Original Article

DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRICMETHOD FOR QUANTITATIVE ESTIMATION OF GLIPIZIDEIN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

Objective: The present work is aimed to develop a simple, rapid, selective and economical UV spectrophotometric method for quantitative determination of Glipizideinbulk and pharmaceutical dosage form.

Methods: In this method Dimethyl Form amide (DMF) was used as solvent, the absorption maxima was found to be275 nm in DMF. The developed method was validated for linearity, accuracy, precision, ruggedness, robustness, LOD and LOQ in accordance with the requirements of ICH guideline.

Results: The linearity was found to be 10-60 µg/ml having linear equation y=0.017x-0.006 with correlation coefficient of 0.997. The% recovery was found to be in the range of 98.7-100%. The % RSD for intra-day and inter-day precision was found to be 0.569923 and 0.40169 respectively. The limit of detection (LOD) and limit of quantification (LOQ) was found to be3.06 µg/ml and 9.27 µg/ml respectively.

Conclusion: The developed method was validated as per ICH Q2(R1) guidelines. The novel method is applicable for the analysis of bulk drug in its pharmaceutical dosage form.

Keywords: Glipizide, UV-Spectrophotometric method, Method Development and validation, Dimethyl Form amide

INTRODUCTION

Glipizide (1-cyclohexyl-3-[[4-[2-[[(5-methylpyrazine-2-yl) carbonyl] amino] ethyl] phenyl] sulphonyl] urea), [1]is a second-generationsulfonyl urea derivative that is widely used as oral antihyperglycemic drug for the treatment non-insulin dependent diabetes mellitus [2-6].
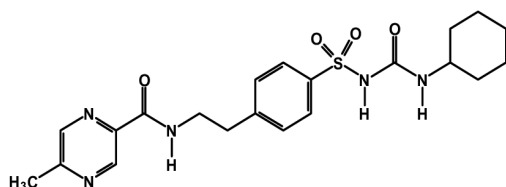
Fig. 1: Structure of glipizide

The present study is aimed to develop a simple, rapid, selective and economical UV spectrometric method for quantitative determination of Glipizide in bulk and pharmaceutical dosage form. The method was demonstrated as per ICH Q2(R1) guidelines [7-11].

MATERIALS AND METHODS

Materials used

Pure standard Glipizide was obtained as a gift sample from Ajanta pharma Ltd. Mumbai. Commercial tablet of Glipizide formulation was purchased as research sample from Wockhardt Ltd, Aurangabad. DMF is used as a solvent.

Instrument used

UV-Visible double beam spectrophotometer (Systronics-2201) with 1 cm matches quartz cell, electronic balance (SHIMADZU-AY220) and asonicator (Oscar ultrasonic cleaner Microclean-103) was used in the study.
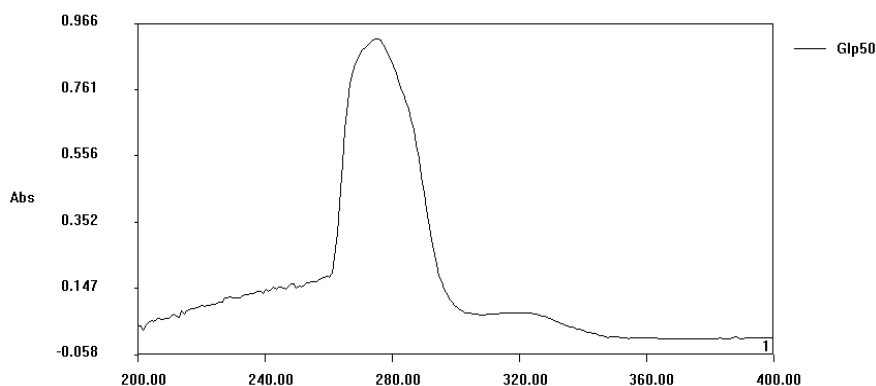
Fig. 2: Absorption maxima of glipizide at 275 nm

Preparation of standard stock solution

Standard stock solution of Glipizide (GLP) was prepared by dissolving 10 mg GLP in 10 ml of DMF to obtain concentration of 1000μg/ml.

Spectrum measurement of glipizide in DMF

The second stock solution was prepared by diluting 0.5 ml of the above standard stock solution upto10 ml and scanned between 200-400 nm in UV Visible double beam spectrophotometer. The UV absorption spectrum of Glipizide showed peak at 275 nm. The maximum wavelength of 275 nm was selected for the present study.

Assay

Weigh and powder 20 tablets. Weigh accurately a quantity of the powder containing 10 mg of glipizide transferred into 10 ml of

volumetric flask and dissolved in DMF. This solution was sonicated and the final volume was made up to the mark with DMF. 1 ml of solution was transferred into 10 ml volumetric flask and adjust upto the mark with DMF. The absorbance of this solution measured at 275 nm. The result of assay was shown in table 1.

Method validation

Validation parameter such as Linearity and range, Accuracy, precision, ruggedness, robustness, LOD and LOQ according to ICH Q2(R1) guideline [12].

Linearity

Aliquots of 0.1, 0.2, 0.3, 0.4,0.5 and 0.6 were taken from standard stock solution and the volume made upto10 ml with DMF. Calibration curve was plotted between absorbance versus concentration (fig. 3).

Table 1: Assay of glipizide tablet

Brand name	Label claim	Assay
Glynase	5 mg	98.5 %

Table 2: Linearity of glipizide

S. No.	Concentration (μg/ml)	Absorbance
1	10	0.144
2	20	0.344
3	30	0.523
4	40	0.693
5	50	0.846
6	60	1.007

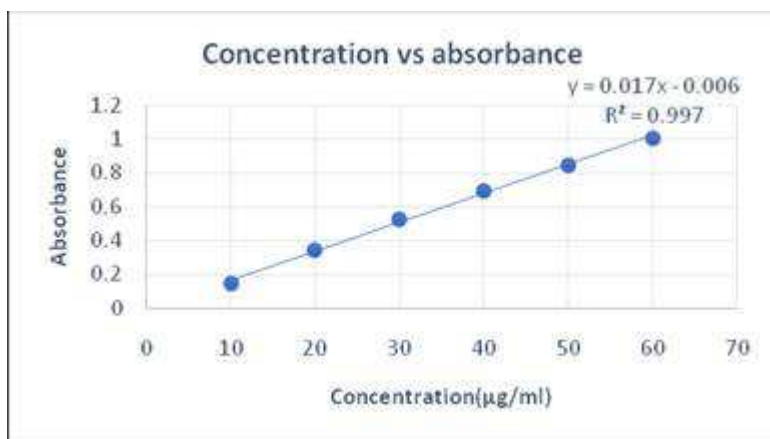Regression equation y=0.0171x-0.0063
R^2=0.9977

Fig. 3: Calibration curve of glipizide in DMF

Range

The range of an analytical procedure is an interval between upper and lower concentration of an analyte in the sample for which it has been showed that the analytical procedure has a suitable level of linearity, accuracy, precision. The obtained range of an analyte is 10 to 60 μg/ml.

Accuracy

Accuracy was determined by preparing solution of different concentration that is 50%, 100%, 150%. The percentage recovery was calculated (table 3).

Precision

The precision (measurement of intra-day, inter-day) determined by analyzing the six samples of same concentration (30 μg/ml) the

absorbance was noted. From the measured absorbance result mean, standard deviation and % RSD was calculated.

Ruggedness

Ruggedness of the method was determined by analyzing same sample by different analysts (analyst 1 and 2) at different condition and the respective absorbance were noted and result was indicated as %RSD.

Robustness

Robustness of the method was determined by carrying out the analysis at two different wavelength (275 and 277) preparing solution 15 μg/ml.

Limit of detection (LOD)

The limit of detection (LOD) was determined by using linearity.

LOD was calculated by using equation-

LOD= 3.3 δ/s   Where δ is a standard deviation and s is the slope.

Table 3: Result for accuracy

Name of drug	Level of recovery	Concentration (µg/ml)	Amount recovery	Mean % recovery
Glipizide	50%	20	19.84	99.2
	100%	40	39.84	99.6
	150%	60	59.25	98.75

Table 4: Intraday precision data of glipizide

S. No.	Concentration (µg/ml)	Absorbance
1.	30	0.524
2.	30	0.529
3.	30	0.528
4.	30	0.526
5.	30	0.532
6.	30	0.531
	Mean	0.528333
	SD	0.003011
	%RSD	0.569923

Table 5: Interday precision data of glipizide

S. No.	Concentration (µg/ml)	Absorbance
1	30	0.524
2	30	0.528
3	30	0.529
4	30	0.527
5	30	0.530
6	30	0.531
	Mean	0.528167
	SD	0.002483
	%RSD	0.40169

Table 7: Result of ruggedness

S. No.	Concentration (µg/ml)	Absorbance (analyst 1)	Absorbance (analyst 2)
1	30	0.524	0.522
2	30	0.520	0.518
3	30	0.519	0.521
4	30	0.521	0.522
5	30	0.518	0.520
6	30	0.522	0.525
	Mean	0.52066667	0.521333
	SD	0.00216025	0.002338
	%RSD	0.41490017	0.448483

Table 8: Robustness at wavelength 275 nm and 277 nm (conc.15 µg/ml)

S. No.	Concentration. µg/ml	Absorbance (275)	Absorbance (277)
1	15	0.253	0.252
2	15	0.255	0.254
3	15	0.254	0.256
4	15	0.254	0.255
5	15	0.251	0.253
6	15	0.254	0.256
	Mean	0.2535	0.2543333
	SD	0.0013784	0.00163299
	%RSD	0.54374940	0.64206808

Table 9: For limit of detection

LOD	Concentration(µg/ml)
Glipizide	3.06

Table 10: For limit of quantification

LOQ	Concentration(µg/ml)
Glipizide	9.27

Table 11: Optimization parameters of glipizide

S. No.	Parameters	Glipizide
1	Beer's Law Limit	10-60 µg/ml
2	Absorption maxima (nm)	275 nm
3	Standard regression equation	Y= 0.0171x-0.0063
4	Correlation coefficient r^2	r^2= 0.9977
5	Assay	98.5%
6	Accuracy	98.75-100 %
7	Precision intra-day and inter-day(%RSD)	0.569923 and 0.40169%
8	Ruggedness (%RSD)	0.4149 and 0.4484
9	Robustness (%RSD)	0.5437 and 0.4484
10	LOD	3.06(µg/ml)
11	LOQ	9.27(µg/ml)

Limit of quantification (LOQ)

The limit of quantification is an individual analytical procedure is the lowest amount of analyte in the sample. LOQ was calculated by using equation-

LOQ= 10 δ/s

Where δ is a standard deviation and s is the slope.

RESULTS AND DISCUSSION

The UV scan of standard stock solution 200-400 nm showed the absorption maxima at 275 nm. The overlay spectra of different concentration range of std Glipizide was recorded (fig. 2). Beers-Lambert's law is applicable in the concentration range between 10 to 60 µg/ml. The regression equation was found to be Y=0.0171x-0.0063 and correlation coefficient was found to be 0.9977. The % assay of Glipizide tablet was found to be 98.5%. Validation parameters are developed as per ICH guideline. Accuracy was found to be 98.75-100% recovery. Precision for intra-day and inter-day of %RSD was found to be 0.5746 and 0.4363. LOD and LOQ was found to be 3.06µg/ml and 9.27µg/ml by using the formula. Ruggedness was calculated by two different analysts and two different laboratories and the % RSD was found to be 0.4149 and 0.4484. Robustness was calculated by two different wavelength 275 and 277and the %RSD was found to be 0.5437 and 0.6420. Hence the proposed method was developed in validation parameters and the method were found to be simple, rapid, accurate and precise for the routine analysis of glipizide in bulk pharmaceutical dosage form.

CONCLUSION

A simple, rapid and precise UV-visible spectrophotometric method has been developed for the determination of glipizide in marked formulation. The developed method was validated for linearity, accuracy, precision (inter-day and intra-day), robustness, ruggedness, LOD and LOQ parameters studies. The result of all these parameters shows that the rapid, accurate, linear and precise. This method can be successfully applied for routine estimation of glipizide in bulk pharmaceutical dosage form.

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AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICT OF INTERESTS

Declare none

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