Research Article

UV Spectrophotometric Method for Determination of Glimepiride in Pharmaceutical Dosage Forms

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ABSTRACT

Glimiperide is an anti-diabetic drug which is used for the treatment of diabetes. In present work, a simple, sensitive, accurate and economical spectroscopic method has been developed for the estimation of glimepiride in bulk and in pharmaceutical dosage forms. An absorption maximum was found to be at 249 nm with the solvent system of chloroform. The drug follows Beer's law limits in the range of 5-30 µg/ml with correlation coefficient of 0.999732. Results of the analysis were validated for accuracy, precision, LOD were found to be satisfactory. The proposed method is simple, rapid and suitable for the routine quality control analysis.

Keywords: Glimiperide, Tablets, UV spectrophotometry.

INTRODUCTION

Chemically, Glimepiride is 1-{(p-[2-(3-ethyl-4-methyl-2-oxo-3- pyrroline-1-carboxamide) ethyl] phenyl) sulfonyl}-3- (trans-4-methylcyclohexyl) urea, is 3rd generation sulfonylurea derivative used for the treatment of type II diabetes mellitus. A survey of pertinent literature revealed that few liquid chromatography[1,2,4,8-19,22-25] and UV spectrophotometry[3,5,12-15,20-23] methods has been developed for the determination of Glimepiride in pharmaceutical formulations. Liquid chromatography-electrospray ionization tandem mass spectrometry[6,7,18] method has been developed for the quantification of Glimepiride in human plasma.

The aim of present work is to develop and validate a simple UV spectrophotometric method to be applied for the quantification of Glimepiride in tablets, which serves as a tool for the quality control of pharmaceutical dosage forms.

MATERIALS AND METHODS

Spectrophotometer used was Spectro 2080plus (double beam UV–Visible spectrophotometer) of Analytical technologies ltd with 10mm matched quartz cell. All the reagents and chemicals used were of Analytical grade. Glimipride tablets were purchased from market.

Method Development

Preparation of standard stock solution

Standard solution of Glimepiride was prepared by transferring accurately weighed 10 mg of drug into a 100 ml volumetric flask and the volume was made up to 100 ml using chloroform as an solvent to get the concentration of 100µg/ml.

Preparation of calibration curve

From the standard stock solution fresh aliquots were pipette out and suitably diluted with chloroform to get final concentration in the range of 5-30 µg/ml. The solutions were scanned under 200-400 nm wave length range and a sharp peak was obtained at 249nm (figure 1). Calibration curve was plotted by taking absorbance on y-axis and concentration of solution on x-axis (figure 2). The method was applied for known sample solution and was found to be satisfactory for analysis of tablet dosage forms.

Optical characteristics

The optical characteristics such as beer's law limit, molar extinction coefficients, % RSD were calculated. Regression characteristics like slope, intercept, correlation coefficient, LOD, LOQ standard were calculated (table 2)

Assay of Glimepiride Tablets

20 tablets of Glimepiride were weighed, powdered and weight equivalent to 10mg was taken and transferred into a 100ml volumetric flask. Then 20 ml of chloroform was added and kept for 15 min with frequent shaking and the volume was made upto mark with chloroform. The solution was then filtered through whatmann filter paper and the absorbance was measured against blank. The amount of Glimepiride was computed by using the equation referring to the calibration curve (Table 2).

Table 1: Linearity results of Glimepiride in chloroform

Concentration (µg/ml)	Absorbance
5	0.085
10	0.178
15	0.259
20	0.351
25	0.430
30	0.512

Table 2: Optical parameters

Parameter	Result
Absorption maxima	249 nm
Linearity range	5-30 µg/ml
Standard regression equation	0.01704x+0.004133
Correlation coefficient	0.999732
Molar absorptivity	8491
Standard deviation	0.159437
LOD (µg/ml)	0.4
LOQ (µg/ml)	1.2

Figure 1: Spectra of Glimepiride in chloroform

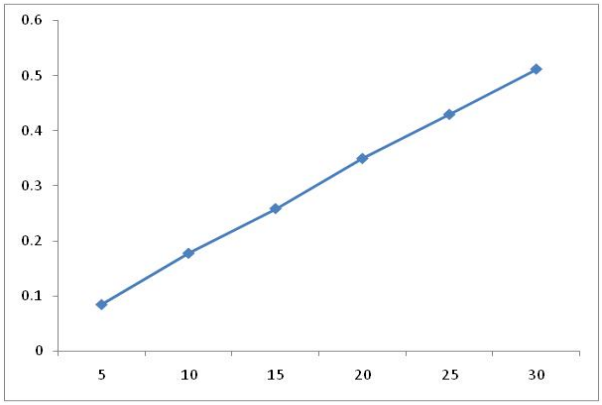

Figure 2: Calibration curve of Glimepiride

Method Validation

The method was validated for different parameters like linearity, accuracy and precision.

Linearity

Fresh aliquots were prepared from the stock solution (100µg/ml) in different concentrations. The samples were scanned in UV –visible spectrophotometer against reagent blank. It was found that the selected drug shows linearity between the 5-30µg/ml (Table 2).

Accuracy

Accuracy of the method was confirmed by studying recovery at 3 different concentrations 80,100,and 120% of these expected, in accordance with ICH guidelines, by replicate analysis (n=6). Standard drug solution was added to a pre analyzed sample solution and percentage drug content was measured. The results from study of accuracy were reported in (Table 3).

Precision

Precision (intra-day precision) of the method was evaluated by carrying out the six independent test samples of the Glimepiride. The intermediate precision (inter-day precision) of the method was also evaluated using two different analyst, and different days in the same laboratory. The percent relative standard deviation (%RSD) obtained was found to be good. The results were tabulated in table 4.

RESULTS AND DISCUSSION

Glimepiride in chloroform exhibited λ_{max} at 659 nm. The Beer's law was obeyed to the method in the concentration range of 5-30 µg/ml respectively. The optical characteristics such as Beer's law limits (mg/ml), Molar extinction coefficient (L/mol.cm), Regression equation(y), Correlation coefficient calculated from five-six measurements containing 3/4th of the amount of upper Beer's law limits and were calculated for Glimepiride and reported in Table 2.

Table 3: Results of assay and accuracy

Brand name	Label claim	Amount of drug estimated	Percentage label claim	Standard deviation	Percentage recovery
Amaryl	3 mg	2.89	97.8%	0.02	99.37%
Sandoz Glimepiride	2 mg	1.92	98.4%	0.05	99.25%

To evaluate the validity and reproducibility of the methods, known amount of pure drug was added to the previously analyzed pharmaceutical preparation and the mixtures were analyzed by the proposed methods. The percent recoveries are given in Table 3. The present method makes it easier for the determination of Glimepiride in pharmaceutical dosage forms in a routine manner.

CONCLUSION

The proposed method was found to be simple, sensitive, accurate, precise, reproducible and can be used for routine quality control analysis of Glimepiride in bulk and in pharmaceutical dosage forms.

Table 4: Precision results

Concentration	Absorbance
15 µg/ml	0.257
15 µg/ml	0.259
15 µg/ml	0.262
15 µg/ml	0.261
15 µg/ml	0.260
15 µg/ml	0.258
Mean	0.259
Standard deviation	0.002
%RSD	0.772

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