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Spectrophotometric Estimation of Glimepiride from Pharmaceutical Dosage Forms

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Two simple and sensitive visible spectrophotometric methods have been developed for the quantitative estimation of glimepiride from its tablet formulation. The developed methods are based on formation of chloroform extractable coloured complex of drug with methylene blue and safranine. The chloroform extracted complex of drug with methylene blue showed absorbance maxima at 652 nm and linearity was observed in the concentration range of 15-50 µg/mL (method-**I**), with safranine showed absorbance maxima at 536 nm and linearity was observed in the concentration range of 10-80 µg/mL (method-**II**). Results of analysis for both the developed methods were validated statistically and by recovery studies.

Key Words: Glimepiride, Chloroform extract, Methylene blue, Safranine.

INTRODUCTION

Glimepiride[1] chemically 1-[4-{2-(3-ethyl,4-methyl,2-oxo,3-pyrroline, 1-carboxamido)ethyl}phenyl]sulfonyl]-3-(4-methyl-cyclohexyl) urea is an antidiabetic drug. Few analytical methods for estimation of glimepiride from biological fluid including RP-HPLC[2], LC[3], LS-MS[4] and derivative UV spectrophotometric[5] are reported.

EXPERIMENTAL

A Shimadzu UV/Visible spectrophotometer-1700 with 1 cm matched quartz cells was used for spectral measurement. All the chemicals used were analytical grade, methylene blue solution (0.025 % w/v) and safranine solution (0.05 % w/v) was prepared in phosphate buffer[6] pH 8.0 and 7.4, respectively and extracted several times with chloroform so as to remove chloroform soluble impurities. Buffer solutions were prepared in double distilled water. The tablet samples of glimepiride were procured from the local market.

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For method-**I**, in a series of 10 mL volumetric flasks aliquots of standard solution of glimepiride (100 µg/mL) in chloroform were transferred and diluted with the same so as to give several dilutions in the concentration range of 15-50 µg/mL of drug. To 10 mL of each dilution taken in a separating funnel, 10 mL of methylene blue solution was added, shaken and allowed to stand for 10 min for the formation of coloured complex. The coloured chloroform layer was separated out and absorbance was measured at 652 nm against a reagent blank. A calibration curve was prepared by plotting concentration *versus* absorbance.

For method-**II**, in a series of 10 mL volumetric flasks aliquots of standard drug solution of glimepiride (100 µg/mL) in chloroform were transferred and diluted with the same so as to give several dilutions in the concentration range of 10-80 µg/mL of drug. To 10 mL of each dilution taken in a separating funnel, 10 mL of safranine solution was added, shaken and allowed to stand for 10 min for the formation of coloured complex. The coloured choroform layer was separated out and absorbance was measured at 536 nm against a reagent blank. A calibration curve was prepared by plotting concentration *versus* absorbance.

For analysis of formulation, 20 tablets of glimepiride were accurately weighed and average weight per tablet was determined. The tablets were powdered and powder equivalent to 100 mg of glimepiride was accurately weighed and extracted four times with 20 mL portions of chloroform, the combined extract was filtered through Whatmann filter paper no. 41 into 100 mL volumetric flask. The residue was washed with chloroform and the washings were added to the filtrate, final volume of filtrate was made up to the mark with chloroform. From the above filtrate 5 mL was further diluted to 50 mL in a volumetric flask to get a tablet sample stock of 100 µg/mL.

For method **I** and **II**, 2 mL of above stock was further diluted to 10 mL with chloroform. This was treated as per the respective procedure for the calibration curve and absorbance was measured at 652 and 536 nm, the amount of drug present in sample was computed from respective calibration curve.

RESULTS AND DISCUSSION

Both the developed method were repeated five times for three different tablet formulations. Results of analysis are reported in Table-2.

Recovery studies were carried out for both the developed methods by addition of known quantity of pure drug solution to preanalyzed tablet sample solution at three different concentration level. The result of recovery studies is reported in Table-2.

The proposed spectrophotometric methods for determination of glimepiride from tablet formulations are based on formation of chloroform extractable coloured complex of drug with methylene blue and safranine. The pH required for method **I** and **II** was optimized at pH 8.0 and 7.4. The optical characterstics such as Beer's law limits, sandell's sensitivity, molar extinction coefficient and per cent relative standard deviation (calculated from the eight measurements with in the Beer's law limits) were calculated and the results are summarized in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION OF THE PROPOSED METHODS I AND II

Parameter	Method-I	Method-II
λ_{max} (nm)	652	536
Beer's law limits (µg/mL)	15-50	10-80
Molar absorptivity (L mol^{-1} cm^{-1})	0.157×10^5	0.937×10^4
Sandell's sensitivity (µg cm^{-2}/0.001 absorbance unit)	0.0312	0.05236
Regression equation (Y = a+bC)		
Slope (b)	0.0320	0.0191
Intercept (a)	-0.0019	0.0000
Correlation coefficient (r)	0.9998	0.9999
Relative standard deviation (%)*	0.3745	0.6596
% Range of error (confidence limits)*		
0.05 level	0.3130	0.55153
0.01 level	0.4633	0.81600

Y = a+bC, where C is concentration in µg/mL and Y is absorbance unit.
*Eight replicate samples.

TABLE-2
ANALYSIS OF TABLET FORMULATION

Sample	Labeled amount (mg/tab)	% Amount obtained (mg/tab)			Recovery* (%)	
		Proposed method†		Reference method‡	I	II
		I	II			
1	10	99.90	100.00	99.80	99.99	100.00
2	10	100.12	99.20	99.70	100.12	99.20
3	10	100.05	100.50	99.90	100.05	100.50

†Average of 5 determinations.
‡Reference UV method developed in our laboratory.
*Average of determination at 3 different concentration levels.

Regression characterstics like standard deviation of slope (S_b), standard deviation of intercept (S_a), standard error of estimation (S_c) and percentage ranges of error (0.05 and 0.01 confidence limits) were calculated and are shown in Table-1.

Recovery studies were satisfactory which shows that there is no interference of excipient. The developed methods were found to be simple, rapid, accurate and can be used for routine analysis of drug from tablet formulation.

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REFERENCES

1. S. Budvari, The Merck Index, Merck and Co., Inc. White House Station, NJ, edn. 13, p. 790.
2. N.R. Lad, S.I. Bhoir, I.C. Bhoir and M. Sundaresan, *Indian J. Pharm. Sci.*, **65**, 650 (2003).
3. M.A. Khan, S. Sinha, S. Vartak, A. Bharatiya and S. Kumar, *J. Pharm. Biomed. Anal.*, **39**, 928 (2005).
4. C. Pistos, M. Koutsopoulou and I. Panderi, *Biomed. Chromatogr.*, **19**, 394 (2004).
5. S. Altinoz and D. Tekeli, *J. Pharm. Biomed. Anal.*, **24**, 507 (2001).
6. Indian Pharmacopoeia, Vol. 2, edn. 4, p. A-145.

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