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[Research article]

Analytical method development and validation of Glimepiride in bulk and tablet dosage form using UV Spectrophotometer

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ABSTRACT

The main objective of the study is to develop and validate an analytical method for quantitative determination of Glimepiride in bulk and tablet dosage form using UV-Visible Spectroscopy. The Glimepiride shows maximum absorption at 231nm and obeys Beer's law in the range of 5-10µg/ml.For the method development we have selected a perfect solvent system using solvent such as NaOH. Calibration curve has been plotted. The assay should be carried and percentage recovery needs to be calculated. For the validation of the analytical method developed is carried out by determining parameters like Linearity, range, LOD, LOQ, Accuracy, Precision, Ruggedness.The calibration plot did not deviate from linearity because of its low intercept value, the LOD and LOQ values were found to be 25.93µg/ml and 86.44µg/ml respectively which shows the sensitivity of the method. The ruggedness is found to be less than 2%. The percentage recovery was assessed using 3 different solutions of 8.0, 10.0, 12.0 µg/ml and the results obtained were 98, 101.2, and 102% respectively. The developed method was applied to the quantification of Glimepiride in tablets available in local market. It can be seen that the results obtained by proposed method was very much similar to that of established methods.

KEY WORDS: Glimepiride, UV- Visible Spectroscopy, Validation, Method Development.

INTRODUCTION

Glimepiride is a medium to long-acting sulfonylurea antidiabetic drug. Glimepiride is indicated to treat type 2 diabetes mellitus; its mode of action is to increase insulin production by the pancreas. It is not used for type 1 diabetes because the pancreas is no longer able to produce insulin.

Side effects of Glimepiride is gastrointestinal tract (GI) disturbance, and rarely thrombocytopenia, leukopenia, hemolytic anemia, and occasionally allergic reactions occur. Alcohol consumption and exposure to sunlight should be restricted in patients taking it because they can worsen the side effects.

Drug Interactions: NSAIDS, MAO Inhibitors, Sulfonamides, Trimethoprim, Chloramphenicol increase the Effect of Glimepiride. Thiazide diuretics, Corticosteroids, Isoniazid, and Minoxidill decrease the effect of Glimepiride. It is contraindicated in

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pregnancy and even it should be avoided to nursing mothers.

Literature survey reveals that very few analytical and bioanalytical methods have been reported for the estimation of Glimepiride in combined dosage form includes HPLC, RPHPLC, UV-VIS spectrophotometric(1-3) and LC-MS ,but only few methods are reported for the analysis of Glimepiride individually. The focus of present study was to develop simple, accurate, economical method for estimation of Glimepiride in bulk and pharmaceutical formulation, to perform the validation for the developed method.

MATERIALS AND METHODS

INSTRUMENT

Spectral and absorbance measurements were carried out by using UV –Visible spectrophotometer model T60, with spectral bandwidth of 2.0nm and wave length accuracy of ±0.5nm. pair of 10mm quartz cells were used for the absorbance measurements connected with UV WIN software version 5.2.0.

Optical system	Split beam monitoring ratio system
Light source	Deuterium lamp
Spectral bandwidth	2nm
Wavelength range	190-1100 nm
Wavelength accuracy	±0.5nm
Wavelength repeatability	±0.2nm
Electrical requirements	110V, 50/60HZ
Dimensions	476mm*362mm*225mm
Monochromator	Grating type
Detector	Photodiode

MATERIALS:

The drug Glimepiride was obtained as a gift sample by Hetero Laboratories Ltd., Hyderabad, India. The marketed formulation used in the study is Amaryl, 2mg manufactured by AVENTIS Pharmaceutical Ltd., India.

METHOD:

PREPARATION OF STOCK SOLUTION:

100 mg of Glimepiride was weighed and transferred to a 100ml volumetric flask and dissolved in NaOH. It is shaken and made up to the mark with NaOH which gives a solution of 1000µg/ml(stock solution A). from this 10 ml is pippeted out and dissolved with NaOH to make a solution of 100µg/ml(stock solution B).

CALIBRATION CURVE OF GLIMEPIRIDE:

appropriate volume of aliquots from standard stock solution B were transferred to different volumetric flasks of 10ml capacity. The volume is adjusted to the mark with NaOH to obtain concentration of 5, 10, 15, 20, and 25µg/ml. absorbance value of each solution was measured at 231nm using NaOH as blank. From the absorption value regression equation and correlation coefficient are determined.

SAMPLE PREPARATON FOR DETERMINATION OF DRUG FROM TABLETS:

20 tablets of AMARYL (2mg) were weighed and powdered. The powder equivalent to 10mg of Glimepiride was accurately weighed and finely powdered and transferred to 100ml volumetric flask which contain 50ml of NaOH and sonicated for 30min. The flask is made up to the mark with NaOH and filtered through wattmann filter paper to give a solution of 100µg/ml. From this solution 1ml is pippeted out and diluted to 10ml with NaOH to give a solution of 10µg/ml which is used for estimation of Glimepiride.

ASSAY OF GLIMEPIRIDE TABLETS:

The solution of concentration 10µg/ml is used to find the % recovery of the Glimepiride solid dosage form.

VALIDATION:

Linearity and Range: the range of the method is the interval between the upper and lower classes of the analyte that have been demonstrated to be determined within the suitable levels of linearity precision and accuracy.

Limit of Detection and Limit of Quantification: Determined by using standard deviation of the response and slope approach as given in ICH guidelines.

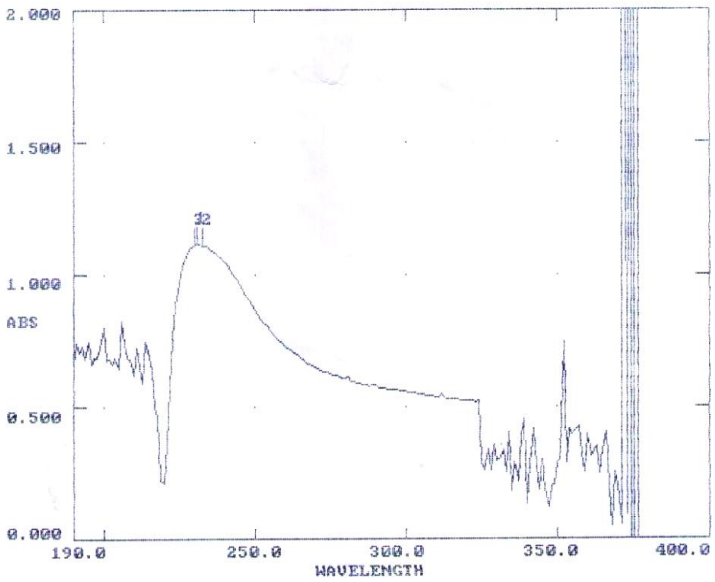
Accuracy: it is the closeness of the test results obtained by the method to the true value. Recovery studies were carried out by standard addition method using known amount of standard drug solution (80, 100, and 120%) to the sample solution.

Precision: it is the degree of agreement among individual test results. It provides an indication of random error results and is expressed as % relative standard deviation (% RSD).

Raggedness: the sample solutions were prepared and analysed with change in analytical conditions like different laboratory conditions, different analysts and results are reported.

RESULTS:

Fig 1: UV Spectrum of glimepiride standard



Linearity:

Table 1: Absorbance values for calibration curve of Glimepiride at 231nm

S.No	CONCENTRATION (µg/ml)	ABSORBANCE
1	0	0
2	5	0.368
3	10	0.689
4	15	1.030
5	20	1.356
6	25	1.610

Fig 2: calibration curve of Glimepiride at 231nm

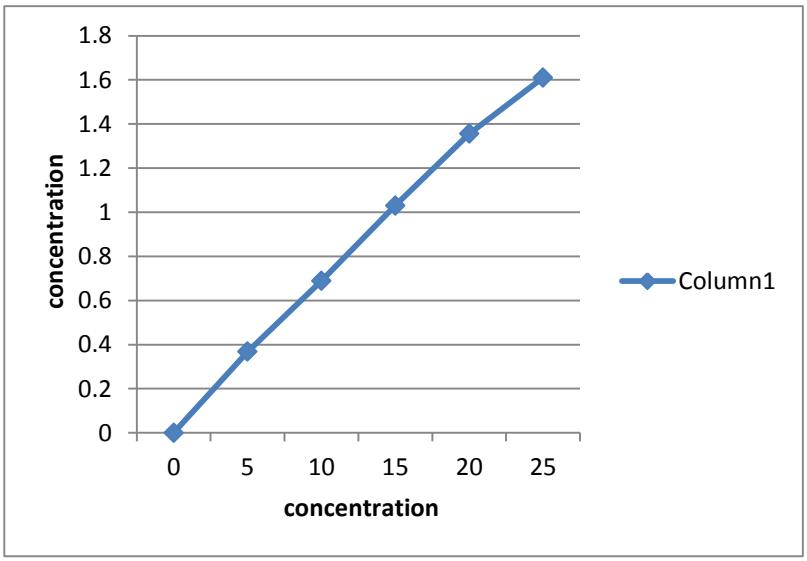


Table 2: optical characteristics and statistical data of the regression equation

parameters	UV method
λmax	231nm
Beer's law limits (µg/ml)	5-10
Regression equation	0.066x
Slope (m)	0.0684
Intercept (c)	0
Correlation coefficient	0.996
LOD (µg/ml)	25.93
LOQ (µg/ml)	86.44

Table 3: Recovery study data of Glimepiride

Level of recovery (%)	Concentration of standard drug(µg/ml)	Concentration of marketed drug (µg/ml)	Total drug concentration	Amount recovered (µg/ml)	% Recovery
80	8	10	18	17.8	98
100	10	10	20	20.12	101.20
120	12	10	22	22.4	102.00

Table 4: Precision study data of Glimepiride

Concentration (µg/ml)	Absorbance	Statistical Analysis
10	0.501	
10	0.501	Mean = 0.530 SD= 0.0033 % RSD= 0.65
10	0.507	
10	0.501	
10	0.508	
10	0.501	
Average	0.503	

Table 5: Intra- assay precision

Concentration(µg/ml)	Intra – day absorbance		Average % RSD
	Abs 1	Abs 2	
10	0.504	0.504	
10	0.504	0.502	
10	0.507	0.502	
10	0.501	0.501	0.59
10	0.503	0.502	
10	0.507	0.503	
Average	0.504	0.502	
% RSD	0.396	0.796	

Table 6: Inter assay precision

Concentration (µg/ml)	%RSD		
	Day 1	Day 2	**Average % RSD**
10	0.65	0.59	0.62

Table 7: Precision study data for Marketed Tablets

S.No	Concentration	Absorbance	Statistical Analysis
1	10	0.501	
2	10	0.504	Mean = 0.504
3	10	0.504	SD = 0.00189
4	10	0.504	% RSD = 0.375
5	10	0.504	
	Average	0.504	

Table 8: Ruggedness study data

sample	Label claim (mg)	Analyst 1			Analyst 2		
		Amount found (mg)	% recovered	SD	Amount found (mg)	% recovery	SD
Amaryl	2	1.98	99	0.001	1.96	98	0.0017

Table 9: Assay of dosage form

Drug	Label claim(mg/tablet)	Amount estimated (mg/tablet)	% label claim
Glimepiride	2	19.6	98

Table 10: Summary of Validation

Parameter	Result
Linearity indicated by correlation coefficient	0.996
Precision indicated by % RSD	0.62%
Accuracy indicated by % recovery	100.4%
Limit of detection (LOD)	23.93µg/ml
Limit of quantification (LOQ)	86.44µg/ml
Range	5-25µg/ml
Linear regression equation	Y= 0.066x
Ruggedness indicated by % recovery	98.5%
Assay indicated by % recovery	98%

CONCLUSION

The proposed method is rapid, accurate, precise and sensitive for the quantification of Glimepiride from its pharmaceutical dosage forms. The method rely on the use of simple working procedures comparable to that achieved by sophisticated and expensive technique like HPLC and hence this method can be routinely employed in quality control for analysis of Glimepiride in tablet dosage form.

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