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Original Article

Design and Characterization of Fast Dissolving Solid Dispersion Tablets of Gliclazide

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ABSTRACT

Background: Diabetic mellitus is the oldest and most commonly occurring disease known as a life-threatening disease in all age groups from the past 3000 years ago, which is taking away the liveliness from the persons and shortening their lives based on the prevalence. **Materials and Methods:** The present research work is to enhance the solubility and dissolution of gliclazide by preparing stable solid dispersions with Polaxomer-188, Polaxomer-407, Cremophor-RH-40, Solutol-HS-15 as solubilizing agents to formulating gliclazide fast-dissolving tablets. Solid dispersions were prepared by physical mixture, solvent evaporation and melting technique with the drug to carrier ratio of 1:1, 1:2, and 1:3 w/w respectively. Prepared formulations were evaluated by FTIR, DSC, XRD, SEM and *in vitro* dissolution performance. **Results and Discussion:** Results showed that the solubility has increased 43.29 folds with enhancement in solubility of prepared solid dispersion formulations when compared to gliclazide drug. FTIR studies showed the retainment of a few individual characteristics group peaks in the drug structure. XRD pattern and DSC thermograms showed a significant change in crystallinity to amorphous of gliclazide. From the study, poloxamer-407 was indicated as the suitable carrier and melting technique as a suitable method for enhancement of solubility and dissolution of gliclazide. Optimized solid dispersion was further prepared into fast-dissolving tablets and was evaluated for pre and post-compression studies. **Conclusion:** From the obtained data, it was concluded that Polaxomer-407 can be used as the solubilizing agent with low concentration in the preparation of fast-dissolving tablets.

Keywords: Gliclazide, fast-dissolving tablet, Polaxomer-188, Polaxomer-407, Cremophor-RH-40, Solutol-HS-15.

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INTRODUCTION

Due to various changes in lifestyle and food habits, the status of health and disease are seen, especially by adapting to other cultures. These changes led to metabolic disorders such as Diabetes Mellitus (DM), which can be identified by hyperglycemia resulting from deficiencies in the secretion of insulin, action of insulin or both.[1] Based on prevalence, DM metabolic disorders has risen to epidemic levels.[4] In the world DM is found to be a growing health disorder, which is a primary cause for psychological stress, depression, mortality and economic status loss.[2-4] In the year 2000, among adults the prevalence of diabetes is 151 million,[5] which has drastically increased worldwide in 2021 to approximately 537 million. The expected diabetics occurrence to be about 643 million in year 2030, and 783 million in the year 2045 based on the demographic changes in the world.[6] Gliclazide (GLZ) is [1-(3-azabicyclo-[3,3,0]-oct-3-yl)-3-(p-tolyl sulphonyl) urea] an oral hypoglycemic agent, one of the second-generation drugs belongs to sulphonylurea group which stimulates insulin release and which is used for the treatment of type 2 DM.[7] Mechanism of action of GLZ is by binding to sulphonylurea receptors of beta-cells of the pancreas. Blood sugar level decreases by activating calmodulin indirectly, which causes exocytosis of insulin vesicles inducing insulin release. According to the biopharmaceutical classification system, GLZ is classified as class II drugs, which shows low solubility and pH-dependent solubility.[8] The solubility of GLZ in acidic and neutral aqueous media is very poor solubility i.e. approximately 0.027mg/mL and has a higher permeability of log P=2.6, which leads to poor dissolution.[9,10] Various approaches used for the improvement of solubility and thence dissolution rate of hydrophobic drugs are size reduction, complexation, solid dispersion, formation of salts and prodrug approach.[11,12] Solid Dispersions (SD) preparation is

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an economical and practicable methods to increase surface area, reduce particle size, improve wettability and convert crystalline to amorphous state. Poloxamer, polyethylene glycols, povidone, crospovidone, polyvinyl pyrrolidones, Cremophor-RH-40, and Solutol-HS-15 are some carriers used to prepare SDs.[12] The most practically and economically used methods are the Physical Method (PM), Solvent evaporation (SM) and Melting techniques (MM). Novel drug delivery systems are mainly aimed at enhancing the drug molecule's safety and efficacy by formulating a better convenient unit dosage form for administration.[13,14] Poor aqueous solubility leads to the *in vivo* efficacy of drugs due to low bioavailability, abnormal pharma kinetic profile, etc., thence poses challenging problems in the development process of oral formulation.[15-18] Fast-Dissolving Tablets (FDT) are the best dosage form, can improve the bioavailability of poorly bioavailable drugs and poorly soluble drugs. Therefore, the present investigation was an attempt made to the possibility for enhancing the dissolution, solubility and bioavailability of GLZ SDs prepared by PM, SM and MM with Poloxamer-188 and Poloxamer-407 in comparison with Cremophor-RH-40 and Solutol-HS-15. SDs is characterized using FTIR, DSC, XRD, SEM and *in vitro* dissolution studies.

MATERIALS AND METHODS

Materials

Gliclazide, Polaxomer-188, and Polaxomer-407 were purchased from Yarrow Chem Product, Mumbai. Cremophor-RH-40 and Solutol-HS-15 were purchased from BASF, Germany. Mannitol procured from Chemica-biochemical reagents, India. All the materials were of pharma grade.

Methods

Pre-formulation studies

Before developing the dosage forms of a drug pre-formulation studies like melting point, UV-visible spectrophotometer, FTIR and solubility studies were performed to identify the quality and purity of the drug. Estimation of drug, compatibility studies such as visual inspection, FTIR, and DSC studies.

Compatibility studies

These studies were performed to know the compatibility of drug and excipients by using FTIR, XRD, DSC and SEM.

Preparation of GLZ SDs

PM, SM and MM were prepared by using four different carriers, Polaxomer-188, Polaxomer-407, Cremophor-RH-40 and Solutol-HS-15 in 1:1, 1:2 and 1:3 drug: carrier ratios, given in Table 1. Formulation SD1-SD12 was prepared by PM, the drug and the polymer were triturated in a motor and pestle for 15 mins, and powders were screened through No. 22 # sieve. In formulation SD13-SD24 prepared by SM, the drug and polymer were separately dissolved in the required amount of methanol. Now, the polymer solution is dissolved in the drug solution and the solution was kept on a hot plate for some time to evaporate some part of methanol. Then the beakers were taken out form the hot plate and keep a side for 24-48 hr to evaporate the remaining methanol until dry form. The powders were screened through No. 22 # sieve. Formulation SD25-SD36 prepared by MM, the polymers were taken in a china dish and melted to their respective temperatures in a heating mantel to obtain a clear transparent solution. To these melted solutions, the drug was added and triturated. The cooling step was done at rapid cooling in an ice bath for the solidification process. Then, the samples were kept aside in a desiccator for 24-48 hr. The powders were screened through No. 22 # sieve, all were packed and kept in the desiccator.

Characterization of the GLZ SDs

SDs were inspected visually using an optical microscope. The funnel method was used to determine the angle of repose. Tapped density and bulk density of the samples were determined in a graduated cylinder of density apparatus. Blend physical properties, Angle of repose, flow rate, Hausner ratio and Carr's index were calculated.

Preparation of GLZ FDT

Based on the physicochemical characterization and release studies, the optimized SD mixtures was used for the preparation of FDTs. SDs equivalent to 40 mg of GLZ drug was taken to formulate the drug product. All the ingredients were weighed separately and passed through sieve # 60. Magnesium stearate and talc were added to the mixture before compression, the formula was given in Table 2.

Evaluation

Pre-compression parameters evaluation

The angle of repose, bulk density and tapped density, Carr's compressibility index and Hausner's ratio were determined.[18,19]

Post-compression parameters evaluation

Weight variation, thickness, hardness, friability, water absorption ratio, disintegration test, wetting time, content uniformity, *in vitro* dispersion time and dissolution studies were determined.[20,21]

Comparison of dissolution profiles

The prepared and optimised GLZ SD and GLZ FDT were compared with pure drug and marketed products.

RESULTS

To improve patient compliance, enormous new technologies have been established to overcome the pharmacokinetic and physicochemical characteristics of drugs. One of these

Table 1: Formulation of GLZ SD prepared by PM, SE and MM techniques.

Formulation code	Formulation Method	Drug: Polaxomer 188	Drug: Polaxomer 407	Drug: Cremophore RH 40	Drug: Solutol HS 15
SD1	Physical Mixture	1:1	-	-	-
SD2		1:2	-	-	-
SD3		1:3	-	-	-
SD4		-	1:1	-	-
SD5		-	1:2	-	-
SD6		-	1:3	-	-
SD7		-	-	1:1	-
SD8		-	-	1:2	-
SD9		-	-	1:3	-
SD10		-	-	-	1:1
SD11		-	-	-	1:2
SD12		-	-	-	1:3
SD13	Solvent Evaporation	1:1	-	-	-
SD14		1:2	-	-	-
SD15		1:3	-	-	-
SD16		-	1:1	-	-
SD17		-	1:2	-	-
SD18		-	1:3	-	-
SD19		-	-	1:1	-
SD20		-	-	1:2	-
SD21		-	-	1:3	-
SD22		-	-	-	1:1
SD23		-	-	-	1:2
SD24		-	-	-	1:3
SD25	Melting Mixture	1:1	-	-	-
SD26		1:2	-	-	-
SD27		1:3	-	-	-
SD28		-	1:1	-	-
SD29		-	1:2	-	-
SD30		-	1:3	-	-
SD31		-	-	1:1	-
SD32		-	-	1:2	-
SD33		-	-	1:3	-
SD34		-	-	-	1:1
SD35		-	-	-	1:2
SD36		-	-	-	1:3

technologies is the preparation of FDTs using SDs of drugs. GLZ FDTs were prepared by using the SD30 containing Poloxamer-407 as carriers.

Melting point

Determined by capillary tube method in the digital melting point apparatus and was found at 153°C (standard value is 159).

FTIR analysis

FTIR analysis of pure drug, Poloxamer-407 and SD30 were shown in Figure 1. FTIR spectrum of GLZ showed a stretching characteristic peak at 3267 cm^{-1} indicating N-H, C=H stretching vibration at 2918.7 cm^{-1}, a stretching at 1707 cm^{-1} indicates C=O, S=O stretch denoting the presence of sulphonyl indicating the drug was pure. SD30 FTIR spectra containing a 1:3 ratio of drug: Poloxamer-407 showed C-H stretching at 2916.6 cm^{-1}, N=H stretching vibration at 2849.5 cm^{-1}, -C=O stretching vibration at 1537 cm^{-1} and -S=O stretching at 1341 cm^{-1}. Stretches present in GLZ were seen in preparation without any changes in peaks which indicates there is no interaction within polymers and drug.

Table 2: **Gliclazide fast-dissolving tablets formulation.**

Sl. No.	Ingredient	Quantity (mg)
1.	SDs equivalent to 40 mg of GLZ drug.	160
2.	Sodium starch glycolate.	8
3.	Mannitol	20
4.	Lactose	10
5.	Talc	1
6.	Magnesium stearate	1
Total weight of tablet		200

DSC Studies

DSC thermograph of GLZ, Poloxamer-407 and SD30 were shown in Figure 2. A sharp endothermic peak at 167.06°C showed in the DSC thermograph of GLZ, the drug melting point as it melts with decomposition, which indicates the pure "crystalline" state of the GLZ. The Poloxamer-407 showed a sharp endothermic peak at 64.8°C. SD30 showed the characteristic peak of polymers used and a broad endothermic peak of GLZ. Melting point of GLZ SDs was disappeared. The disappearance of the melting peak of GLZ in SD30 signifies the transition of GLZ in formulation from crystalline to amorphous state. The amorphous state of GLZ may enhance the solubility due to more surface free energy. The DSC thermogram of SD30 did not show any new peaks that indicates compatibility between drug and polymer.

XRD studies

XRD pattern of GLZ, placebo and SD30 was depicted in Figure 3, diffractogram at 2θ equivalent to 10.68°, 22.93°, 28.36° and 28.49°. This signifies the crystalline nature of GLZ. The absence and lower intensity of the peaks in the results depicted an absence of obvious peaks representing crystals of GLZ in SD indicating that the drug was in an amorphous or disordered crystalline phase SD mixture.

SEM studies

The microphotograph of GLZ and SD30 is shown in Figure 4. The photograph of GLZ reveals that the drug was crystalline in

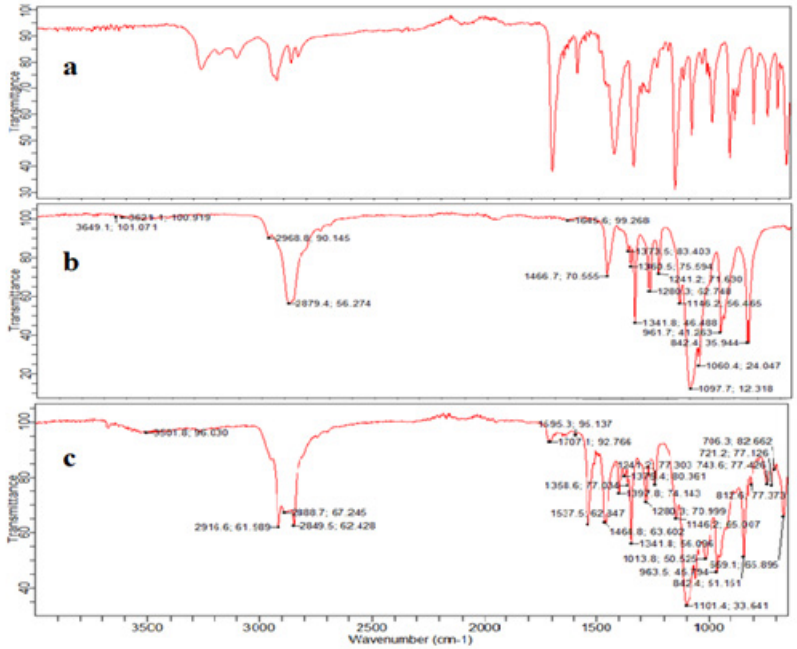

Figure 1: FTIR Spectrum of a) GLZ pure drug b) Poloxamer-407 and c) SD30.

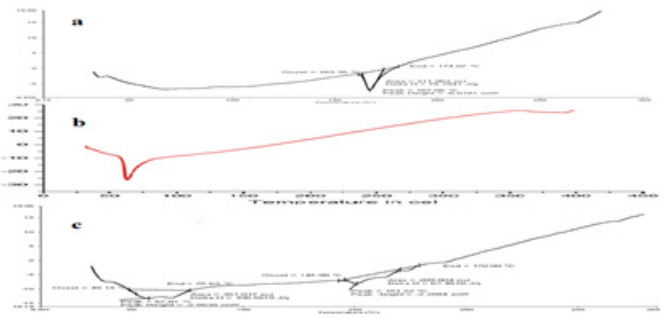

Figure 2: DSC thermogram of a) GLZ b) Poloxamer 407 M and c) SD30.

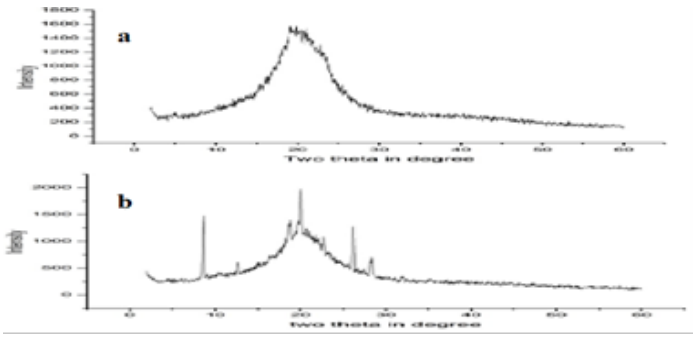

Figure 3: XRD studies of a) GLZ and b) SD30.

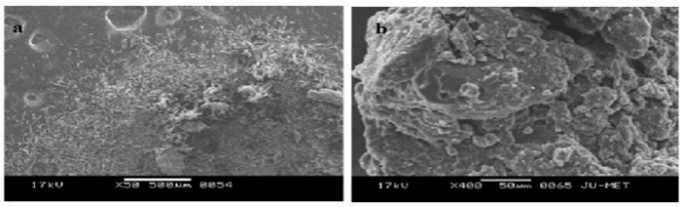

Figure 4: SEM studies of a) GLZ and b) SD30.

nature. This was in agreement with the XRD and DSC study. The SEM images of SD30 did not show any crystalline nature of GLZ on the surface of the formulation. This indicates that the drug and carrier are mixed homogenously and the absence of crystalline GLZ. This indicated the presence of amorphous GLZ in the formulation.

Characterization of the prepared GLZ SDs

Flow properties of the prepared GLZ SDs were characterized and the results of all formulation SD1-SD36, angle of repose values was in the range of 20.99º to 24.68º, which indicates their flow properties are excellent. Compressibility index values of all the prepared SD formulations showed good compressibility index value within 15% and their values were within the range of 10.74-14.83% respectively, indicating good to excellent flow characteristics and which clearly describes about the frictional and the cohesive interactions nature of the polymers shown in the formulation. Formulations SD1-SD36 Hausner's ratio values are <1.25 indicating the polymers having low interparticle friction and the Hausner's ratio also indicates good flow properties for prepared blends and its lubricated nature. The percent yield of all the formulations were in the range of 87.6 to 97.5%. The drug content of all prepared formulations was in the range of 81.7 to 99.7%.

In vitro dissolution studies

In vitro dissolution studies of all the prepared SDs were performed in pH 1.2 gastric fluid buffers for 1 hr at 37±0.5ºC, 50 rpm using USP type II apparatus and the *in vitro* drug release profiles were given in Figure 5. Drug release from formulation SD1-SD12, SD13-SD24 and SD25-SD36 was found to be 4.9 to 90.0%, 1.4 to 67.5%, 0.4 to 77.5% in 10 min and 42.9 to 99.8%, 21.6 to 90.8% and 51.23 to 94.02% in 60 min. From all the above studies formulation SD30 was optimized for the preparation of FDTs.

Compatibility studies of optimized tablet

FTIR spectra of the tablet mixture containing Poloxamer-407 and SD showed characteristic peaks at 1,709 cm^{-1} (C=O carbonyl sulphonylurea group), 2871.9 cm^{-1}(N=H group) and 1,280.3 cm^{-1} (S=O sulphonyl group). The SD30 containing GLZ showed similar characteristics peaks as the GLZ and excipients used. There is no shifting of the bonds and no new peaks, indicates the drug and excipients were compatible with each other.

Pre-compression properties

Angle of repose, Hausner's ratio and Compressibility index were performed to see the flowability characteristics of the optimized table formulation angle of repose is 24.01º indicates good flow characteristics. The compressibility index value is 14.28%, with the good compressibility index value within 15% proves that results in excellent flow characteristics, which describes the cohesive interactions and frictional nature of the polymers in FDT formulation. Hausner's ratio of the formulation is 1.16, indicated good flow property of the prepared lubricated blends, indicating the polymers with low interparticle friction.

Post-compression parameters

FDT formulation was evaluated for post-compression parameters such as general appearance, weight variation, thickness, hardness, friability, *in vitro* disintegration and *in vitro* dissolution studies.

GLZ FDT was with a weight of ≠ 200 mg (0.200 g) and is within the ±7% range and hence qualify the uniformity of weight test. FDT formulation thickness was in the range of 2.62 to 2.74 mm. Tablets hardness was in the range of 3 to 4 kg/cm^2. The percentage weight loss in friability test was less than 0.5%. FDT formulation disintegration time was 45 sec.

In vitro dissolution of the GLZ FDT formulation was 99.17% and the dissolution profile is shown in Figure 6a. Thus, the prepared GLZ FDT formulation with the selected polymer Polaxomer-407 with fusion method was regarded as good quality candidature for maintaining the official standards of tablets.

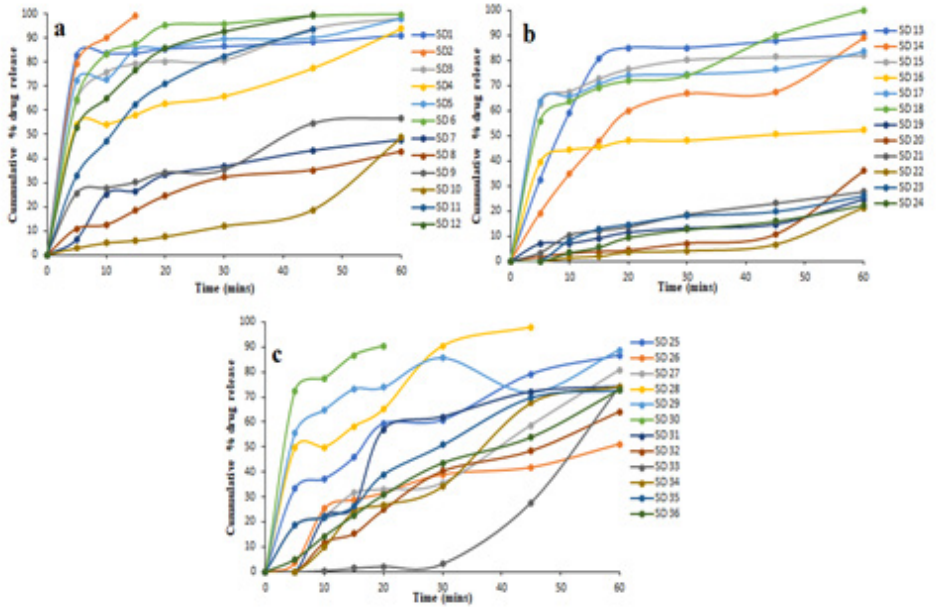

Figure 5: *In vitro* % cumulative drug release profiles of GLZ SD formulations a) SD1-SD12 b) SD13-SD24 and c) SD25-SD36.

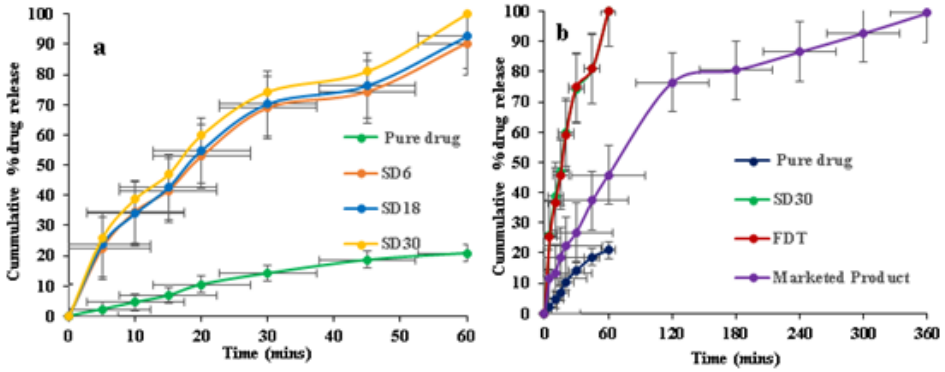

Figure 6: %Cumulative drug release profile of a) GLZ, Optimized SD6, SD18 and SD30 formulations and b) Comparison of GLZ, SD30, FDT with marketed product.

Comparison of dissolution profiles

Prepared GLZ SD30 and GLZ FDT were compared with GLZ and marketed product. From the drug release data, it was observed that SD30 and GLZ FDT dissolution profile showed more than 35% of GLZ release within 10 min and complete release was observed within 60 min whereas, the GLZ marketed product showed less than 15% of GLZ release within 10 min and complete release was observed within 360 min and shown in Figure 6b.

DISCUSSION

The objective of the present study was to develop FDTs of GLZ using three different polymers with different preparation methods in 1:1, 1:2 and 1:3 ratios for preparing SD. GLZ FDT were developed by the direct compression technique.[18] Thickness of the tablets showed that the FDTs maintained uniform dimensions. As per the IP specifications, tablets with 200 mg or less weight should be within ±7.5% the weight variation of the prepared FDT results was within the acceptable limits i.e., <7.5%. The hardness test revealed that all the prepared tablets have sufficient crush strength to withstand during transportation. Friability study results demonstrate that the formulations developed could withstand mechanical shock during transportation. Drug content results proves that the SD mixtures were free-flowing and therefore, the die cavity was filled uniformly during filling from the hopper and while compression; hence tablets with uniform weight were obtained. The most critical parameter for the development of FDT is disintegration time. Tablets' faster onset of action will be seen in immediate release or FDT dosage form in the stomach, which thereby produces local absorption of the drug.[22] The Disintegration time of the FDT formulation was found to be 45 sec, which may be due to the breakdown of the inter particulate

bonds, which was forced during the tablet compression. Therefore, FDT formulation with less than 50 sec disintegration time has achieved the goal of fast disintegrating to immediately release the drug. GLZ FDTs were prepared with microcrystalline as a directly compressible vehicle and Polaxomer-407 synthetic polymer when tablets come in contact with the gastric fluid, which may cause a burst rupture of the tablet core. Due to the burst rupture of the core of the tablet by disintegrants, which causes the tablet to break into fragments or granules surrounded by the 1.2 pH gastric fluid, leads to an increase in the particles' surface area and increased drug release from the tablet. It was confirmed that the formulation FDT showed better dissolution characteristics from the data of *in vitro* dissolution study and comparative dissolution studies of marketed products. FTIR data explains that FDT could be a suitable FDT formulation without any drug-polymer interactions. The absence of drug-excipient interactions has been proven by the results of the DSC study, which exhibit the developed FDT formulation was modified and converted or changed into an amorphous form. XRD results of FDT formulation has shown a less intense and broad peaks and also the absence of extra characteristic peaks, indicating the amorphous nature of drug.

CONCLUSION

Among all the people with diabetes, type II DM cases are more than 90%. It is a complex metabolic disorder which is caused from variable contributions of decreased insulin action or insulin resistance in target tissues and relatively decreased pancreatic insulin secretion, primarily in the liver and muscle. GLZ has poor water solubility and it shows low and variable bioavailability oral. So, solubility enhancement techniques have been employed, to improve the drug's Oral bioavailability. It has a short plasma half-life (1 hr). In this research work, an approach was made to formulate and characterize GLZ SD FDT. From the results, it was concluded that Poloxamer-407 in the ratio 1:3 in the fusion method could enhance the solubility of GLZ, which gives maximum drug release in minimum time i.e., within 5 min. From the results, it was found that the nature of the synthetic polymer and the technique used in the preparation of the tablet has influenced the release rate. Hence, the FDT formulation is optimized and Polaxomer-407 is a suitable candidate for the preparation of SD with the MM method to improve the solubility of GLZ drug.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DM: Diabetes mellitus; **GLZ:** Gliclazide; **SD:** Solid dispersion; **PM:** Physical method; **SM:** Solvent evaporation; **MM:** Melting techniques; **FDT:** Fast-dissolving tablets; **FTIR:** Flourier transfer infrared spectroscopy; **DSC:** Differential scanning calorimetry; **PXRD:** Powder X-ray diffractometry; **SEM:** Scanning electron microscopy; **hr:** Hour; **min:** Minutes; **mg/mL:** Milligram per millilitre; **mg:** Milligram; **kg:** Kilogram; **kg/cm^2:** Kilogram per centimetre square; **g:** Gram; **rpm:** Revolution per minute; **˚C:** Degrees centigrade; **i.e.:** that is; **log:** Logarithm; **nm:** Nanometres; **mm:** Millimetres.

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