg/cm². From each formulation, six tablets were chosen at random, and the mean and standard deviation values were determined.

Friability Test: ¹⁷⁻²²

The Roche friabilator was used to assess the friability of tablets. In a plastic chamber that rotates at 25 revolutions per minute and drops the tablets from a height of 6 inches with each revolution, this apparatus treats the tablets to the combined effects of abrasion and shock. Tablets that had been preweighed were put in the friabilator and rotated for 100 revolutions. A delicate muslin cloth was used to dust the tablets, and they were reweighed, to calculate the % loss in weight:

$$\% F = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Tablets with less than 1% friability are deemed acceptable.

Weight variation test: ¹⁷⁻²²

Twenty tablets (20) were chosen at random from each formulation, and each tablet was weighed individually to ensure weight uniformity. The weight of a tablet may vary slightly under the British Pharmacopoeia.

The weight variation may deviate by the following percentage.

Table 2: BP limits for weight (variation) uniformity of tablets

Sr. No.	Average mass	Percentage deviation
1.	110mg or less	±10
2.	More than 110mg and less than 324 mg	±7.5
3.	324 mg or more	±5

Wetting Time and water absorption ratio: ¹⁷

A small petridish holding 6 ml of distilled water was filled with a piece of tissue paper folded twice. A tablet was then placed on the tissue paper, and the amount of time it took for the paper to get completely wet was recorded. After that, the wet tablet was weighed. Each batch underwent three trials, and the standard deviation was also calculated.

R, the water absorption ratio, was calculated using the formula below.

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

Where,

R = Water absorption ratio

W_a = Weight of tablet after water absorption

W_b = Weight of tablet before water absorption

In-vitro disintegration test: ¹⁷⁻²²

Six immediate release Glibenclamide tablets were selected randomly from each formulation for disintegration test. The test was carried out in pH 0.1 N hydrochloric acid buffer at 37± 0.5 °C for 3 minutes. The complete disintegration of the tablet with no palpable mass in the apparatus was measured in second.

Drug Content (Assay): ¹⁷⁻²²

The mortar and pestle were used to grind twenty tablets. 0.1 M methanolic hydrochloric acid was added to a precise amount of powder containing 20 mg of Glibenclamide, which was then shaken with 40 ml of the acid before being gently heated and centrifuged. To the extract, 100 ml of 0.1 M methanolic hydrochloric acid were added, and the absorbance at 301 nm was measured.

In Vitro Dissolution Studies: ¹⁷⁻²²

Dissolution studies were carried out by USP type II method at 37± 0.5 °C, taking 900ml of pH 1.2 N hydrochloric acid buffer at 50 rpm. At predetermined intervals (5, 10,15,20,25, and 30 minutes); the test sample of 5 ml was removed and replaced with new dissolving media. The test sample was filtered, and a UV spectrophotometer operating at 301 nm was used to calculate the amount of medication that had been dissolved. For this test, six tablets were chosen, and the mean and standard deviation of each were computed.

4. RESULTS AND DISCUSSION:

Description and Melting point:

The preformulation parameter indicates there organoleptic properties and Melting point was found to be white, crystalline, odorless powder and 172 °C respectively.

Calibration Curve:

The UV visible spectrum of Glibenclamide in ethanol is shown at maximum λ_{max} corresponding to 301nm. Glibenclamide calibration curve in ethanol was plotted for the concentrations between concentration 5-25 µg/ml ranges, R² was equal to 0.99. From the standard curve of Glibenclamide it was observed that the drug obeys beer's law in concentration range of 5-25µg/ml in ethanol. The linear regression equation generated was used for the calculation of amount of drug.

Table 3: Calibration curve of Glibenclamide

Sr. No.	Concentration (µg/ml)	Absorbance
1.	5	0.103
2.	10	0.212
3.	15	0.321
4.	20	0.434
5.	25	0.548

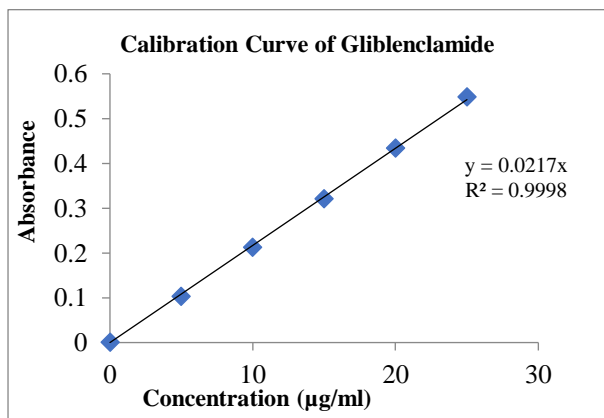


Fig.1: Calibration curve of Glibenclamide in ethanol

Drug-Excipient compatibility study:

i) Infrared spectroscopy:

IR Spectroscopy was employed to carry out the study on the compatibility between drug excipients. IR spectra of Glibenclamide, physical mixture are shown in the Fig.2, 3. The resulting spectra were analysed to identify or investigate any potential interactions between drugs and polymers; however, spectral analysis did not find any such interactions.

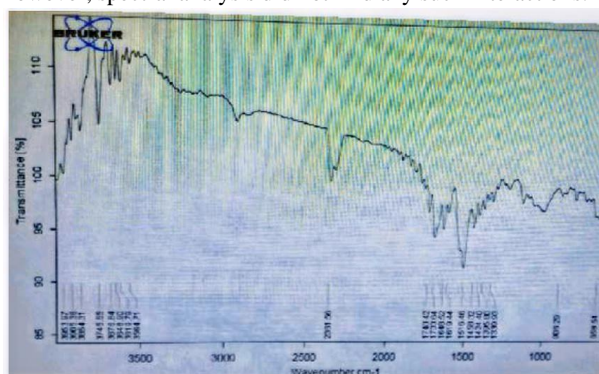


Fig. 2: IR spectra of pure drug Glibenclamide

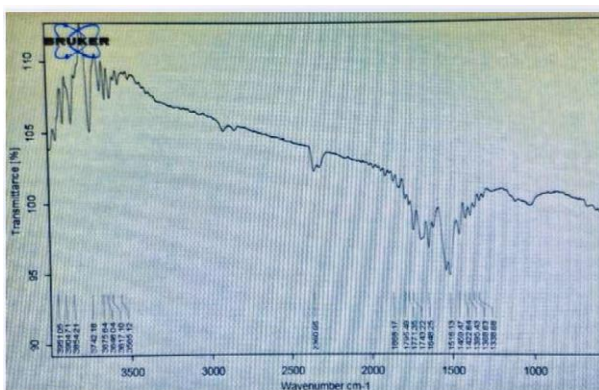


Fig. 3: IR spectra of Glibenclamide and physical Mixture

DSC Study:

Glibenclamide was subjected to DSC analysis. The thermogram was recorded using Mettler thermal analyser. The rate of heating was set to 10 °C/min. The normal melting process of glibenclamide was visible in the DSC thermogram of the glibenclamide and excipient mixture. Glibenclamide melts at temperatures between 155°C and 169 °C, with a sharp peak at 165.5°C following an endothermic reaction.

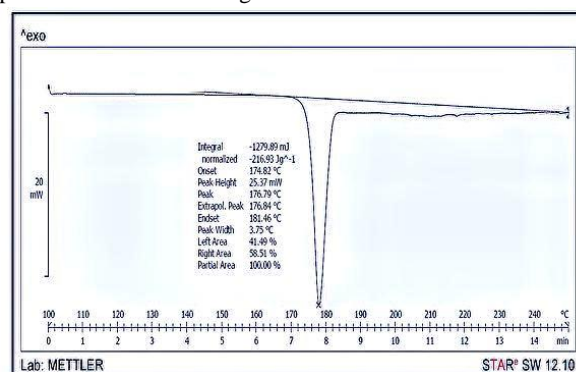


Fig.4: DSC thermogram of glibenclamide.

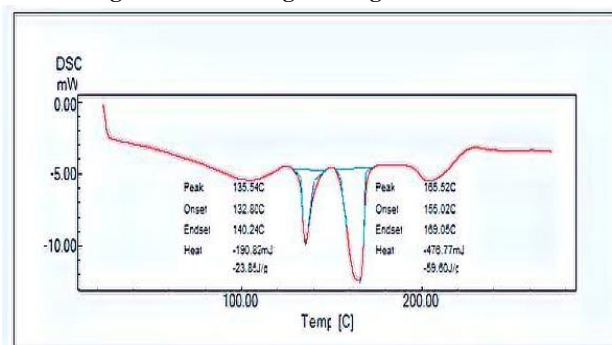


Fig.5: DSC of Glibenclamide and (mixture of different excipients and polymer)

Pre-compression Studies:

Table 4 summarizes the results of different pre-compression studies.

Table 4: Flow properties for Batches F-01 to F-09

Properti es	F-01	F0 2	F-03	F-04	F-05	F-06	F-07	F-08	F-09
Bulk density (gm/cm ³)	0.294	0.303	0.296	0.297	0.289	0.287	0.290	0.294	0.295
Tapped bulk density (gm/cm ³)	0.335	0.335	0.326	0.326	0.325	0.331	0.333	0.328	0.333
Angle of Repose (°)	27.18	30.15	30.69	24.09	32.14	31.21	28.73	31.69	29.35
Compressibility Index (%)	12.33	9.86	11.10	8.90	10.47	13.23	13.95	10.58	11.25



Hausner ratio	1.13	1.10	1.24	1.09	1.11	1.15	1.16	1.11	1.12
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7	30	88.16	87.39	87.34	99.84	90.08	88.2	89.28	89.12	89.98
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Post-compression Study:

Table 5 summarizes the results of different post-compressional studies.

Table 5: Various Evaluation parameters for tablets (F-01 to F-09)

Parameter	F-01	F-02	F-03	F-04	F-05	F-06	F-07	F-08	F-09
Hardness (kg/cm ²)	3.512	3.801	3.900	3.883	3.933	3.483	3.750	3.866	3.555
Weight Variation	199.17	195	197	200	201	198.2	197.8	202	199.2
Thickness (mm)	4.82	4.83	4.81	4.84	4.82	4.83	4.84	4.85	4.83
Friability (%)	0.112	0.384	0.133	0.100	0.100	0.343	0.356	0.524	1.057
Disintegration time (sec.)	16.7	17.2	18.4	14.2	16.8	20.2	22.00	24.4	26.7
Wetting time (sec.)	53.70	41.165	36.21	24.23	42.23	48.53	51.02	53.02	52.45
Water absorption ratio (%)	43.81	50.25	44.47	42.97	49.75	48.30	50.5	46.15	45.25
Drug Content	93.78	93.064	92.298	99.92	99.44	98.96	96.4	95.608	94.806

In vitro drug release studies:

In-vitro drug studies were performed using the USP type II method at 37± 0.5 °C and 50 revolutions per minute with 900ml of pH 1.2 N hydrochloric acid buffer. The 5 ml test sample was removed and fresh dissolving media was added at predefined intervals (5, 10, 15, 20, 25, and 30 minutes). The test sample was filtered, and the amount of medication that has been dissolved was evaluated using an UV spectrophotometer adjusted to 301 nm.

Table 6: In-vitro % drug release of Glibenclamide tablets of batches F1 to F9

Sr. No.	Time in min	% Drug release for Glibenclamide								
		F-01	F-02	F-03	F-04	F-05	F-06	F-07	F-08	F-09
1	0	0	0	0	0	0	0	0	0	0
2	5	23.64	22.10	21.87	18.03	22.84	21.32	21.31	20.56	20.72
3	10	26.86	29.82	26.42	33.08	34.32	32.12	32.3	33.82	33.9
4	15	41.78	39.03	36.08	50.16	51.96	49.42	50.22	48.78	50.22
5	20	52.48	49.40	50.57	69.08	65.12	64.12	66.42	64.88	64.76
6	25	70.2	66.41	66.48	86.72	82.22	80.68	80.74	84.38	84.9

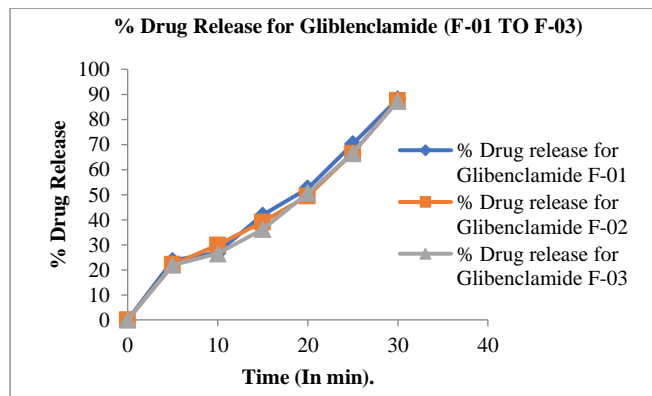


Fig. 6: In-vitro % drug release of Glibenclamide from tablets for the batches F1 to F3.

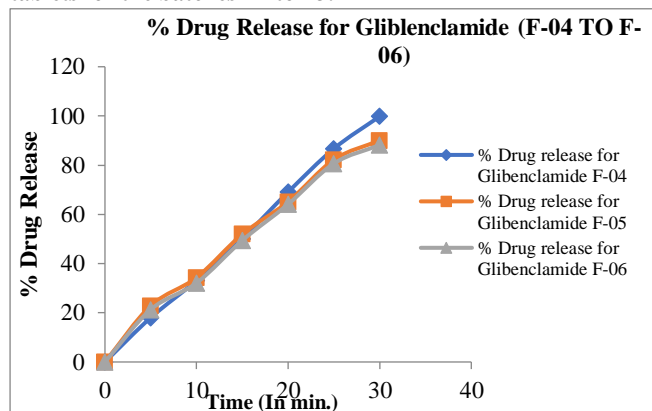


Fig. 7: In-vitro % drug release of Glibenclamide from tablets for the batches F4 to F6.

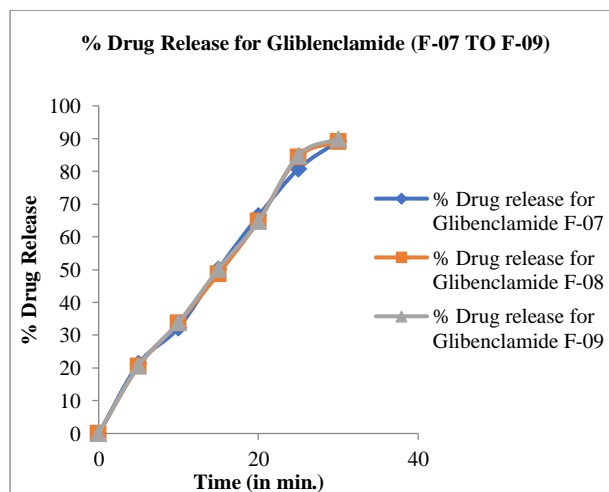


Fig. 7: In-vitro % drug release of Glibenclamide from tablets for the batches F7 to F9.

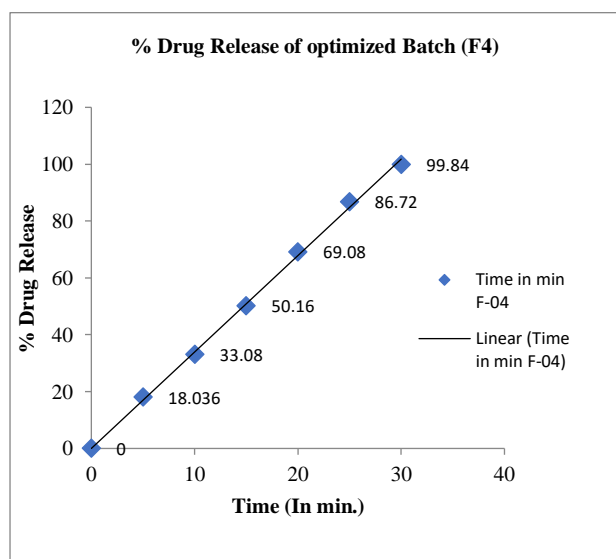


Fig. 7: In-vitro % drug release of optimized Batch F4.

5. Conclusion:

Glibenclamide immediate release tablet were formulated and evaluated with the objective of increasing bioavailability and minimizing side effects. The developed Glibenclamide immediate release tablet were evaluated for compatibility studies, flow properties and various physical parameter like hardness, thickness, content uniformity, in-vitro disintegration time, in-vitro dissolution and stability studies of immediate release tablets. Glibenclamide immediate release tablet-containing formulations were formulated, and evaluated for both pharmacopoeial and non-pharmacopoeial studies. Excipients and concentration of excipients were optimized for immediate release tablets. For immediate release tablets in vitro release was carried out in pH 1.2 hydrochloric acid buffer using USP type II dissolution test apparatus.

In vitro release profiles of optimized formulations of Glibenclamide immediate release tablets shows (F-4) released 99.84% within 30 minutes.

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