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{Research Article}

Development and Evaluation of Liquisolid-Based Sustained Release Tablets of Glipizide

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Abstract: By creating prolonged release systems, the liquid solid approach is proposed as a means of lowering the pace at which drugs dissolve. Glipizide was dissolved in propylene glycol, which served as the liquid vehicle for this investigation. After that, a binary mixture of coating and carrier materials silica as the coating material and Eudragit S or L as the carrier was added to the liquid medication while it was being continuously mixed in a mortor. Using the manual tableting machine, the finished mixture was compacted. The creation of any compound between the drug and excipients or any changes in crystallinity during the production process were examined using Differential Scanning Calorimetry and Fourier transform infrared spectroscopy. Liquisolid-prepared glipizide tablets had superior retardation characteristics when compared to traditional matrix tablets. The employed liquisolid vehicles demonstrated potential for improving and regulating Glipizide medication release from liquisolid compacts.The majority of the liquisolid formulations, according to the kinetics investigations, adhered to the Zero order equation, which stipulates that drug release follows Zero order kinetics.

Keywords: Glipizide; Liquisolid technique; Sustained release tablets; Eudragit; Drug release kinetics; In-vitro dissolution.

INTRODUCTION

Because of its affordability, ease of use, and high patient compliance, the oral route is still the recommended method of drug administration. A medication must dissolve in the stomach contents in order to enter the systemic circulation after oral delivery. Furthermore, because to their high lipophilicity and poor solubility, up to 50% of therapeutic molecules taken orally experience formulation issues[1-4].

This method involves dissolving the medication in an organic solvent and then soaking the mixture in a high-surface-area carrier, like silica. However, using hazardous solvents its drawbacks because the medication formulation contains leftover solvent. [5-7]

The "liquisolid compacts" technology is a recently created, promising addition to the novel dissolution enhancement approach that can be used to solve the problem. The drug was in a molecular state of subdivision in these systems, which were free-flowing, dry-looking granules that adhered to one another.[8–9.]

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Low amounts of carrier are needed to provide a dry powder with free flowability and acceptable compatibility when such materials are added to liquid medications [10–11].
Liquisolid compacts of water-insoluble compounds may exhibit improved drug release characteristics and, as a result, greater oral bioavailability because of the greatly increased wetting properties and surface area of the medication available for dissolution. [12] In this way, BCS contributes to the scientific method for predicting the pharmacokinetics of oral quick release medicinal products in vivo.[13].

Introduction to sustained release dosage forms:

For once-daily drug dosing, SR formulations that would sustain drug plasma levels for 8 to 12 hours may be enough. Better patient compliance and increased clinical efficacy of the medication for its intended use are frequently the results of the goal to keep the blood level of a medication close to constant or uniform[15]. In the sphere of pharmaceutical technology, the introduction of matrix tablets as sustained release (SR) has led to a new breakthrough for novel drug delivery systems (NDDS). When creating an SR dosage form, a hydrophilic polymer matrix is frequently utilized[16–18]. Intense research has recently focused on the designation of SR systems for weakly water-soluble drugs[19]. Several SR oral dosage forms have been created, including membrane controlled systems, matrices with water soluble/insoluble polymers or waxes, and osmotic systems.

MATERIALS AND METHODS

Chemicals

Materials used for the experimental work are shown in Table 2.

Table 2 List of chemicals

Sr. No.	Drug/Excipients	Gifted/Manufactured by
1.	Glipizide	Microlabs, Goa
2.	Tween 80	Mahendra's pure chem,Mumbai
3.	Propylene glycol	Vishal chem,Mumbai
4.	HPMC K 100	Colorcon Asia Pvt .Ltd.,Mumbai
5.	Eudragit L 100	Evonik Degussa Pvt. Ltd. Mumbai
6.	Eudragit S 100	Evonik Degussa Pvt. Ltd. Mumbai
7.	Silica	Research lab fine chem,Mumbai

Characterization of drug

Characterization of Glipizide

Characterization of Glipizide was carried out using following tests:

1. Organoleptic properties
2. Determination of melting point
3. Determination of pH and solubility
4. Spectroscopic characterization using
   - UV- Visible spectroscopy

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- IR spectroscopy

5. Determination of thermal behaviour by Differential Scanning Calorimetry (DSC)

1. Organoleptic properties

The powder was examined for appearance (colour, odour) and nature.

2. Melting point determination

Melting point equipment was used to determine Glipizide's melting point. By adding a little amount of material to the capillary connected to the graduated thermometer and applying continuous heat while the assembly was suspended in the paraffin bath, the melting point was ascertained. The drug sample was tested between 30 and 300 degrees Celsius, and the point at which the substance melted was recorded.

3. Determination of pH and solubility

Glipizide's pH in distilled water was measured with a digital pH meter, and the result was recorded. Glipizide's solubility was assessed by adding too much dig to the solvent. Glipizide solubility tests were conducted in four distinct non-volatile solvents—PEG 400, PEG 200, Propylene Glycol, and Polysorbate 80—in order to determine the optimal non-volatile solvent for suspending the drug in liquid medication. Glipizide was added in excess to the vehicle and shaken on a shaker for 48 hours while being constantly stirred to create a saturated solution. Following this time frame, the solutions were filtered, diluted at least 1000 times with distilled water, and then examined using a UV spectrophotometer set to 276 nm. For every sample, three analyses were performed to calculate the solubility of Glipizide.

4. Spectroscopic characterization of Glipizide

A) UV- Visible Spectroscopy characterization

a) Determination of λ-max

Glipizide's UV spectrum was measured using 0.1N HCl and phosphate buffer (pH 7.4). After precisely weighing 10 mg of glipizide, it was transferred to a 100 ml volumetric flask. To dissolve the medication, 0.1N HCl was added, and the volume was increased to 100 ml. This solution, which contains 100 µg/ml of Glipizide, was used as the stock solution. A concentration of 5–30 µg/ml was achieved by suitably diluting this solution with 0.1N HCl. The cuvette held the solution. Using a Labindia twin beam UV-visible spectrophotometer, the UV spectrum was recorded between 200 and 400 nm in relation to a blank (0.1N HCl). The wavelength with the highest absorption was noted. The process was performed using phosphate buffer pH 7.4 in place of 0.1 N HCl.

b) Calibration Curve by UV Spectroscopy

Preparation of standard curve of Glipizide

Glipizide 100 µg/ml in 0.1N HCl was made into a stock solution. Then, to create a solution with varying concentrations of 3–30 µg/ml, appropriate aliquots of the stock solution

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(0.5–3 ml) of Glipizide were put into a 10 ml volumetric flask and diluted with 10 ml 0.1 N HCl. All solutions' absorbance was measured at 276 nm using 0.1N HCl as a blank. This concentration-absorbance data was used to plot the Beers-Lambert graph. Glipizide release from liquisolid sustained release tablet formulations in the dissolution fluid was estimated using this standard curve. To create the Glipizide calibration curve in phosphate buffer pH 7.4, the identical process was carried out again. The percentage drug content and cumulative drug release of Glipizide from liquisolid tablets were calculated using these calibration curves.

B) IR spectroscopy

The FTIR Spectrophotometer (FTIR-8400S, Shimadzu) was used to record the infrared spectra of Glipizide (pure drug) using the potassium bromide dispersion procedure, which involved placing a combination of the drug and potassium bromide in a sample holder. The sample was verified by comparing the discovered peaks with the principal peaks of the Glipizide IR spectra that was published.

5. Determination of thermal behavior by Differential Scanning Calorimetry (DSC)

Glipizide was evaluated using thermal analysis. Throughout the experiment, nitrogen gas was purged at a rate of 40 milliliters per minute to maintain the inert atmosphere. For precise results, the samples (1-2 mg) were carefully moved and cooked in a crimped aluminum pan. At a rate of 10°C per minute, the samples were heated from 30°C to 250°C.

Characterization of polymers

Eudragit, HPMC K100M used for the formulation were characterized for following parameter

Determination of IR spectrum

The FTIR Spectrophotometer (FTIR-8400S, Shimadzu) was used to record the infrared spectra of Eudragit, HPMC K100M using the potassium bromide dispersion procedure, which involved placing a combination of polymer and potassium bromide in a sample holder. The samples were verified by comparing the discovered peaks with the principal peaks of the reported infrared spectra of the corresponding polymer.

Compatibility studies

Fourier Transform Infrared Spectroscopy (FTIR)

By using the potassium bromide dispersion technique, which involves placing a mixture of the polymers Glipizide and potassium bromide in a sample holder, the infrared spectrum of a physical mixture of Eudragit: Glipizide (1:1) was captured using an FTIR Spectrophotometer (FTIR-8400S, Shimadzu). The principal peaks of the reported infrared spectra of Glipizide and the corresponding polymers were compared with the discovered peaks.

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Differential Scanning Calorimetry (DSC)

The DSC study of physical mixture of Eudragit: Glipizide (1:1) for compatibility study was recorded.

Formulation and development

Preparation of liquisolid tablets[20]

1. A 20 ml glass beaker containing precisely calculated amounts of drug and nonvolatile solvent is heated to dissolve the drug in the solvent.
2. Calculated amounts of coating and carrier components are mixed with the resultant hot medicine.
3. According to Spireas et al., the mixing procedure is completed in three steps. The first step involves blending the system for about a minute at a rate of around one rotation per second to disperse the liquid medication equally throughout the powder.
4. To allow the medication solution to be absorbed into the interior of the powder particles, the liquid/powder admixture is dispersed evenly as a homogeneous coating on the mortar's surfaces in the second stage and let to stand for about five minutes.
5. Using an aluminum spatula, the powder is scraped off the mortar surfaces in the third stage. It is then combined with sodium starch glycolate for an additional 30 seconds, much like in the first stage.
6. The Rimek minipress-1 tablet compression machine (10 stations) with a 7.5 size punch is used to compress the final liquisolid formulation.

Table 3 Formulation batches of tablets

Batch code	Drug (mg)	Liquid vehicle	Liquid medication (mg)	Carrier	Quantity of carrier	Lf	Silica (mg)	R	Total
F1	10	PG	33	Eudragit R	107.14	0.30	10.71	10	150
F2	10	PG	33	Eudragit S	107.14	0.30	10.74	10	150
F3	10	PG	36	Eudragit R	103.44	0.34	10.34	10	150
F4	10	PG	36	Eudragit S	103.44	0.34	10.34	10	150
F5	10	PG	42.62	Eudragit R	97.62	0.43	9.76	10	150
F6	10	PG	42.62	Eudragit	97.62	0.43	9.76	10	150

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				S					
F7	10	PG	35	HPMC K 100M	105	0.33	10.5	10	150
F8	10	PG	29	HPMC K 100M	110	0.26	11.0	10	150

Evaluation parameters for liquisolid powder

Flow properties

The flow properties of the liquisolid powder were evaluated from the changes in the volume due to rearrangement and packing occurring during tapping in a graduated measuring cylinder.

Evalution of prepared tablets:[21,22]

Hardness

Tablets were randomly selected from each batch and hardness of each tablet was determined by Monsanto tablet hardness tester.

Friability

It is the ability of tablets to withstand mechanical shocks during handling and transportation.

Weight variation test

Tablets (20) were randomly selected from each batch and weighed on electronic balance. Average weight from each batch was noted.

Drug content determination

The IP 1996 was used to measure the tablets' drug content. Glipizide liquisolid tablet drug content homogeneity was measured at 276 nm. Ten randomly selected samples of all Glipizide liquisolid tablets, each containing an equivalent of five milligrams of the drug, were precisely weighed and dissolved in five milliliters of phosphate buffer (pH 7.4) in order to determine the content homogeneity. The drug content was measured using spectrophotometry at 276 nm.

Thickness and diameter

The thickness and diameter of the tablets was determined using a digital caliper. Five tablets from each batch were used and average values and S.D.s were calculated.

***In vitro* Dissolution Studies:[21]**

USP Dissolution test apparatus II (paddle type) was used to conduct in vitro dissolution tests for every formulation. Glipizide (10 mg) sample tablets that had been precisely weighed were put in the paddle. For the dissolution investigation, 900 mL of 0.1N HCl (pH

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1.2) was used for two hours. After that, the 0.1N HCl was replaced with phosphate buffer (pH 7.4), which was kept at 37ºC ± 0.5ºC and the paddle was rotated at 50 rpm. At half an hour intervals, aliquots (5 mL) of the samples were taken out, and the quantities were replaced with an equivalent volume of simple dissolution medium (0.1N HCl) that was maintained at 37ºC. A Labindia UV-visible double beam spectrophotometer is used to examine the samples at λmax 276 nm versus 0.1N HCl and Phosphate buffer pH 7.4 as blank. The dissolution study performed in replicates and results expressed were the mean of two experiments. Analysis of data was done by using 'PCP Disso V-3' software, India.

Kinetics analysis of drug release

To analyze the mechanism of drug release from the tablet, the *in vitro* dissolution data were fitted to zero order, first order, Higuchi release model, Hixson and Crowell powder dissolution method and Korsmeyer and Peppas model by using PCP Disso Version 3 software, and the model with the higher correlation coefficient was considered to be the best model.

Comparison with marketed formulation

The developed product was quantitatively evaluated. and comparative dissolution profile of developed and marketed product was presented in Figure. Details of marketed product are shown below in Table 4.

Table 4 Details of marketed product

Manufacturer	USV Pharmaceuticals (India)
Brand Name	Glynase XL 10 mg

Stability Studies and Storage Condition (ICH guide lines)

As a technical criterion for the registration of medicines for human use, ICH defines stability criteria to examine the impact of storage conditions or environmental conditions on formulation.

The optimized tablet batch F5 was chosen, and the tablets were packaged in aluminum packaging with polyethylene coating inside. For three months, different replicates were stored in a humidity chamber that was kept at 40 °C and 75% relative humidity.

RESULTS AND DISCUSSION

Characterization of Glipizide

In the present study, an attempt was made to formulate the sustained release liquisolid tablets using Eudragit. The characterization of drug was done by the melting point, pH, solubility, UV spectroscopy, IR Spectroscopy and Differential Scanning Calorimetry.

Organoleptic properties

The Glipizide was shown following organoleptic properties

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Table 5 Organoleptic properties of Glipizide

Sr. No.	Properties	Glipizide
1	Colour	White
2	Appearance	Powdered form
3	Odour	Odourless

Melting point

The melting point was practically obtained 208-210^{0}C which was in a range as compared to standard.

Table 6 Standard and practical melting point of Glipizide

Sample Name	Standard	Practical
Glipizide	208-209^{0}C	208-210^{0}C

pH study

The pH of Glipizide was shown 4.2-5.

Table 7 pH of Glipizide in distilled water

Sample Name	pH
Glipizide	4.2-5

Solubility study

The solubility study was found to be

Table 8 Solubility study Glipizide of at room temperature

Glipizide	Solubility g/ml
Distilled Water	2 g/ml
Propylene glycol	2.41 g/ml
Polyethylene glycol 600	3.82 g/ml
Polyethylene glycol 400	4.29 g/ml
Glycerine	10.4 g/ml

Ultraviolet absorbance spectroscopy:

The UV study shows λ max 276 nm which is similar to standard.

Table 9 λ max values of Glipizide in 0.1N HCl and Phosphate buffer (pH 7.4)

Sr. No	Solvent	λmax in nm
1	0.1N HCl	276
2	Phosphate buffer (pH 7.4)	276

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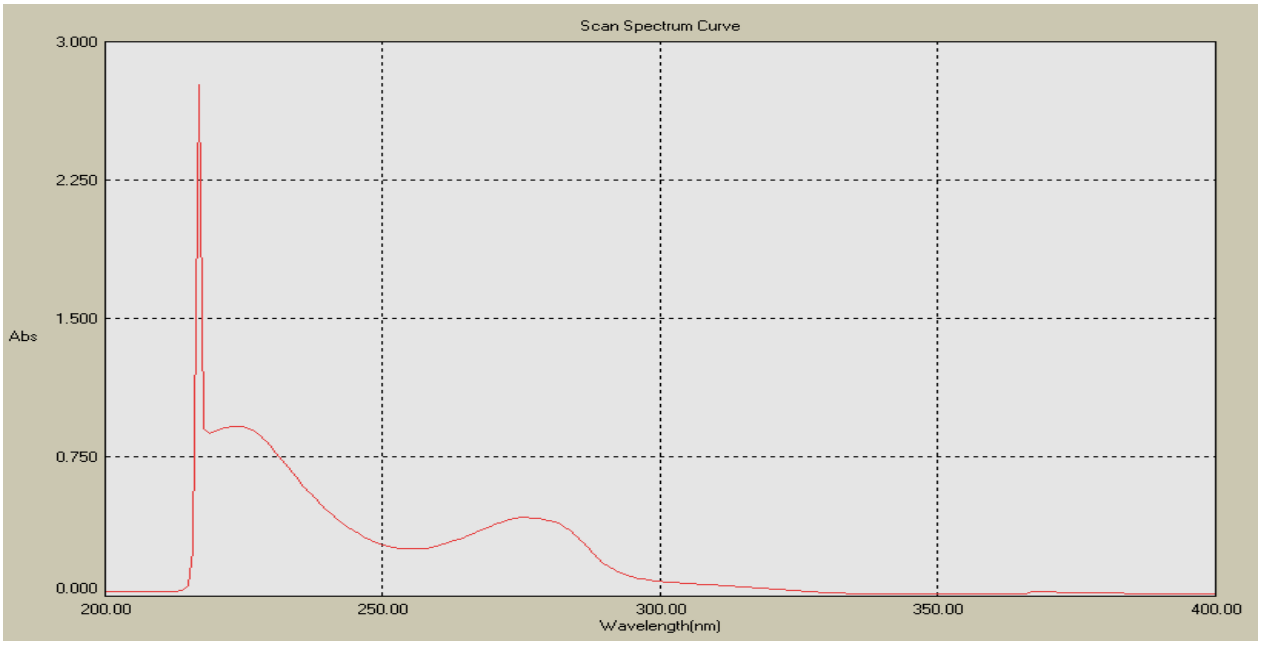

Fig. 1 U.V. absorption spectrum of Glipizide in 0.1N NaOH

Calibration curves of Glipizide

The UV absorption data at the wavelength 276 nm (in 0.1N HCl) is shown in Table 10. It was observed that Glipizide showed good linearity (r^2 = 0.9968) over the range of 5-30 µg/ml in 0.1N HCl.In same way Glipizide shows absorption at 276 nm (in pH7.4 phosphate buffer) and linearity (r^2 = 0.9955) observed in range of 5-30 µg/ml. Hence, calibration curves of Glipizide were found to obey Beer-Lambert's law over this range.

Table 10 Concentration and absorbance data of Glipizide in 0.1N HCl

Conc. of Glipizide (µg/ml)	Absorbance at 276 nm
0	0±0.0000
5	0.127±0.0035
10	0.223±0.0059
15	0.351 ±0.0066
20	0.467±0.0011
25	0.546±0.0005
30	0.763±0.0019
Coefficient of correlation (r^2)	0.9978
Equation of line (y = m x + c)	y=0.0221x + 0.005

*All values are expressed as Mean ±S.D., n = 3

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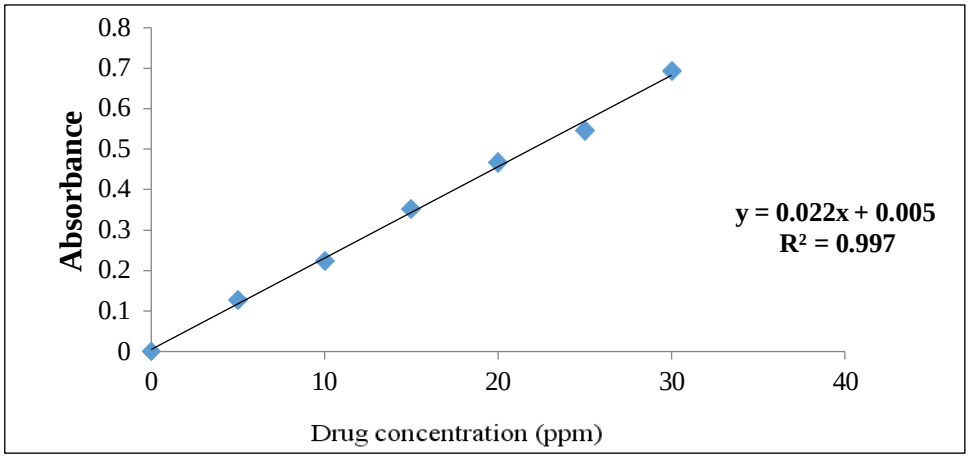

Fig 2 Calibration curve of Glipizide in 0.1N HCl

Table 11 Concentration and absorbance data of Glipizide in phosphate buffer pH 7.4

Conc. of Glipizide (µg/ml)	Absorbance at 276 nm
0	0±0.0000
5	0.145 ±0.0032
10	0.255 ±0.0019
15	0.362 ±0.0043
20	0.469 ±0.0016
25	0.615 ±0.0013
30	0.772 ±0.0013
Coefficient of correlation (r^2)	0.9955
Equation of line (y = m x + c)	Y =0.0248x + 0.0022

*All values are expressed as Mean ±S.D., n = 3

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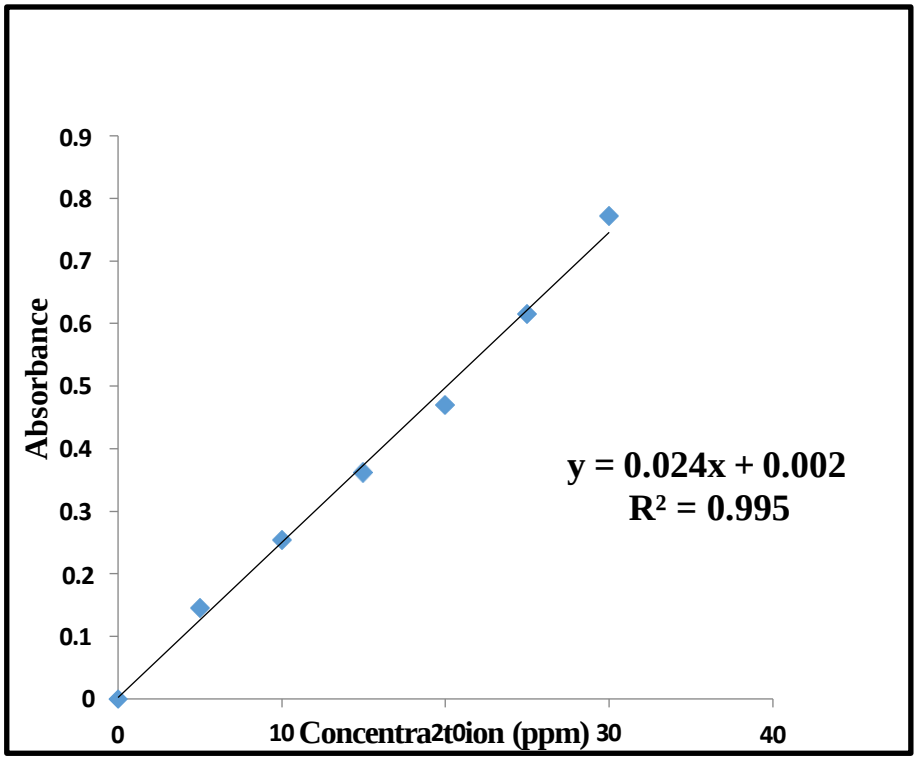

Fig 3 Calibration curve of Glipizide in phosphate buffer pH 7.4

Interpretation of IR Spectrum

Table 24 Shows peaks observed at different wave numbers and the functional group associated with these peaks.

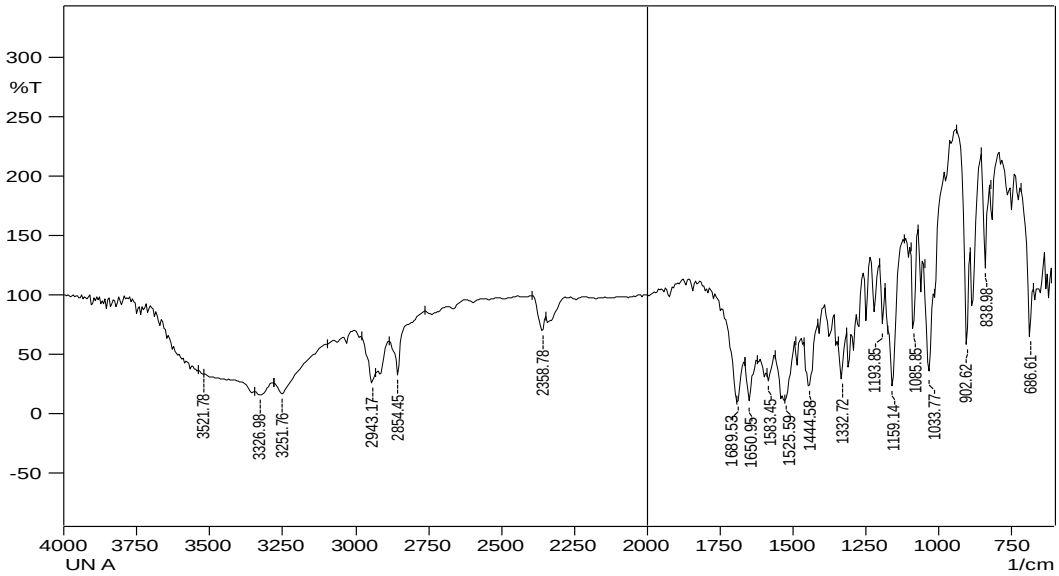

Fig 4 FTIR Interpretation of Glipizide

Drug-Polymer interaction study

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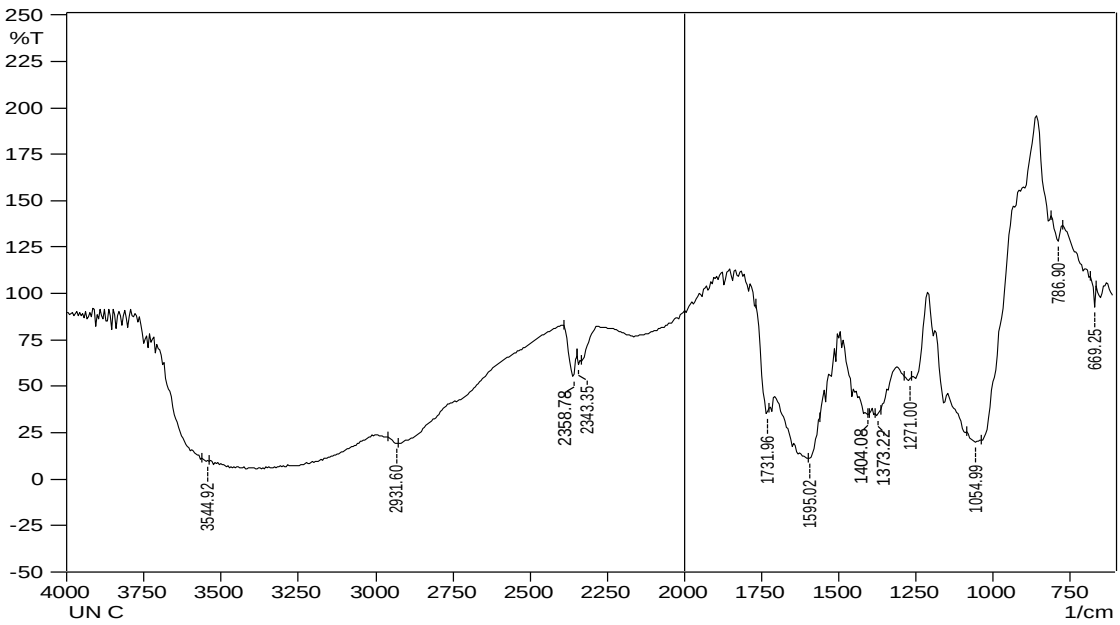

Fig 5 FTIR spectra of mixture Glipizide and Eudragit

DSC studies

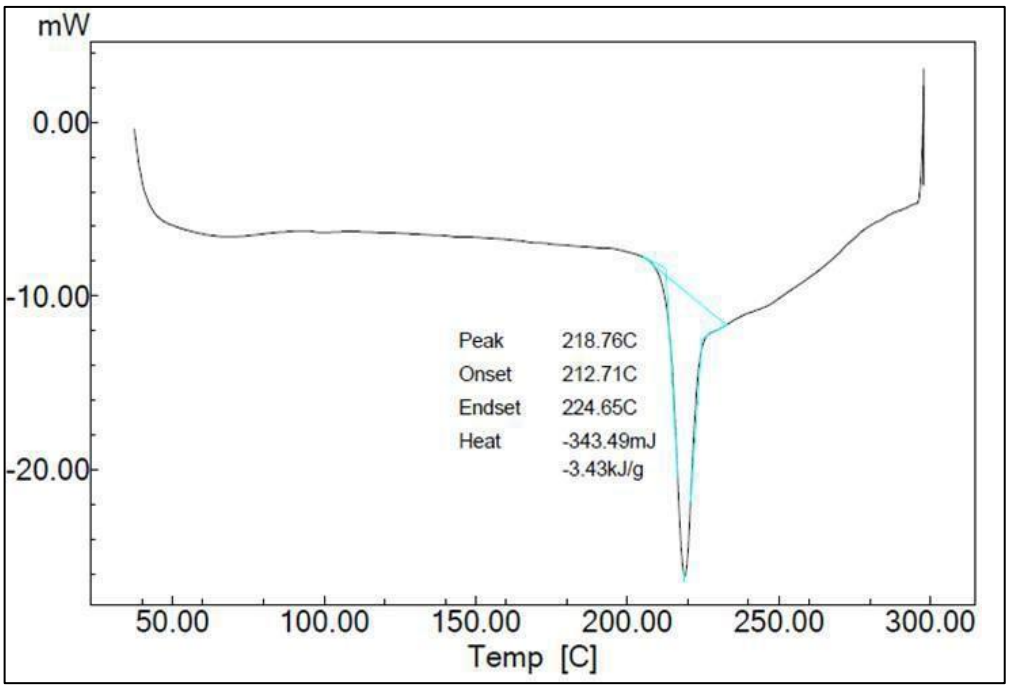

Fig 6 DSC thermogram of pure Glipizide.

Glipizide was confirmed by differential scanning calorimetry (DSC) at scan rate of 10°C/min. It exhibits a sharp melting endotherm with onset temperature 212.71°C and peak temperature 218.76°C.It was confirmed with the reported melting point of Glipizide i.e. 208°C – 210°C.

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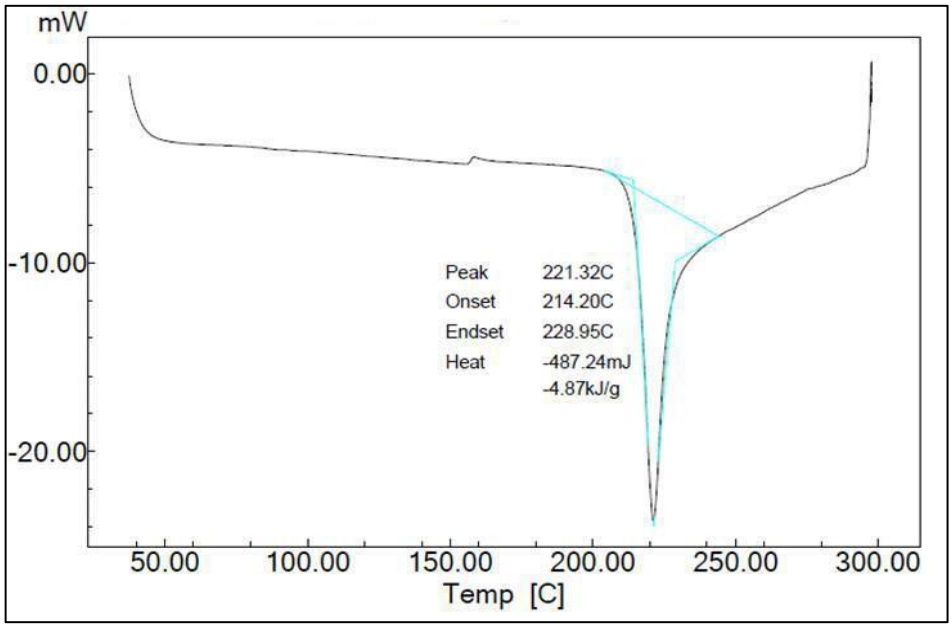

Fig 7 DSC thermogram of mixture of Glipizide, Eudragit.

DSC thermogram of pure drug Glipizide powder showed a sharp endothermic peak near to 212.71^{0}C which indicating of its melting temperature. melting endotherm of Glipizide was observed to 214.20^{0}C. DSC thermogram showed that there was no much more difference in onset temperature and peak temperature, when compared with pure drug's thermogram. So no interaction was found between drug and polymers used.

Formulation Evaluation

Evaluation of liquisolid powder

Flow properties

Powder prepared for direct compression method was evaluated by following parameters such as; Bulk density, Angle of repose, Hausner's ratio, carr's index, the results are shown in table 12.

Table 12 Values of precompressive parameters(n=3)

Batch Code	Angle of Repose*	Carr's Compressibility Index*	Hausner Ratio * (HR)	Bulk Density* (g/ml)±S.D.	Tapped Density* (g/ml)±S.D.
F1	27.98±0.97	8.38±1.09	1.09±0.0057	0.76±0.01	0.83±0.01
F2	27.76±0.62	5.78±1.98	1.05±0.02	0.81±0.01	0.86±0.01
F3	29.75±0.70	5.84±1.23	1.05±0.70	0.81±0.01	0.86±0.01
F4	28.54±0.65	9.63±1.15	1.10±0.01	0.75±0.01	0.83±0.01
F5	27.73±0.58	6.85±1.88	1.07±0.02	0.72±0.01	0.71±0.01
F6	28.64±1.34	12.63±3.42	1.14±0.04	0.71±0.01	0.81±0.01
F7	27.19±0.53	10.90±5.33	1.12±0.015	0.81±0.01	0.91±0.01
F8	27.89±0.75	9.5±3.03	1.10±0.04	0.81±0.01	0.90±0.01

*All values are expressed as Mean ±S.D., n = 3

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Evalution of tablets

The tablet formulations were subjected to various post-compressive evaluation tests, such as

Official tests

Hardness

States that all the formulations were found in the range 4-6 kg/cm^2 which was in limit as pharmacopoeial standard.

Friability

Compressed tablets that lose less than 1% of their weight are generally considered acceptable,as per pharmacopoeial standard.

Drug content

Was also carried out as per official method and it was found that all batches shows good content uniformity. The all values for all formulations were ranges from 95.42 to 103.5%.

Weight variation

was also carried out as per official method and average percent deviation of all formulations was found to be within limit (as per Pharmacopoeial standard) in range 150.02 to 152.55.

The results for all formulation were shown in Table 13

Table 13 Values of post-compressive parameters (n=3)

Formulation code	Hardness* (kg/cm^2)	Friability* (%)	weight variation* (mg)	Drug content* (%)
F1	4.04±0.20	0.49±0.12	152.44±5.48	97.63±0.61
F2	4.42±0.50	0.34±0.028	151.18±5.78	95.42±0.65
F3	4.16±0.20	0.37±0.10	150.02±6.6	102.44±0.81
F4	4.22±0.63	0.36±0.01	150.96±4.25	99.9±1.2
F5	4.12±0.16	0.33±0.01	151.23±4.7	96.12±0.85
F6	4.64±0.55	0.42±0.15	151.65±6.72	103.50±3.41
F7	4.8±0.68	0.33±0.05	152.55±4.10	99.5±1.05
F8	4.4±0.46	0.32±0.055	151.00±5.48	103.1±1.05

*All values are expressed as Mean ±SD, n = 3

Non-official tests

Diameter found in range 7.40±0.012 to 7.41±0.016 mm and Thickness(mm) was found to be 3.39±0.018 to 3.76±0.24.

Table 14 Values of post-compressive parameters (n=3)

Formulation code	Thickness(mm)	Diameter(mm)
F1	3.39±0.018	7.41±0.016
F2	3.43±0.06	7.40±0.012
F3	3.41±0.044	7.41±0.015

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F4	3.4±0.031	7.40±0.012
F5	3.46±0.09	7.40±0.014
F6	3.41±0.04	7.40±0.0084
F7	3.50±0.078	7.40±0.004
F8	3.76±0.24	7.40±0.012

In-vitro % drug release

In-vitro % drug release study was found given in table 15

Table 15 In vitro % drug release study

Batch Code	% Drug release (after 12 hrs.)
F1	65.01
F2	64.07
F3	90.8
F4	98.2
F5	99.69
F6	98.46
F7	91.43
F8	80.09
Fm	99.50

Cumulative% drug release

Cumulative% drug release of formulation F1-F4 shown in table 16.

Time (hr)	Cumulative % Drug release			
	F1*	F2*	F3*	F4*
0	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00
1	4.71±0.20	4.24±0.36	5.93±2.20	5.43±0.41
2	6.80±0.33	4.36±0.58	7.41±1.53	6.17±0.42
3	7.93±0.36	6.22±0.47	9.15±2.38	10.86±1.77
4	21.14±0.48	9.39±0.51	16.04±0.47	19.56±0.57
5	22.72±0.82	13.35±1.29	24.53±0.87	34.96±0.57
6	25.27±0.43	23.93±0.90	36.66±1.28	48.9±0.95
7	33.79±2.11	30.60±1.03	44.06±1.80	53.9±0.52
8	37.25±0.48	51.49±1.88	59.6±1.80	68.2±1.03
9	42.55±0.52	53.56±1.49	64.91±1.76	76.4±3.79
10	57.19±0.52	54.65±1.10	80.36±0.49	84±0.62
11	60.06±0.52	58.26±1.27	85.3±0.43	96.43±1.10
12	65.01±0.47	64.07±2.00	90.8±1.01	98.2±0.55

Table 16 In-vitro Cumulative % Drug release study (F1-F4)

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*All values are exressed as Mean ±SD, n = 3

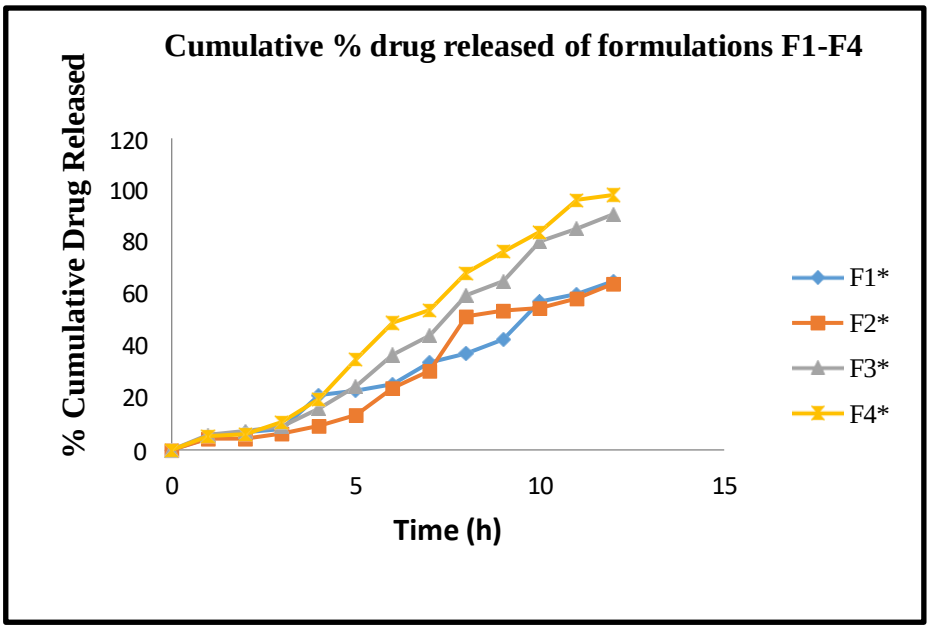

Fig 8 Percent cumulative drug release of formulation F1 to F4

Cumulative% drug release of formulation F5-F8,Fm shown in table 17.

Table 17 In-vitro Cumulative % Drug release study(F5-F8,Fm)

*All values are expressed as Mean ±SD, n = 3

Time (hr)	Cumulative % Drug release				
	F5*	F6*	F7*	F8*	Fm* (marketed)
0	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00
1	5.67±0.72	6.75±0.36	5.04±0.59	3.99±1.09	7.86±1.00
2	6.77±0.36	7.86±0.72	7.13±0.72	7.00±0.20	8.90±0.88
3	14.86±0.48	18.95±2.33	8.64±0.77	8.76±0.49	14.82±1.32
4	28.15±1.28	29.91±0.14	9.25±0.87	10.15±1.57	26.97±1.68
5	43.5±0.9	48.31±1.36	14.94±0.45	15.25±0.92	33.3±1.87
6	61.5±2.13	56.99±0.52	24.5±0.90	25.11±0.58	38.27±0.89
7	70.5±1.13	67.2±1.37	38.31±2.53	41.03±0.84	60.34±2.09
8	87.6±1.05	80.75±1.03	44.66±0.05	46.08±0.81	64.06±1.00
9	91.3±0.6	90.36±1.97	62.87±0.92	62.34±1.51	88.79±1.74
10	94.4±1.13	94.75±2.33	77.66±6.28	75.65±0.70	95.68±2.13
11	97.9±1.55	97.05±1.82	85.58±1.44	78.09±0.30	98.59±1.41
12	99.69±0.32	98.46±1.10	91.43±0.57	80.09±0.42	99.50±1.44

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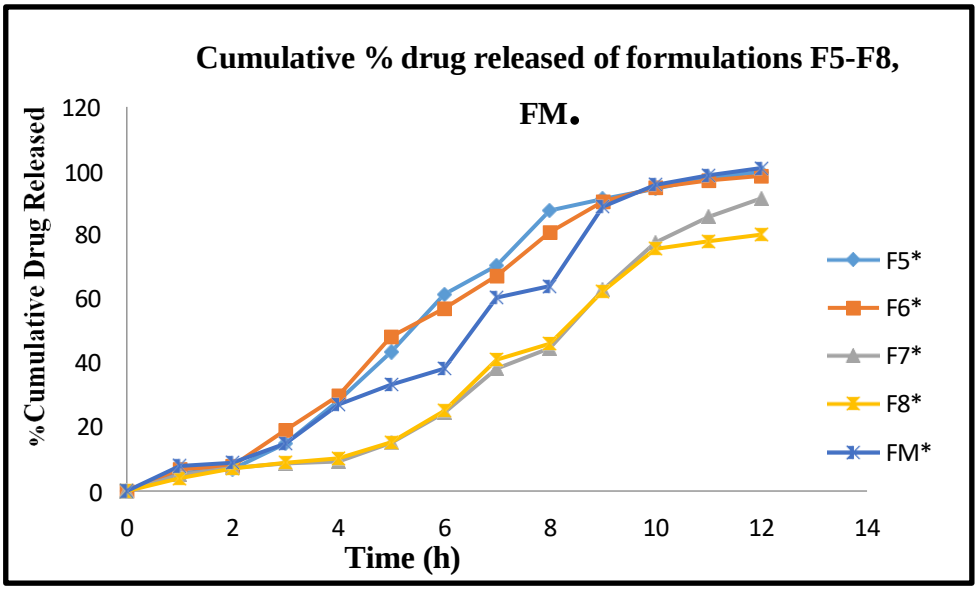

Fig 9 Percent cumulative drug release of formulation F5 to F8 and FM

Comparative dissolution profile of developed and marketed formulation

Comparative dissolution profile of developed and marketed formulation shown in fig 10

Table 18 Comparative dissolution profile of developed and marketed formulation

Time (Hrs)	Cumulative Drug Release (%)	
	Developed formulation	Marketed formulation
0	0.00±0.00	0.00±0.00
1	5.67±0.72	7.86±1.00
2	6.77±0.36	8.90±0.88
3	14.86±0.48	14.82±1.32
4	28.15±1.28	26.97±1.68
5	43.5±0.9	33.3±1.87
6	61.5±2.13	38.27±0.89
7	70.5±1.13	60.34±2.09
8	87.6±1.05	64.06±1.00
9	91.3±0.6	88.79±1.74

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10	94.4±1.13	95.68±2.13
11	97.9±1.55	98.59±1.41
12	99.69±0.32	99.50±1.44

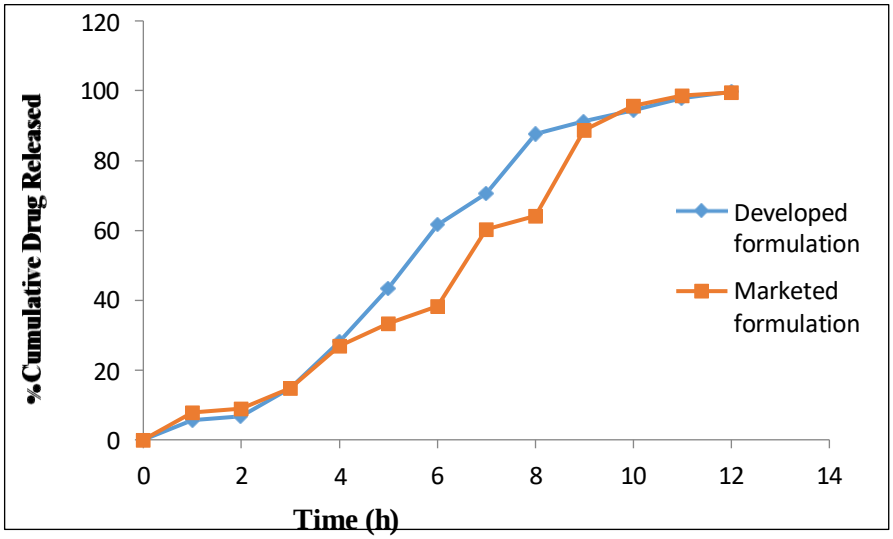

Fig 10 Dissolution profile of developed and marketed formulation

Stability studies

The results of appearance, hardness, drug content, friability, weight variation and in-vitro dissolution study of formulation F5 at 1, 2, and 3 months are shown below. The results indicate that the samples were stable for 3 months.

Table 18 Stability data of formulation F5 at 40°C/75% RH

Evaluated Parameters	Initial	After 1 month	After 2 month	After 3 month
Appearance	White, acceptable	White, acceptable	White, acceptable	White, acceptable
Hardness± S.D.	4.12±0.16	4.1	4.0	3.9
Drug content (%) ± S.D.	96.12±0.85	96.10	96.9	96.6
Friability± S.D.	0.33± 0.01	0.32	0.30	0.29
Weight variation	151.23± 4.7	151.12	151.9	150.6
Cumulative % drug released	99.69±0.32	99.67	99.32	99.29

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