International Journal of
Medicinal Chemistry & Analysis
e ISSN 2249 – 7587
Print ISSN 2249 - 7595
www.ijmca.com
Research Article

DEVELOPMENT AND VALIDATION OF SPECTROPHOTOMETRIC FOR SIMULTANEOUS ESTIMATION OF GLIMEPIRIDE AND METFORMIN HYDROCHLORIDE IN PURE AND TABLET DOSAGE FORM

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ABSTRACT

The method for the simultaneous estimation of Glimepiride and Metformine hydrochloride from tablet dosage form has been progress ,establish on simultaneous equation method at duplet determine wavelength 226nm and 232nm respectively, and also absorbance ratio method at two selected wavelength 251 nm (Iso-absorptive point) and 226 nm (lamda max of glimepiride). The linearity, was obtained in the concentration ranges of 5-25 µg/ml and 5-25µg/ml for glimepiride and metformine hydrochloride respectively. These method are simple accurate and result of analysis have been validated stastically and by recovery studies.

Keywords: Glimepiride, Metformin Hydrochloride, Simultaneous equation method, Absorbance ratio method.

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INTRODUCTION

Glimepiride,1-(p-(2-(3-ethyl-4-methyl-2-oxo-3-pyrroline-1-carboxamido) ethyl) phenyl) sulfonyl)-3-(trans-4-methylcyclohexyl) urea is a 3rd generation of sulfonylurea derivative used for the treatment of type II diabetes mellitus [1]. Which is helpful in the management of non-insulin dependent diabetes mellitus (NIDDM) [2-4]. Glimepiride is a white crystalline powder comparatively insoluble in water (pka=6.2) Glimepiride show dull GI absorption rate and inter independentvariant in its bioavailability due to its deficient water solubility [3]. From commercial point of vision little bioavailability of drug leads to loss of extra amount of drug later oral administration, in case of expensive drug expand expensive of formulation .mode of action is to increase insulin production by the pancreas [5]. The reported method are time consuming expensive and relatively complicated [6-10].

Metformin Hydrochloride is 1-1-dimethyl metformin is a first line agent for the treatment of type 2 diabetes [6]. Hydrochloride, (structures shown in figure a) Metformin Hydrochloride enhance liver and surrounding tissue susceptibility to insulin without the difficulty of major lactic acidosis. Metformin HCl is worn as antibiotic drug from the biguanide class worn in the controlling of the type 2 diabetes. Crucial action of metformin lay in expand glucose deliver over the cell membrane in skeletal muscle

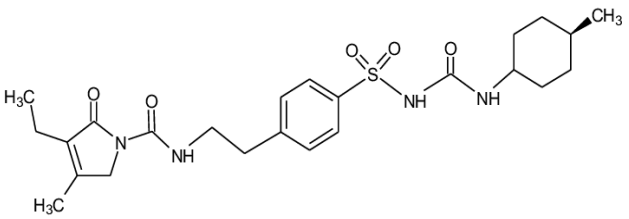
Access this article online

Home page: http://ijmca.com/

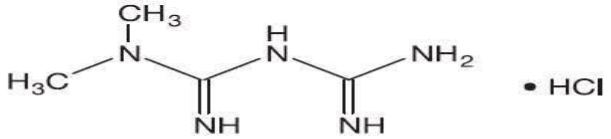
DOI: http://dx.doi.org/10.21276/ijmca.2019.9.2.1

Quick Response code

Received:07.06.19 **Revised**:24.06.19 **Accepted**:15.07.19



GLIMEPIRIDE



Metformin Hydrochloride

EXPERIMENTAL

Instrumentation

A double-beam jasco UV-2075; UV visible spectrophotometer, spectral bandwidth of 2nm wavelength accuracy 0.5nm and a pair of matched quartz cells was worn to quantify absorbance of the resulting solution.

MATERIALS

Excellence samples of Glimepiride and Metformin hydrochloride were taken. Incorporate dose glimepiride and metformine tablet 20 mg glimepiride and 15 mg metformine produce by Anwita Drugs and chemical Pvt.Ltd [7].

Solvent

Hydrochchloric acid prefer as solvent for progress spectral aspect of the drug. The choosing was make later measure the soluble of together the drugs on separate solvents.

Preparation of standard stock Solution

Glimepiride and Metformin (10mg every were correctly weight and disintegrate individually in 100ml of methanol to give stock (100µg/ml) ^{2} .from the excellence stock solution ,1ml every of glimepiride and metformin was taken in 100ml volumetric flask .proportions was make up to dot with methanol .whole part was properly diluted together o.1 N HCL to obtain terminal concentration of 5-25µg/ml(glimepiride) and 5-25µg/ml (Metformine) make respectively to give terminal concentration and scanned between 200-400nm [3].

METHOD

Application of the Proposed Method for the determination of Glimepiride and Metformin Hydrochloride in Tablet Dosage Form:

1) Simultaneous Equation Method: Twenty tablet were weight and mean weight was measure Tablet powder equal to 10mg of Glimepiride was transport to 100ml volumetric flask and ultra sonicated for 15min .The volume was make upto the mark together HCL. The resulting solution was after purify through a whatmann filter paper (No. 41).

Specific part was correctly diluted with HCL to get final concentration of 25µg/ml. The concentration of both Glimepiride and Metformin hydrochloride were decide by quantify absorbance of sample at 226 nm,232 nm in spectrum mode (fig. 1) and values were exchange in Appropriate formulae to achieve the concentration .

$C_x = A_{2ay1} - A_{1ay2}/ax2\ ay1\text{-}ax1\ ay2$

$C_y = A_{1ax2} - A_{2ax1}/ax2\ ay1 - ax1\ ay2$

Where,

C_x = Concentration of Glimepiride,

C_Y = Concentration of Metformin Hydrochloride,

A1 = Absorbance of mixture at 226 nm;

A2 = Absorbance of mixture at 232 nm;

$_{ax1}$ = Absorptivity of Glimepiride at 226nm;

$_{ax2}$ = Absorptivity of Glimepiride at 232nm;

$_{ay1}$= Absorptivity of Metformin Hydrochloride at226nm;

$_{ay2}$ = Absorptivity of Metformin Hydrochloride at 232nm;

2) Absorbance Ratio Method: In the absorbance ratio method from the over lay spectra of drug (fig. 2) wavelength 251 nm (Iso-absorptive point) and 226 nm (λ_{max} of glimepiride) were chose for evaluation. The calibration curve for glimepiride and metformin were indicate in the concentration range 5-25µg/ml and 5 - 25µg/ml at both the wavelengths severally . The absorptivities values were determined for both the drugs at both the wavelengths (fig.2)

From the following set of equation the concentration of every portion in sample was quantify,

C_X =Qm-Qy/Qx-Qy .A_1/ax_1 ..... (1) and;

Cy=Qm - Qx/Qy-Qx .A_1/a.....(2)

Where

Cx= concentration of glimepiride

Cy= concentration of metformin Hydrochloride

A_1= absorbance of sample at wavelength 226 nm

Ax_1= absorptivity of glimepiride at 226 nm

Ay_1 =absorptivity of metformin Hydrochloride at 232 nm

Qm = ratio of absorbance of sample solution at 251 nm and 226 nm,

Qx = ratio of absorptivities of glimepiride at 251 nm and 226 nm and

Qy = ratio of absorptivities of metformin Hydrochloride at 251 nm and 232 nm.

Linearity

The linearity was get in the concentration range 5-25µg/ml and 5-25µg/ml for glimepiride and metformin severally in two technique which obeys Beer-Lamber' s Law. The conclusion of the same areexhibit in fig.3 and fig 4 [8].

Accuracy

To identify accuracy of the advance technique, improvement learning were transfer by excellence addition technique [9].

Limit of Detection (LOD) and Limit of Quantitation (LOQ)

The LOD and LOQ by prefer technique were decide utilize calibration excellence .LOD and LOQ were calibrate as 3.3s/ S and 10s/S, severally, where s is decline of the calibration curve and s is the excellence deviation of respond .The conclusion of the exact are exhibit in Table 1and Table 2.

Fig 1. Simultaneous spectra for glimepiride and metformin hydrochloride in the range 200-400nm

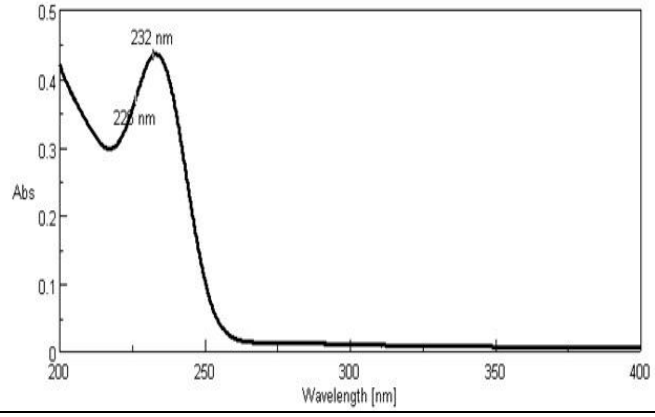


Fig 2. Overlain or absorbance spectra for glimepiride and metformin hydrochloride in the range 200-400 validation parameter

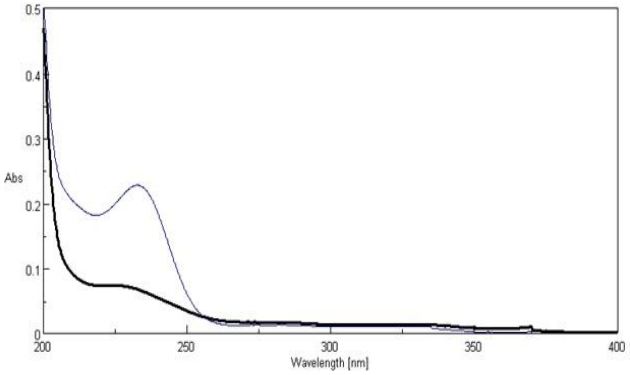


Fig 3. Linearity of glimepiride

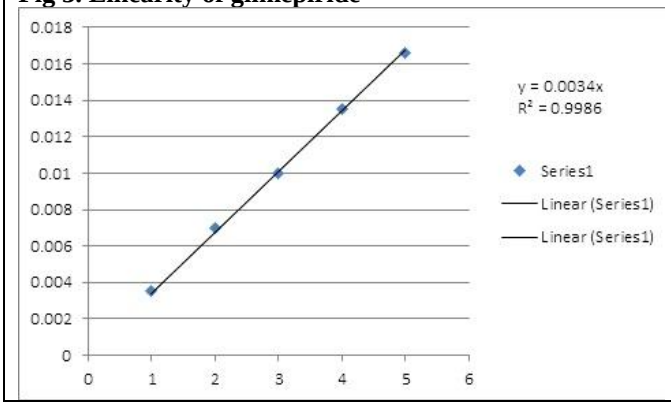


Fig 4. Linearity of metformin hydrochloride

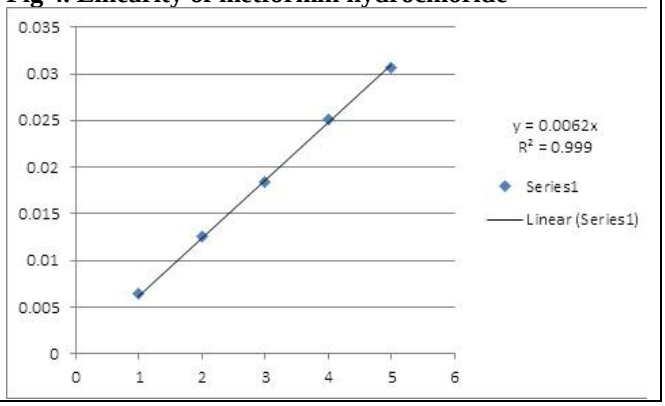


Table 1. Simultaneous equation method

Drug	Label Claim (µg/ml)	Amount Taken (mg/tab)	Amount Found (mg)	% Recovery	S.D	S.E	C.V	LOD (µg/ml)	LOQ (µG/ML)
MET	500mg/tab	10	9.87 9.78 9.73	98.7 97.8 97.3	0.916	0.529	0.931	0.015	0.070
GLI	2mg/tab	0.004	0.0031 0.0038 0.0032	77.5 95 80	0.202	0.116	0.204	0.009	0.074

Table 2. Absorbance ratio method

Drug	Label Claim (µg/ml)	Amount Taken (mg/tab)	Amount Found (mg)	% Recovery	S.D	S.E	C.V	LOD (µg/ml)	LOQ (µG/ML)
MET	500mg/tab	10	9.80 9.78 9.94 0.0038	98 97.8 99.4 95	1.014	0.581	1.031	0.123	0.375
GLI	2mg/tab	0.004	0.0036 0.004	90 100	1.017	0.588	1.036	0.124	0.377

RESULTS AND DISCUSSION

From the proposed research was found that metformine hydrochloride and glimepiride obeys linearity within the concentration rangr 5-25µg/ml respectively. Percentagelable claim for MET and GLI in tablet by simultaneous equation and absorption ratio method was found in the rangre of 97.3% to 98.7% to 77.5% to 95% respectively.For Coefficient of variation (CV) were calculated, which was found to be less than 2% indicating the both method has good producibility.

Accuracy of proposed method was ascertained by and recovery studies and results are expressed as %recovery .Percent recovery for MET and GLI by simultaneous equation and absorption ratio method was found in range of 97.3% to 98.7% to 77.5% to 95% respectively ,values of standard deviation ,standard error and coefficient of variation for both method were in range of 0.202 to 0.916 and 1.014 to 1.017,0.116 to 0.529 and 0.581 to 0.0.588,0.204 to 0.931 and 1.031 to 1.036 respectively indicating the accuracy of proposed method.

CONCLUSION

Based on the results obtained, it is found that the proposed method are accurate precise ,reproducible and economical and can be employed for routine quality control of metformine hydrochloride and glimepiride in combined dose tablet formulation.

ACKNOWLEDGEMENT

The author is thankful to Prof. (Dr).P.Y.Pawar Principal of Dr.Vithalrao Vikhepatil Foundations, College of Pharmacy, Viladghat, Ahmednagar and Prof. (Dr).S.Z.chemate HOD Department of pharmaceutics for providing necessary facilities to carry out research work.

CONFLICT OF INTREST

No interest

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