DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHOD FOR QUANTITATIVE ESTIMATION OF GLIPIZIDE IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

Objective: The present work is aimed to develop a simple, rapid, selective and economical UV spectrophotometric method for quantitative determination of Glipizide in bulk and pharmaceutical dosage form.

Methods: In this method Dimethyl Formamide (DMF) was used as a solvent, the absorption maxima was found to be 275 nm in DMF. The developed method was validated for linearity, accuracy, precision, ruggedness, robustness, LOD and LOQ in accordance with the requirements of ICH guideline.

Results: The linearity was found to be 10-60 µg/ml having linear equation y=0.017x-0.006 with correlation coefficient of 0.997. The % recovery was found to be in the range of 98.7-100%. The % RSD for intra-day and inter-day precision was found to be 0.569923 and 0.40169 respectively. The limit of detection (LOD) and limit of quantification (LOQ) was found to be 3.06 µg/ml and 9.27 µg/ml respectively.

Conclusion: The developed method was validated as per ICH Q2(R1) guidelines. The novel method is applicable for the analysis of bulk drug in its pharmaceutical dosage form.

Keywords: Glipizide, UV-Spectrophotometric method, Method Development and validation, Dimethyl Formamide

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INTRODUCTION

Glipizide (1-cyclohexyl-3-[[4-[[5-methylpyrazine-2-yl]carbonyl]amino]ethyl]phenyl sulphonyl)urea), is a second-generation sulfonylurea derivative that is widely used as oral antihyperglycemic drug for the treatment non-insulin dependent diabetes mellitus [2-6].

Fig. 1: Structure of glipizide

The present study is aimed to develop a simple, rapid, selective and economical UV spectrometric method for quantitative determination of Glipizide in bulk and pharmaceutical dosage form. The method was demonstrated as per ICH Q2(R1) guidelines [7-11].

MATERIALS AND METHODS

Materials used

Pure standard Glipizide was obtained as a gift sample from Ajanta Pharma Ltd, Mumbai. Commercial tablet of Glipizide formulation was purchased as research sample from Wockhardt Ltd, Aurangabad. DMF is used as a solvent.

Instrument used

UV-Visible double beam spectrophotometer (Systronics-2201) with 1 cm matches quartz cell, electronic balance (SHIMADZU-AY220) and asonicator (Oscar ultrasonic cleaner Microclean-103) was used in the study.
Preparation of standard stock solution

Standard stock solution of Glipizide (GLP) was prepared by dissolving 10 mg GLP in 10 ml of DMF to obtain concentration of 1000 µg/ml.

Spectrum measurement of glipizide in DMF

The second stock solution was prepared by diluting 0.5 ml of the above standard stock solution up to 10 ml and scanned between 200-400 nm in UV Visible double beam spectrophotometer. The UV absorption spectrum of Glipizide showed peak at 275 nm. The maximum wavelength of 275 nm was selected for the present study.

Assay

Weigh and powder 20 tablets. Weigh accurately a quantity of the powder containing 10 mg of glipizide transferred into 10 ml of volumetric flask and dissolved in DMF. This solution was sonicated and the final volume was made up to the mark with DMF. 1 ml of solution was transferred into 10 ml volumetric flask and adjusted up to the mark with DMF. The absorbance of this solution measured at 275 nm. The result of assay was shown in Table 1.

Method validation

Validation parameter such as Linearity and range, Accuracy, precision, ruggedness, robustness, LOD and LOQ according to ICH Q2(R1) guideline [12].

Linearity

Aliquots of 0.1, 0.2, 0.3, 0.4, 0.5 and 0.6 were taken from standard stock solution and the volume made up to 10 ml with DMF. Calibration curve was plotted between absorbance versus concentration (fig. 3).

Table 1: Assay of glipizide tablet

| Brand name | Label claim | Assay |
|------------|-------------|-------|
| Glynase    | 5 mg        | 98.5 %|

Table 2: Linearity of glipizide

| S. No. | Concentration (µg/ml) | Absorbance |
|--------|-----------------------|------------|
| 1      | 10                    | 0.144      |
| 2      | 20                    | 0.344      |
| 3      | 30                    | 0.523      |
| 4      | 40                    | 0.693      |
| 5      | 50                    | 0.846      |
| 6      | 60                    | 1.007      |

Regression equation: $y = 0.0171x - 0.0063$

$R^2 = 0.9977$

Fig. 3: Calibration curve of glipizide in DMF

Range

The range of an analytical procedure is an interval between upper and lower concentration of an analyte in the sample for which it has been shown that the analytical procedure has a suitable level of linearity, accuracy, precision. The obtained range of an analyte is 10 to 60 µg/ml.

Accuracy

Accuracy was determined by preparing solution of different concentration that is 50%, 100%, 150%. The percentage recovery was calculated (table 3).

Precision

The precision (measurement of intra-day, inter-day) determined by analyzing the six samples of same concentration (30 µg/ml) the absorbance was noted. From the measured absorbance result mean, standard deviation and % RSD was calculated.

Ruggedness

Ruggedness of the method was determined by analyzing same sample by different analysts (analyst 1 and 2) at different condition and the respective absorbance were noted and result was indicated as %RSD.

Robustness

Robustness of the method was determined by carrying out the analysis at two different wavelength (275 and 277) preparing solution 15 µg/ml.

Limit of detection (LOD)

The limit of detection (LOD) was determined by using linearity. LOD was calculated by using equation-
Where $\delta$ is a standard deviation and $s$ is the slope.

### Table 3: Result for accuracy

| Name of drug | Level of recovery | Concentration (µg/ml) | Amount recovery | Mean % recovery |
|--------------|-------------------|-----------------------|-----------------|----------------|
| Glipizide    | 50%               | 20                    | 19.84           | 99.2           |
|              | 100%              | 40                    | 39.84           | 99.6           |
|              | 150%              | 60                    | 59.25           | 98.75          |

### Table 4: Intraday precision data of glipizide

| S. No. | Concentration (µg/ml) | Absorbance |
|--------|-----------------------|------------|
| 1      | 30                    | 0.524      |
| 2      | 30                    | 0.529      |
| 3      | 30                    | 0.528      |
| 4      | 30                    | 0.526      |
| 5      | 30                    | 0.532      |
| 6      | 30                    | 0.531      |
| Mean   |                       | 0.528333   |
| SD     |                       | 0.003011   |
| %RSD   |                       | 0.569923   |

### Table 5: Interday precision data of glipizide

| S. No. | Concentration (µg/ml) | Absorbance |
|--------|-----------------------|------------|
| 1      | 30                    | 0.524      |
| 2      | 30                    | 0.528      |
| 3      | 30                    | 0.529      |
| 4      | 30                    | 0.527      |
| 5      | 30                    | 0.530      |
| 6      | 30                    | 0.531      |
| Mean   |                       | 0.528167   |
| SD     |                       | 0.002483   |
| %RSD   |                       | 0.40169    |

### Table 7: Result of ruggedness

| S. No. | Concentration (µg/ml) | Absorbance (analyst 1) | Absorbance (analyst 2) |
|--------|-----------------------|------------------------|------------------------|
| 1      | 30                    | 0.524                  | 0.522                  |
| 2      | 30                    | 0.520                  | 0.518                  |
| 3      | 30                    | 0.519                  | 0.521                  |
| 4      | 30                    | 0.521                  | 0.522                  |
| 5      | 30                    | 0.518                  | 0.520                  |
| 6      | 30                    | 0.522                  | 0.525                  |
| Mean   |                       | 0.52066667             | 0.521333              |
| SD     |                       | 0.00216025             | 0.002338              |
| %RSD   |                       | 0.41490017             | 0.449483              |

### Table 8: Robustness at wavelength 275 nm and 277 nm (conc. 15 µg/ml)

| S. No. | Concentration (µg/ml) | Absorbance (275) | Absorbance (277) |
|--------|-----------------------|------------------|------------------|
| 1      | 15                    | 0.253            | 0.252            |
| 2      | 15                    | 0.255            | 0.254            |
| 3      | 15                    | 0.254            | 0.256            |
| 4      | 15                    | 0.254            | 0.255            |
| 5      | 15                    | 0.251            | 0.253            |
| 6      | 15                    | 0.254            | 0.256            |
| Mean   |                       | 0.2535           | 0.254333         |
| SD     |                       | 0.0013784        | 0.00163299       |
| %RSD   |                       | 0.54374940       | 0.64206808       |

### Table 9: For limit of detection

| LOD   | Concentration (µg/ml) |
|-------|-----------------------|
| Glipizide | 3.06                 |

### Table 10: For limit of quantification
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RESULT AND DISCUSSION

The UV scan of standard stock solution 200-400 nm showed the absorption maxima at 275 nm. The overlay spectra of different concentration range of standard Glipizide was recorded (fig. 2). Beer's-Lambert's law is applicable in the concentration range between 10 to 60 µg/ml. The regression equation was found to be Y=0.0171x-0.0063 and correlation coefficient was found to be 0.9977. The % assay of Glipizide tablet was found to be 98.5%. Validation parameters are developed as per ICH guideline. Accuracy was found to be 98.75-100% recovery. Precision for intra-day and inter-day of % RSD was found to be 0.5437 and 0.4484. Robustness was calculated by two different wavelength 275 and 277 nm and the % RSD was found to be 0.5437 and 0.6420. Hence the proposed method was developed in validation parameters and the method were found to be simple, rapid, accurate and precise for the routine analysis of glipizide in bulk pharmaceutical dosage form.

CONCLUSION

A simple, rapid and precise UV-visible spectrophotometric method has been developed for the determination of glipizide in marked formulation. The developed method was validated for linearity, accuracy, precision (intra-day and inter-day), robustness, ruggedness, LOD and LOQ parameters studies. The result of all these parameters shows that the rapid, accurate, linear and precise. This method can be successfully applied for routine estimation of glipizide in bulk pharmaceutical dosage form.

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AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICT OF INTERESTS

Declare none

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