

Spectrophotometric Method for Estimation of Metformin Hydrochloride

*Mubeen .G, Khalikha Noor and Vimala M N

Al-Ameen College of Pharmacy, Hosur Road, Bangalore-560027, India.

*Corres.author: mubeenghani@hotmail.com

Abstract: A simple Spectrophotometric method has been developed and validated for the estimation of Metformin hydrochloride in bulk and in tablet formulation. The primary amino group of Metformin hydrochloride was oxidized using hydrogen peroxide to form a yellow chromogen, which is determined spectrophotometrically at 400 nm. It obeyed Beer's law in the range of 4-26mcg/ml. The percentage recovery of the drug for the proposed method ranged from 99-101.3% indicating no interference of the tablet excipients. The proposed method was found to be accurate and precise for routine estimation of Metformin hydrochloride in bulk and in tablet dosage forms.

KEYWORDS: Metformin Hydrochloride, Hydrogen peroxide.

Introduction

Metformin hydrochloride^[1-2] chemically 1,1-dimethylbiguanide hydrochloride is white crystalline powder, hygroscopic and freely soluble in water, used as a hypoglycemic drug. Literature survey reveals that methods like HPLC^[3-5] and Spectrophotometric^[6] have been reported for estimation of the Metformin hydrochloride in pharmaceutical formulations and biological fluids. Official method includes UV Spectrophotometric method for estimation of the drug from the tablets. The present work describes the development and validation of a new Spectrophotometric method for estimation of Metformin hydrochloride in bulk and in tablets.

Materials and Methods

The reference standard of Metformin hydrochloride was procured as gift sample from Micro Labs, Bangalore and tablets (Obimet 500mg, Kare Labs Pvt.Ltd. Goa) from the market were utilized for the study. Hydrogen peroxide and all other chemicals, solvents utilized were of AR grade. A double beam spectrophotometer(shimadzu) was employed for measurement of absorbance.

A standard solution of Metformin hydrochloride was prepared by dissolving 100mg of the drug in 100ml of distilled water and further diluted with water to get

concentration of 100µg/ml. Twenty tablets were weighed, powdered and the powder equivalent to 100mg of Metformin hydrochloride was accurately weighed, dissolved in 100ml of distilled water, filtered through Whatmann filter paper No-41 and diluted further to get a concentration of 100µg/ml.

To a series of (S1,S2,S3,S4,S5)25ml volumetric flasks, aliquots of 1 to 5ml of the standard solution of Metformin hydrochloride, 3.8ml of 5M Sodium hydroxide and 0.6ml of hydrogen peroxide was added. The solutions were heated on a water bath for 20mins, cooled and the volume was made up to 25ml with water and the absorbance was measured at 400nm against reagent blank. The absorbances of standard and sample solutions were measured and the amount of Metformin hydrochloride present in tablet formulation was determined by extrapolating from standard graph.

Results and Discussion

A spectrometric method has been developed for determination of Metformin hydrochloride in bulk and in tablets. The proposed method was validated as per the standard analytical procedures^[7]. The precision studies of the method and system were carried out and the % RSD was found to be less than 2% indicating that the method is precise. The

percentage recovery were carried out by adding known quantities of standard Metformin hydrochloride to the previously analyzed sample and mixtures were reanalyzed by proposed method was found in the range of 99-101% indicating that there is no interference by excipients in the method (Table1). The summary of the

results obtained are shown in the Table 2. The proposed method was found to be simple, accurate, precise stable and can be successfully applied for routine quantitative estimation of Metformin hydrochloride in bulk and solid dosage forms (tablets).

Table 1: Recovery studies of Metformin hydrochloride

Sl No	Sample Metformin HCl($\mu\text{g/ml}$)	Standard Metformin HCl($\mu\text{g/ml}$)	Abs*at 400nm	Conc. From standard graph($\mu\text{g/ml}$)	Amount** of Metformin HCl in tablet formulation	Percentage purity
1	10	10	0.111	09.91	495.5	99.10
2	12	10	0.123	09.84	492.0	98.40
3	14	10	0.140	10.00	500.0	100.0

*Average of three readings.

Table 2: Summary of the method developed

Parameter	Results
Absorption maxima(λ max)	400nm
Beer's range	4-26 $\mu\text{g/ml}$
Percentage recovery	99-101.3%
Precision (%RSD)	
Method	1.112%
System	0.378%
Molar extinction coefficient	1.12×10^4
Sandell's sensitivity	8.928×10^{-2}

Acknowledgement

The authors are thankful to principal B.G.Shivananda, Al-Ameen College of Pharmacy, Bangalore for providing all facilities to carry out the proposed work.

References

1. The Indian Pharmacopoeia, 4th ed.vol.I, New Delhi: The controller of publications, 1996: 469.
2. Budavari .S. editors.In; The Merck index.13th ed, Whitehouse Station Merck & Co.Inc:2001:998.
3. Cheng CLO, Chou Ch. HPLC method for determination of Metformin in human plasma. J Chromatogr B Biomed Sci Appl.2001: 762:51-7.
4. Vesterquist O, Nabbie F and Swanson BJ. Determination of Metformin in plasma by HPLC after ultrafiltration. J Chromatogr B Biomed Sci Appl. 1998;176:229-304.
5. Benzi L, Marchetti P, Cecchetti P, Navalesi R . determination of Metformin and phenformin in human plasma and urine by RP-HPLC. J Chromatogr Biomed appl. 1986;9:184-6.
6. Mubeen G, Noor K. Spectrophotometric method for Analysis of Metformin hydrochloride. Indian J Pharm Sci. 2009; 71(1):100-2.
7. Guidelines for industry In:Q2A, validation of Analytical procedures; methodology, Geneva; 1995.
