

Original Research

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Development and Validation of UV Spectrophotometric Method for Simultaneous Estimation of Metformin and Glipizide in Tablet Dosage Form

K. Ganesh¹, G. Nikitha¹, D. Sireesha^{2*}, B. Vasudha³

1. Department of Pharmaceutical Analysis, Anurag Group of institutions (Lalitha College of Pharmacy), Venkatapur, Ghatkesar, Telangana, India.
2. Associate Professor, Department of Pharmaceutical Analysis, Anurag Group of institutions (Lalitha College of Pharmacy), Venkatapur, Ghatkesar, Telangana, India.
3. Principal, Anurag Group of institutions (Lalitha College of Pharmacy), Venkatapur, Ghatkesar, Telangana, India.

Corresponding author: D. Sireesha

Email address: sireeshapharmacy@cvsr.ac.in

Address: Department of Pharmaceutical Analysis, Anurag Group of institutions (Lalitha College of Pharmacy), Ghatkesar, Telangana, India.

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ABSTRACT:

A simple, rapid and precise spectrophotometric method has been developed for simultaneous estimation of Metformin and Glipizide. The method involved estimation of Metformin and Glipizide by simultaneous equation at 272nm and 232nm respectively in their solution in water. This method was validated with respect to linearity, accuracy, precision, LOD and LOQ. Beer's law obeyed in the concentration range of 5-25µg/ml and 20-50µg/ml for Metformin and Glipizide respectively with the correlation coefficient of above 0.99. Limit of detection and quantification values were determined to be 0.214µg/ml and 0.649µg/ml for Metformin and 0.608µg/ml and 1.854µg/ml for Glipizide respectively. Mean recovery of Metformin and Glipizide were found to be in the range of 98-102% signifies the accuracy of the method. The method was found to be precise as %RSD was less than 2.

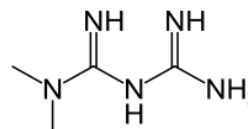
1. INTRODUCTION

Metformin is chemically Dimethylimido dicarbonimidic diamide (RamanjiReddy et al., 2011) (Figure 1). Metformin is primarily used for type 2 diabetes, but is increasingly being used in polycystic ovary syndrome (Gong et al., 2012). Metformin decreases hyperglycemia primarily by suppressing glucose production by the liver (hepatic gluconeogenesis) (Ripudaman et al., 2000).

Glipizide is chemically N-(4-[N-(cyclohexylcarbamoyl) sulfomoyl] phenyl)-5-methylpyrazine-2-carboxamide (Figure 2). It is an oral

rapid and short-acting anti-diabetic drug from the sulfonylurea class. It is classified as a second generation sulfonylurea which are both more potent and have shorter half-lives than the first-generation sulfonylureas (Bhaskar et al., 2011).

Figure 1: Chemical structure of Metformin



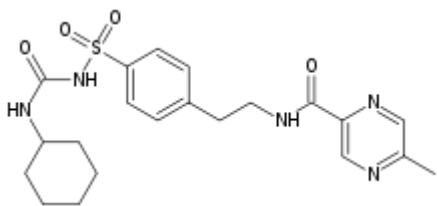


Figure 2: Chemical structure of Glipizide

Literature survey revealed that there are only few methods reported for the estimation of metformin and Glipizide, individually or with other drugs using UV-spectrophotometry (Lakshmi et al., 2009; Rashmi et al., 2011; Adhikari et al., 2012) and RP-HPLC (Triveni et al., 2012; Lakshmi D et al., 2015; Sabyasachi et al., 2015). Hence present study aim to develop a precise, linear, simple, rapid, validated and cost effective UV-spectrophotometry method for the estimation of Metformin and Glipizide in tablet dosage forms.

2. MATERIALS AND METHODS

2.1 Instruments used

SHIMADZU double beam UV/Visible Spectrophotometer model UV 1800s was employed with a spectral band width of 1nm and a wavelength accuracy of 0.3 nm (with automatic wavelength correction with a pair of 1cm matched quartz cells). SHIMADZU Electronic balance model AX 200 and Ultra Sonicator (Fast clean) model 2k811056 were also used during the analysis.

2.2 Materials

Analytically pure sample of Metformin and Glipizide were obtained as gift sample from Dr. Reddy's Laboratories (Hyderabad). Tablets of brand "Metaglip" (500mg of Metformin and 5mg of Glipizide) were purchased from local pharmacy.

2.3 Selection of solvent and wavelength

The UV spectra of Metformin and Glipizide in different solvents like water, acetonitrile, methanol and ethanol were recorded. The drugs showed good absorbance when dissolved in water and also as water is economic it was selected as the solvent. In this the Metformin and Glipizide were showing good absorbance at wavelengths of 272nm and 232nm respectively.

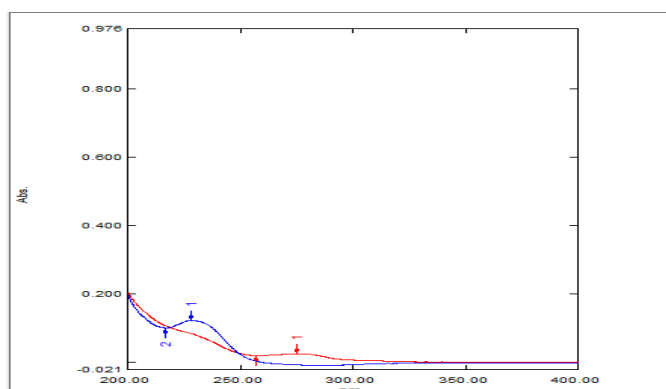
2.4 Preparation of standard solutions

Metformin and Glipizide of 100mg were separately weighed and transferred to a 100 ml volumetric flask and dissolved in water to get solutions of concentration 1000µg/ml.

2.5 Preparation working standard solutions

Working standard solutions of 10µg/ml were prepared by diluting 1ml each of above standard solution to 100ml with water and scanned it in the range 200nm-400nm to obtain the absorbance spectra (Figure 3).

Figure 3: Absorbance spectra of Metformin and glipizide



2.6 Preparation of sample solutions

Twenty Metaglip tablets each containing 500mg of Metformin and 5mg of Glipizide were weighed, average weight was calculated and powdered. A quantity equivalent to 25mg of Metformin was weighed and transferred to 25ml volumetric flask. An accurately weighed 99.75mg of Pure Glipizide was added and dissolved in water. With the addition of pure Glipizide, the ratio of Metformin and Glipizide was brought to 1:4. The solution was made up to the volume with water and filtered. The sample solution containing 10µg/ml Metformin and 40µg/ml Glipizide was obtained by diluting 1ml of the above solution to 100ml.

3. RESULTS AND DISCUSSION:

The analytical method developed was validated according to ICH guidelines with respect to parameters such as linearity, precision, accuracy, limit of detection (LOD), limit of quantification (LOQ).

3.1 Linearity and Range

Linearity was established by least squares linear regression analysis of the calibration curve. The calibration curve was linear over the concentration range of 5-25 µg/ml for Metformin and 20-50 µg/ml for Glipizide. Correlation coefficients were found to be 0.9979 and 0.9964 for Metformin and Glipizide respectively (Figure 4 and Figure 5).

Figure 4: Calibration curve of Metformin

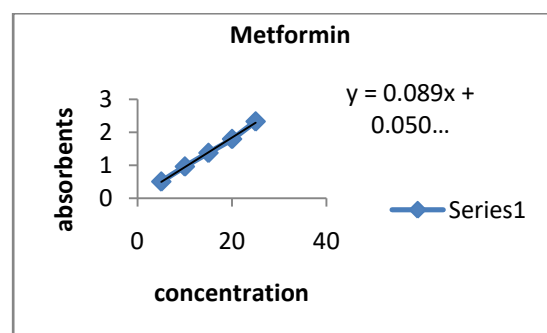
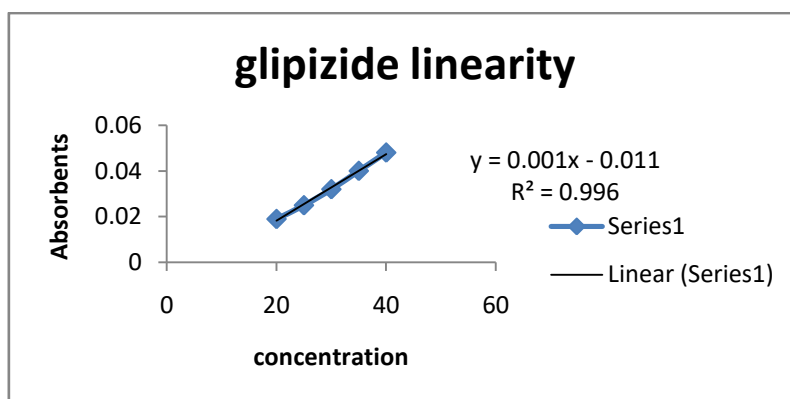


Figure 5: Calibration curve of Glipizide



3.2 Precision

The precision of the analytical method was studied by multiple sampling of the homogenous sample. The precision was done by measuring the absorbance for six times. The %RSD value was found to be 0.68 and 0.17 respectively indicating that the method is precise. The results are given in Table.1.

Table 1: Precision studies

| Drug and Amount taken(µg/ml) | % recovery | Amount added (µg/ml) | Total amount recovered (µg/ml) | % Recovered |
|------------------------------|------------|----------------------|--------------------------------|-------------|
| Metformin 10 | 80 | 8 | 17.80 | 98.88 |
| | 100 | 10 | 20.04 | 100.20 |
| | 120 | 12 | 21.78 | 99.00 |
| Glipizide 40 | 80 | 32 | 72.22 | 100.30 |
| | 100 | 40 | 80.63 | 100.78 |
| | 120 | 48 | 88.59 | 100.67 |

3.3 Accuracy

Recovery studies were carried out by applying the method to drug sample to which known amount of Metformin and Glipizide at three concentration levels of 80, 100 and 120 % were added. At each level %recovery was determined, which are in the range of 98-102%. The results are given in Table 2.

3.4 Sensitivity

LOD and LOQ decide about the sensitivity of the method. LOD is the lowest detectable concentration of the analyte by the method while LOQ is the minimum quantifiable concentration. LOD and LOQ were calculated by standard calibration curves. LOD and LOQ were found to be 0.214µg/ml and 0.649µg/ml for Metformin and 0.608 µg/ml and 1.854 for Glipizide respectively.

Table 2: Accuracy studies

| S.No | Concentration µg/ml | Absorbance | | %RSD | |
|------|-----------------------------------|------------|-----------|-----------|-----------|
| | | 272n m | 232n m | 272n m | 232n m |
| 1 | Glipizide 40 + Metformin 10 | 0.280 | 1.065 | 0.68 | 0.17 |
| 2 | | 0.281 | 1.062 | | |
| 3 | | 0.285 | 1.060 | | |
| 4 | | 0.283 | 1.064 | | |
| 5 | | 0.282 | 1.061 | | |
| 6 | | 0.280 | 1.062 | | |

3.5 Analysis of marketed formulation

The developed and validated method was applied for the assay of marketed formulation. The results are shown in Table 3.

Table 3: Analysis of marketed formulation

| Drug | Labeled amount, mg/ tablet | Amount found, mg/ tablet | % Label claim |
|------------------|----------------------------|--------------------------|---------------|
| Metformin | 500 | 500.52 | 100.10 |
| Glipizide | 5 | 4.91 | 98.20 |

4. CONCLUSION

The evaluation of obtained values suggests that the proposed UV Spectrophotometry method provide simple, precise, rapid and accurate analytical method for simultaneous determination of Metformin and Glipizide in tablet dosage form. Correlating the obtained results with the standard values, the method is found to be valid and hence the method can be easily and conveniently adopted for routine estimation Metformin and Glipizide in tablet dosage form.

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