



Simple and Economical Method for the Determination of Metformin in the Bulk and its Tablets

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Abstract

A sensitive, economical, simple precise and accurate UV spectrophotometric method for the determination of metformin hydrochloride in bulk and its tablet dosage form has been developed and validated. The various parameters, such as linearity, precision, accuracy, limit of detection and limit of quantitation were studied according to International Conference on Harmonization guidelines (ICH). The method is accurate, precise (% CV=0.103) and linear within the range 10-40 µg/mL with $y = 0.0274x - 0.1369$ and coefficient of correlation $R^2 = 0.9579$. The limit of detection and limit of quantitation were found to be 0.80 and 2.67 µg/mL respectively. The proposed method was successfully employed for the quantitative determination of metformin tablet dosage form with no interference from any other excipients and diluents.

Keywords: UV spectrophotometric methods, economical metformin hydrochloride

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1. Introduction

Metformin hydrochloride (MET) is chemically (N, N dimethyl imidodicarbonimidic diamide hydrochloride) is a member of the biguanide class of oral anti-hyperglycemics improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by increasing peripheral glucose uptake and utilization [1-3]. The chemical structure of Metformin Hydrochloride was shown in Fig. 1.

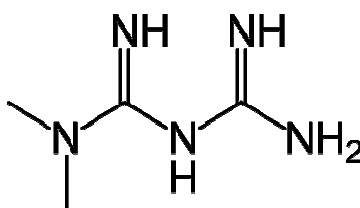


Figure 1. Chemical structure of Metformin

It is official in Indian Pharmacopoeia [4], British Pharmacopoeia [5], European Pharmacopoeia [6] and United States Pharmacopoeia [7]. All the pharmacopoeias describe HPLC method for estimation of metformin. A literature survey revealed spectrophotometry [8], HPLC [9-10], LC-MS/MS [11] and LC-electrospray tandem mass spectrometry [12 and 13] methods for simultaneous estimation of metformin in pharmaceutical formulation. And Few UV-Spectrophotometric methods [14- 17], have been reported for the estimation of MET. The current aim of this research work was to develop a simple and most economic method for the determination of metformin in bulk and as well as its pharmaceutical dosage forms.

2. Materials and Methods

Materials

Metformin was obtained as a gift sample from Matrix laboratories, Hyderabad. Distilled water was prepared in-house. Potassium hydroxide (KOH) was purchased from SD Fine chem ltd, Mumbai. PG Instruments T60 UV-Vis Spectrophotometer with a fixed slit width (2 nm) and 10 millimeter quartz cell was used to obtain spectrum and absorbance measurement. All the chemicals and reagents used were analytical reagent grade.

Methods

Preparation of standards

1mg/mL metformin stock solution was prepared by dissolving accurately weighed amounts of finely powdered pure metformin in small quantity of 0.1 N KOH and the final volumes were made the same solvent. Suitably diluted samples from the stock was utilized for λ_{\max} determination of the drug.

Sample preparation

Commercial metformin tablets was analyzed. The tablets was analyzed as per the following process: at least 10 tablets were taken and finely crushed to powder. A suitable amount of the obtained powders was separately weighed, dissolved in 0.1 N KOH, sonicated for 10 min, and filtered through a 0.5 μm membrane filter. Each sample solution was prepared in triplicate and measured in random order.

Selection of wavelength (λ_{\max})

The standard and sample drug solutions were scanned separately between 200nm to 400nm and λ_{\max} was observed at 232 nm as shown in Fig. 2.

3. Results and Discussion

Method development

A dilute standard solution of Metformin was scanned between 200 – 400 nm and it was found to show the λ_{\max} at 232 nm. The representative spectra of metformin were shown in Fig. 2. The linearity of Metformin was shown in Fig. 3.

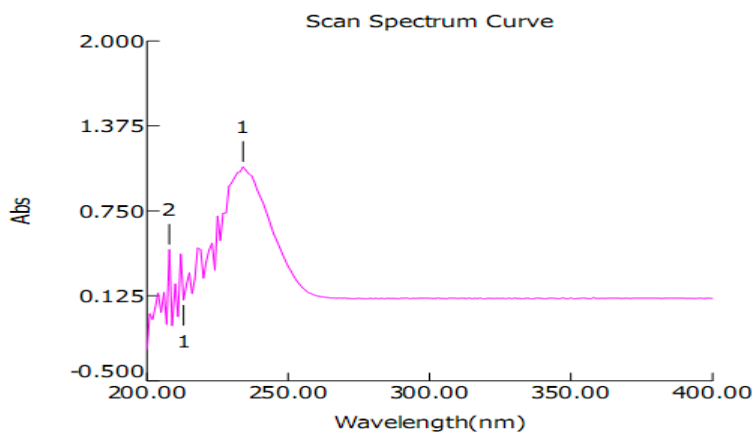


Figure 2. Spectrum of Metformin in UV region

Method validation

Metformin was freely soluble in Methanol, KOH, and Ethanol. 0.1 N KOH was chosen as a solvent. The drug has maximum absorbance at 232nm. The optical characteristic of drug was found to be Beer's law limits 10-40 µg/mL, Correlation coefficient is 0.958, Std error is 0.012089, Molar Absorbance is 37058.33. The drug sample was analyzed by UV spectroscopy using 0.1 N KOH as solvent and the average content of drug present in the formulation was found to be 99.4%. The Mean recovery of accuracy studies was found to be 99.31±0.352. The % RSD of precision was found to be 0.103%. The degradation studies of tablet formulation were found to be less at pH 6-8. The force degradation studies of metformin tablet formulation was done on Stress degradation by hydrolysis under alkaline condition by using 0.1N Na OH was found to be 8.07% for 60min, 11.95% for 90min. Stress degradation by hydrolysis under acidic condition by using 3N HCl and product degradation was found to be 9.75% for 60min and 12.79% for 90 min. Dry heat induced degradation was done by using 70°C temperature was found to be 20.94% for 48 hrs. Oxidative degradation was done by using hydrogen peroxide and product degradation was found to be 12.65% for 15 min. Photolytic degradation was found to be 10.53% for 3hrs and 14.36% for 6hrs. The limit of detection was found to be 22.34 ng /ml. The summary of all the results were shown in table 1.

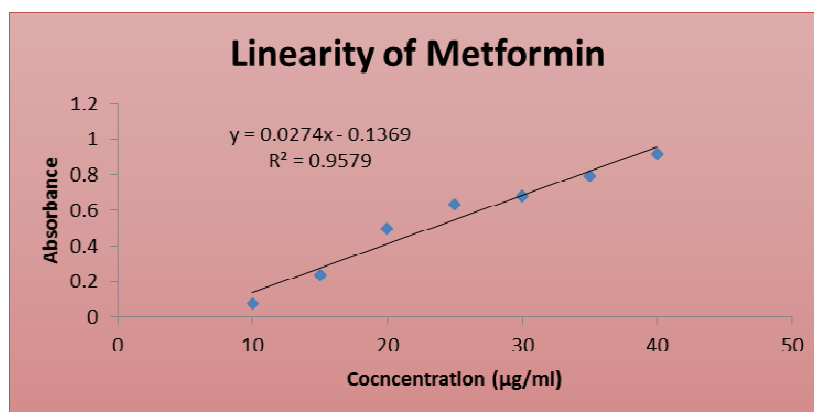


Figure 3. Linearity of Metformin

Table 1. Summary of results of the method

Validation Parameter	Result
λ_{\max} (nm)	232
Beer's law limits (µg/ml)	10- 40
Correlation coefficient (R ²)	0.9579
Regression equation (y)	0.0274x - 0.1369
Intercept(c)	0.1369
Slope	0.0274
Molar Abs	37058.33
LOD (µg/ml)	0.8
LOQ (µg/ml)	2.67
% RSD	0.103

4. Conclusion

Thus the proposed method for the estimation of Metformin HCL, in bulk and its tablet dosage forms was found to be rapid, sensitive, simple, accurate, and economical. High percentage of recovery shows that the method is free from the interference of excipient (s) used in formulation. Therefore the method can be useful in routine quality control of metformin.

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