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Original Research Paper

SPECTROPHOTOMETRIC DETERMINATION AND VALIDATION OF METFORMIN HYDROCHLORIDE AND GLIMEPIRIDE IN BULK AND TABLET DOSAGE FORM

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ABSTRACT

Simple, precise accurate and economical UV Spectrophotometric methods have been developed and validated for the routine estimation of Metformin hydrochloride and Glimepiride in bulk drug and pharmaceutical preparations. Absorbance maxima method based on measurement of absorption at maximum for Metformin hydrochloride and Glimepiride wavelength. The method validated according to ICH guidelines in respect of precision, accuracy, sensitivity and linearity

Keywords: Metformin hydrochloride, Glimepiride, λmax, Absorbance maxima method.

INTRODUCTION

In India, most commonly attacking disease to a common man has been found to be diabetes. Type-2 diabetes is a progressive disorder with a consistent and steady increase in glycosylated hemoglobin (HbA1C) overtime associated with enhanced risk of micro- and macrovascular complications and a substantial reduction in life expectancy. Glimepiride is a medium-to-long acting sulphonyl urea antidiabetic drug. It is chemically 1-[[p-[2-(3-Ethyl-4- methyl-2-oxo-3-pyrroline-1 carboxamido) ethyl] phenyl] sulfonyl]-3-(trans-4methyl cyclohexyl) urea. The primary mechanism of action of glimepiride in lowering blood glucose appears to be dependent on stimulating the release of insulin from functioning pancreatic beta cells. Metformin hydrochloride is also antidiabetic drug in the biguanide class and it is chemically 1,1-dimethyl biguanide mono hydrochloride. It decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

MATERIALS AND METHODS

The commercially available tablets, (Label claim: Metformin HCl 500 mg and Glimepiride 4 mg) was procured from local market

Selection of Common Solvent

After assessing the solubility of drugs in different solvents Methanol has been selected as common solvent for developing spectral characteristics.

Experimental

Method: Absorption maxima method

Stock solution was prepared by diluting 10 mg of each drug in sufficient quantity of methanol in separate volumetric flask and volume was made up to 100 ml to get the concentrations of 100 µg/ml for each drug. Dilutions from stock solution were prepared in the range of 5-25 µg/ml for Metformin HCl and 5-25 µg/ml for Glimepiride. Methanol was used as a blank solution. Two wavelength selected for method are 236 nm for Metformin HCl and 228 nm for Glimepiride that are absorption maxima were selected for analysis. Aliquots of standard stock solution were made and calibration curve was plotted figure 4 and 5.

Method Validation

Linearity

The linearity of measurement was evaluated by analyzing different concentration of the standard solution of Metformin HCl and Glimepiride. Result should be expressed in terms of correlation co-efficient.

Accuracy

Accuracy of an analysis was determined by systemic error involved. Accuracy may often be expressed as % Recovery by the assay of known, added amount of analyte. It is measure of the exactness of the analytical method. Recovery studies carried out for both the methods by spiking standard drug in the powdered formulations 80%, 100%, 120% amount of each dosage content as per ICH guidelines**.**

Precision

The reproducibility of the proposed method was determined by performing tablet assay at different time intervals (morning, afternoon and evening) on same day (Intra-day assay precision) and on three different days (Inter-day precision). Result of intra-day and inter-day precision is expressed in % RSD.

RESULTS AND DISCUSSION

Based on the results obtained (table 1 and 2), it is found that the proposed methods are accurate, precise, reproducible & economical and can be employed for routine quality control of Metformin HCl and Glimepiride in bulk drug and its pharmaceutical dosage form. The methods discussed in the present work provide a convenient and accurate way for analysis of Metformin HCl and Glimepiride in its bulk and pharmaceutical dosage form.

CONCLUSION

The developed methods are accurate, precise and selective and can be in work successfully for the estimation of Metformin HCl and Glimepiride in bulk and pharmaceutical dosage form.

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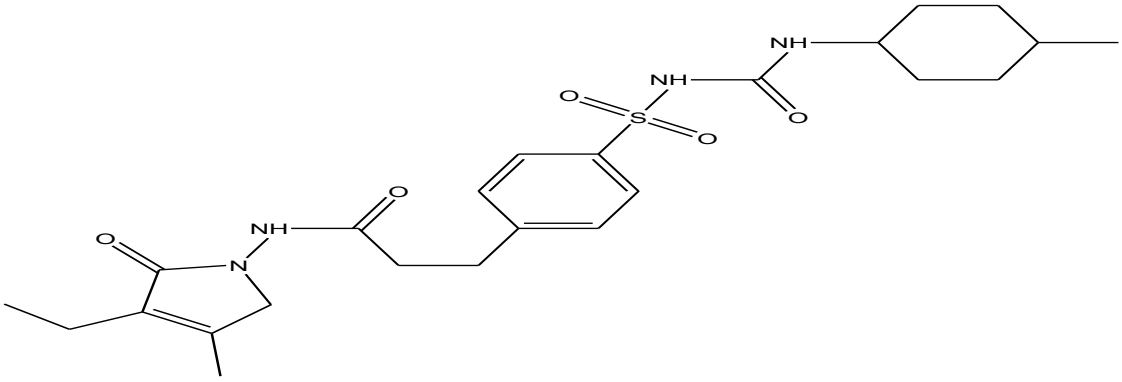
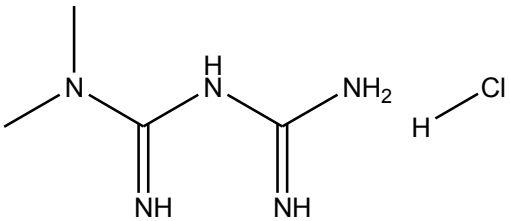


Glimepiride



Metformin hydrochloride

Figure 1: Structure of Glimepiride and Metformin hydrochloride

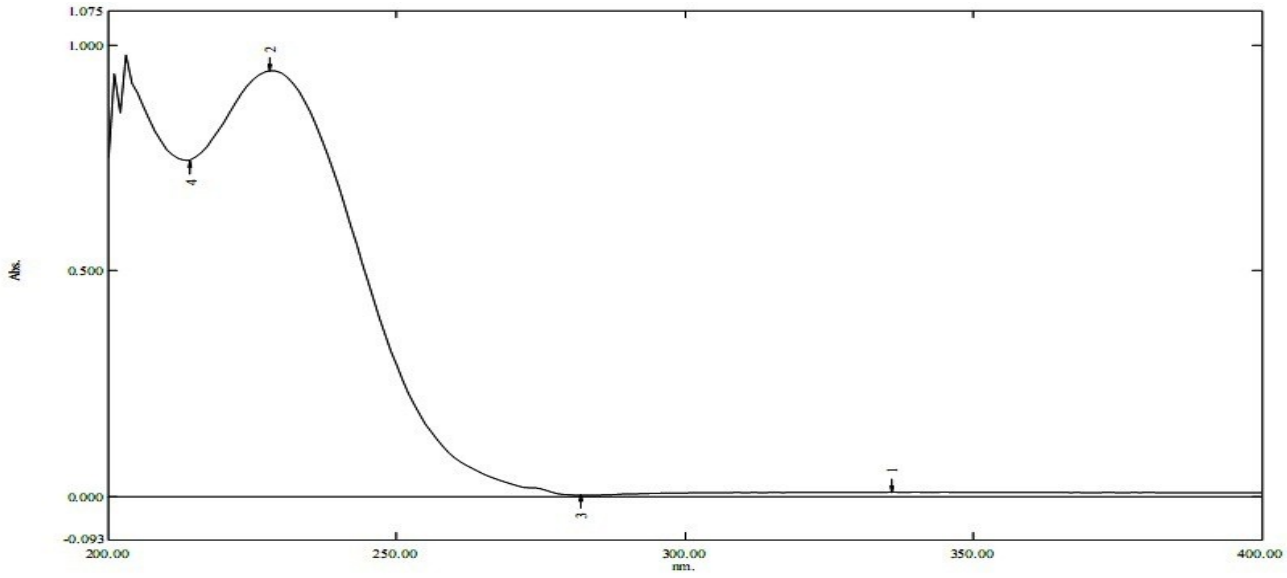


Figure 2: Wavelength maxima at 228 nm of Glimepiride

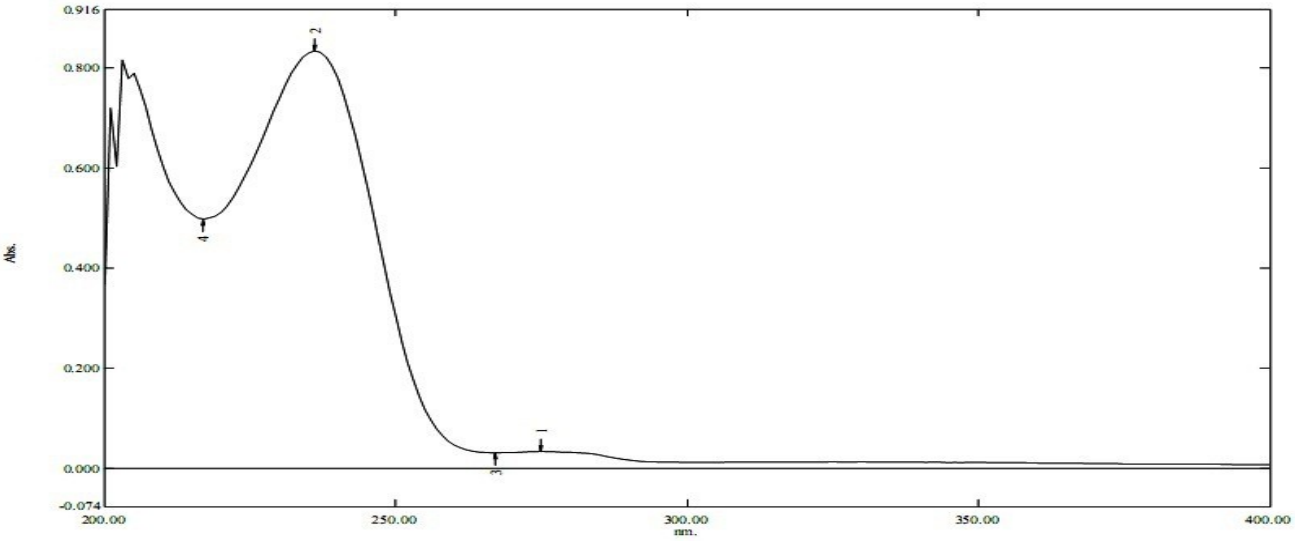


Figure 3: Wavelength maxima at 236 nm of Metformin HCl

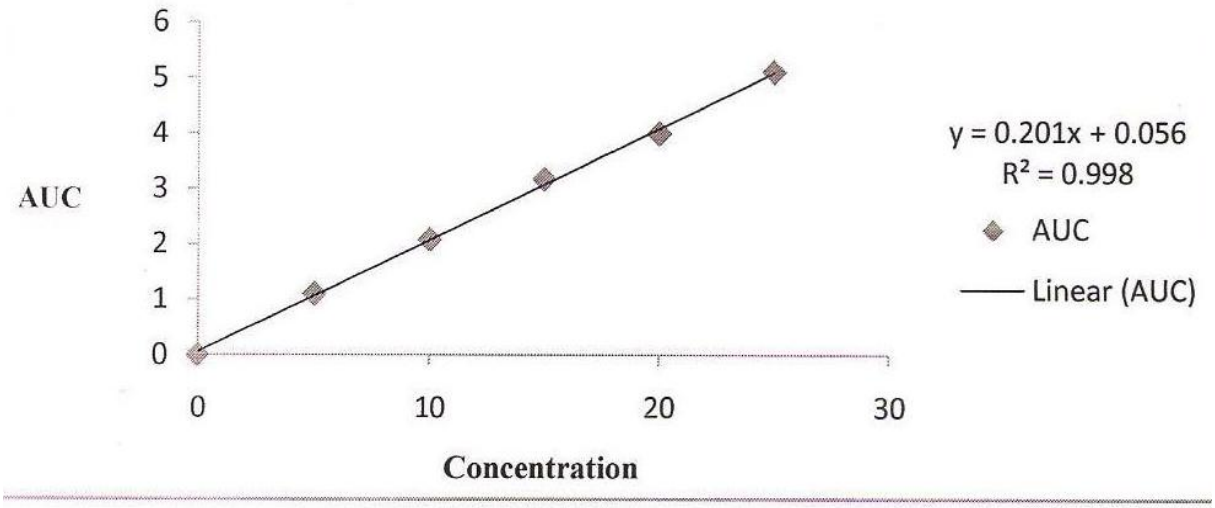


Figure 4 : Calibration curve for Metformin HCl at 236 nm

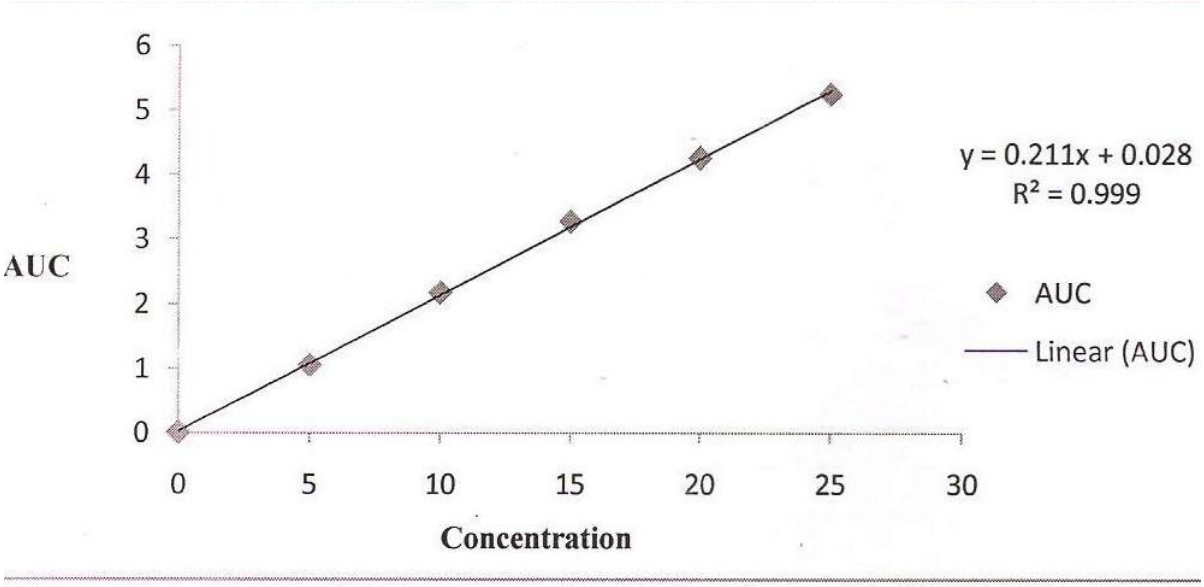


Figure 5 : Calibration curve for Glimepiride at 228 nm

Table1: Analysis of Tablet Formulation

Method	Drug	Label Claim mg	Sample Solution Concentration (µg/ml)	Amount found (%)*±	% Recovery	% RSD
A	Metformin HCl	500 mg	20	100.18 ±1.24	100.69	0.6394
B	Metformin HCl	500 mg	20	99.47±0.98	99.07	
A	Glimepiride	4 mg	20	101.29±1.47	101.54	0.6481
B	Glimepiride	4 mg	20	99.69±1.76	101.96	

Table 2: Optical Characteristics and Precision

Sr. No.	Parameter	Glimepiride	Metformin HCl
1	λ range	200-400nm	200-400 nm
2	Regression Equation (y= mx+c)	Y=0.211x+0.028	Y=0.201x+0.056
3	Measured wavelength	228 nm	236 nm
4	Linearity range	5-25µg/ml	5-25µg/ml
5	Slope	0.211	0.201
6	Intercept	0.028	0.056
7	Correlation coefficient (R2)	0.999	0.998
8	Limit of Detection (LOD) µg/ml	0.7904	0.7480
9	Limit of Quantitation (LOQ) µg/ml	2.3718	2.4491

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