AMERICAN JOURNAL OF PHARMTECH RESEARCH
Journal home page: http://www.ajptr.com/

Spectrophotometric Determination and Validation of Glimepiride Concentration in Bulk and Dosage Form

Sonali. D. Labhade[1], Dipti .G .Phadtare[1*], R B Saudagar[3]
1.R G Sapkal College of Pharmacy , Anjaneri , Nashik

ABSTRACT

A simple, sensitive, rapid, accurate and precise spectrophotometric method has been developed for estimation of Glimepiride in bulk and tablet dosage forms. The zero order spectra shows maximum absorbance at 249 nm. Calibration graph was found to be linear over the concentration range of 5-30 µg/ml. Results of analysis were validated for precision, range, linearity, interference study and recovery studies, The method can be adopted in its routine analysis.

Keywords: Glimepiride, Tablets, Ultraviolet Method, Spectrometric method.

*Corresponding Author Email: aditi24aug@gmail.com
Received 01 April 2015, Accepted 12 April 2015

Please cite this article as: Phadtare DG *et al*., Spectrophotometric Determination and Validation of Glimepiride Concentration in Bulk and Dosage Form. American Journal of PharmTech Research 2015.

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 3rdgeneration sulfonylurea derivative used for the treatment of type II diabetes mellitus. A survey of pertinent literature revealed that few liquid chromatography method and UV spectrophotometry methods has been developed for the determination of Glimepiride in pharmaceutical formulations. High performance Liquid chromatography, mass spectrometry method and other methods 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

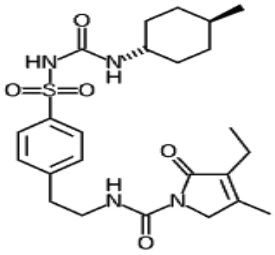

Figure 1: Structure of Glimepiride

MATERIALS AND METHOD

Absorbance was measured, and the Spectra was recorded over the wavelength of 200-400 nm using a double beam UV- Spectrophotometer Jasco V-630. Glimepiride USP were obtained from gift sample from Sun pharma, Amaryl Tablet of M/s Sanofi Aventis. Methanol, Distilled water and other reagents were of analytical grade. Standard Glimepiride 10 mg was weighed and dissolved in5 mL of methanol in a 100 mL volumetric flask. After dissolution of the drug, the volume was made up to the mark with distilled Water to give a solution containing 100 µg /mL(stock solution A).

Analytical Range determination

From the standard stock solution A of Glimepiride , appropriate aliquots were pipetted out into 10 ml volumetric flasks and dilutions were made with distilled water to obtain working standard solutions of concentrations from 2 to 16 µg / mL. Absorbance for these solutions were measured at 249 nm were reported in Table 2.

Calibration curve for the Glimepiride (2 – 16 µg / ml)

Appropriate volume of aliquots from standard Glimepiride stock solution A were transferred to different volumetric flasks of 10 mL capacity. The volume was adjusted to the mark with distilled

water to obtain concentrations of 2,4,6,8,10,12,14, and 16 µg / mL. Absorbance spectra of each solution against distilled water as blank were measured at 249 nm and the graphs of absorbance against concentration were plotted and shown in Figure 1. The regression equation and coefficient of determination was determined.

Sample preparation for determination of Glimepiride from dosage form

Ten tablets of a brand were weighed and finely powdered. The powder equivalent to 10mg of Glimepiride was accurately weighed and transferred to volumetric flask of 100 mL capacity containing 5 mL of the methanol and sonicated for 5 min. The flask was shaken and volume was made up to the mark with distilled water to give a solution of 100 µg / mL (stock solution B). The above solution carefully filtered through Whatmann filter paper (No. 41) and used for the estimation of Glimepiride. To examine the absence of either positive or negative interference of excipients used in formulation recovery studies were done.

Validation Method Accuracy

Accurately weighed formulation sample equivalent to 10 mg of sample were mixed with 10 mg of Glimepiride pure drug. From above equivalent 20 mg mixture 10mg equivalent weight of sample were dissolved in 5 ml of methanol and further volume make up with distilled water.

Precision

The parameter was validated by assaying number of aliquots samples of Glimepiride and its validity was estimated using parameters such as Standard deviation and Relative Standard deviation.

Recovery Studies

Accurately weighed formulation sample equivalent to 10 mg of sample were mixed with 10 mg of Glimepiride pure drug. From above equivalent 20 mg mixture 10mg equivalent weight of sample were dissolved in 5 ml of methanol and further volume make up with distilled water. Different concentrations like 2, 4, 6, 8, 10, 12, 14, 16 µg / mL were taken and absorbance was recorded.

RESULTS AND DISCUSSION

Determination of wavelength and calibration graph

The λmax of Glimepiride was found to be 249 nm in methanol and distilled water. The absorbance was measured at 249 nm against methanol and distilled water. The calibration curve was prepared by plotting absorbance versus concentration of drug.

Determination of Molar Absorptivity

Absorptivity constant is the ratio of the absorbance of the sample of the product of the thickness of the medium and concentration of the sample. Increase or decrease in absorbance depends upon Increase or decrease in concentration which always remain constant. The absorbance of different concentrations was determined at 249nm and molar absorptivity calculated using following formula,

a= A/ bc

Where,

a= Absorptivity A= Absorbance b= Path length c= Concentration

Effect on Absorbance with Time (Stability)

The stability of sample was checked by taking absorbance at regular interval of time. Absorbance remains stable for 240 min. than the absorbance decreased with time.

Table 1: Optical Characteristics of Glimepiride

Parameters	Result
Absorption Maximum	249 nm
Beers law limit (µg / ml)	2-16(µg / ml)
Correlation coefficient (r 2)	0.9992
Regression equation (y = mx + c)	0.1491X -0.0223
Slope (m)	0.1491
Intercept (c)	-0.0223

Table 2: Results of calibration curve at 249 nm for Glimepiride USP by UV spectroscopy

Sr. no	Concentration (µg / ml)	Absorbance (nm)
1	2	0.1472
2	4	0.2633
3	6	0.4416
4	8	0.5890
5	10	0.7360
6	12	0.8832
7	14	1.0304
8	16	1.1780

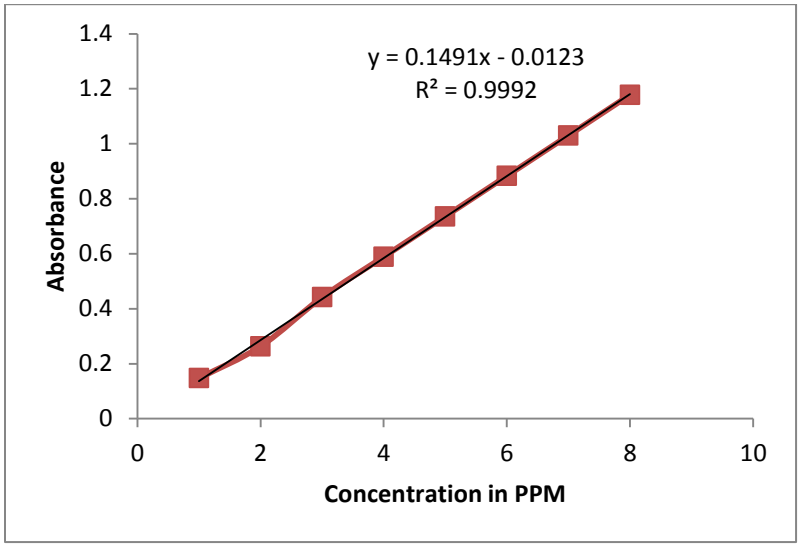

Figure 2: Calibration curve of Glimepiride

Table 3: Accuracy results of Glimepiride at 249 nm

Amount of sample (µg / ml)	Amount fo drug added (µg / ml)	Amount of drug recovered(µg / ml)	% Recovery± SD
8	6.4	6.32	98.75
8	8.0	7.95	99.37
8	9.6	9.53	99.27

Table 4: Precision results of Glimepiride at 249 nm

Conc (µg / ml)	Interday absorbance	% RSD	Intraday Absorbance	% RSD
2	0.1473	0.0055	0.1469	0.0142
4	0.2633	0.0413	0.1828	0.0163
6	0.4414	0.0191	0.4409	0.0139
8	0.5885	0.0039	0.5879	0.0160
10	0.7361	0.0142	0.7359	0.0050
12	0.8837	0.0057	0.8845	0.0041
14	1.0307	0.0180	1.031	0.0178
16	1.1759	0.0020	1.1763	0.0056

Table 5: Ruggedness results of Glimepiride at 248 nm

Analyst	Label Claim in mg	Amount found mg	% Recovery ± SD
Analyst I	2	1.97	98.5± 0.11
Analyst II	2	1.99	99.5±0.18

CONCLUSION

From the results, it can be concluded that the proposed method for the estimation of Glimepiride is simple, convenient, accurate, sensitive and reproducible. It can be successfully used for routine analysis of the Glimepiride in bulk and pharmaceutical dosage forms.

REFERENCES

1. USP 28, NF 23, The United States Pharmacopoeial Convention Inc, 1985, 3489

2. Ashenafi Dunge, Nishi Sharda, Baljinder Singh and Saranjit Singh. Validated specific High Performance Liquid Chromatography method for determination of Zidovudine during stability studies. J Pharma Bio Anal 2005;37(5), 1109- 1114.
3. International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human use. Validation of Analytical procedures: Methodology. ICHQ2B, Geneva, (CPMP/ICH/281/95). 1996.
4. I. C. H. Harmonized Tripartite guideline. Recommended for adaptation at step-4 of the ICH process, By ICH steering committee1996.
5. Sharma B. K. Instrumental Method of Chemical Analysis, 18th edition, Krishna Prakashan Media Pvt. Ltd., Merrut, 1999:39- 139.
6. N. Hari krishanan. Simultaneous estimation of Lamivudine, Zidovudine and Nevirapine by R. P. HPLC in pure and pharmaceutical dosage form, Asian J Chemistry 2008;20 (4): 2551-2556.
7. Vogel's Textbook of Quantitative Chemical Analysis, 5th edition, ELBS Longman, London, 1997, 661-672.
8. Geetha Ramachandran, Hemanthkumar AK, Kumaraswami V, Soumya Swaminathan. A simple and rapid Chromatographic method for simultaneous determination of Zidovudine and Nevirapine in plasma. J Chromatography B 2006;843 (2): 339-344.
9. NeerajKaul. Stability indicating HPTLC determination of Zidovudine as the bulk drug and in pharmaceutical dosage form. J Planar Chromatography-Modern TLC 2004;17 (1):264- 274.