Development And Validation Of UV Spectrophotometric Method For Estimation Of Glipizide In Bulk Drug And Pharmaceutical Formulation

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ABSTRACT:

A selective, simple, accurate and reproducible spectrophotometric method has been developed for the estimation of Glipizide in bulk and pharmaceutical formulation. Glipizide is a second generation sulfonylurea which lowers blood glucose in patients with diabetes mellitus type II. The drug obeyed the Beer's law and showed good correlation. It showed absorption maxima at 275 nm in 0.5N NaOH. The developed method was validated with respect to linearity, accuracy and precision in accordance with the requirements of ICH guidelines. The linearity was observed between 10-30µg/ml having line equation Y= 0.0219X + 0.0 132 with correlation coefficient of 0.999.The limit of quantification and limit of detection were found to be 1.892 and 0.624 ug/ml respectively. Moreover, the proposed analytical method is thus potentially useful for a routine laboratory because of its simplicity, rapidity, precision and accuracy.

KEYWORDS: Method Validation , Glipizide

INTRODUCTION:

Glipizide is Chemically *N*-[2-[4-(cyclohexylcarbamoylsulfamoyl)phenyl]ethyl] -5-methylpyrazine-2 carboxamide.

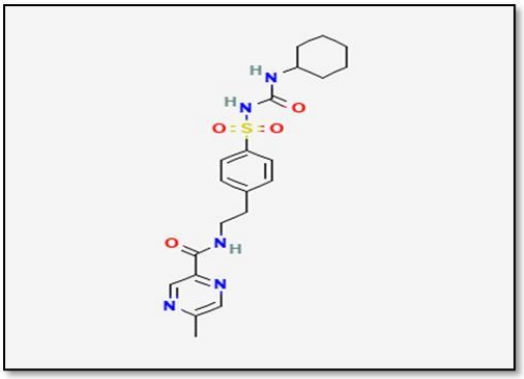

Fig.1 Structue of Glipizide[3]

Mechanism of action of Glipizide is to stimulate insulin release from the pancreatic beta cells; for this reason, they are only effective when the patient has some residual pancreatic beta cell activity.The sulfonylureas act by closing the ATP-sensitive potassium (K_{ATP}) channels in the cell membrane of the pancreatic beta cells and therefore cause: membrane depolarisation, calcium influx and insulin release. Normally, the K_{ATP} channels close when the intracellular levels of glucose increases; firstly, glucose enters the pancreatic beta cells via the glucose transporters (GLUT2), secondly, it is phosphorylated by the enzyme glucokinase and finally, it is metabolised which generates ATP and the subsequent closure of the K_{ATP} channels.

METHOD DEVELOPMENT:

Selection of Solvent system:

The selection of solvent was made after assessing the solubility of Glipizide in different solvent like water, methanol, and NaOH. Glipizide is insoluble in water and soluble in NaOH so economical point of view NaOH selected as a solvent system for this UV-method development.

Preparation of standard stock solution:

Glipizide standard stock solution (100 µg/ml):

A 10 mg of Glipizide standard was weighed and transferred to a 100 ml volumetric flask &10 ml of NaOH was transferred to this volumetric flask make up the volume with 0.5N NaOH up to 100 ml.

NaOH Preparation (0.5N NaOH):
A 2.25g of Sodium Hydroxide is transferred in 100 ml Volumetric flask , and make up the volume with distilled water up to 100 ml[8].

Selection of wavelength:

The drug is soluble in NaOH, Prepare different concentrations of solution. These solution scan or recorded spectrum between 200-400nm using as blank NaOH. In UV-Spectrophotometric method wavelengths 275nm was selected for determination of Glipizide.(Fig.2)

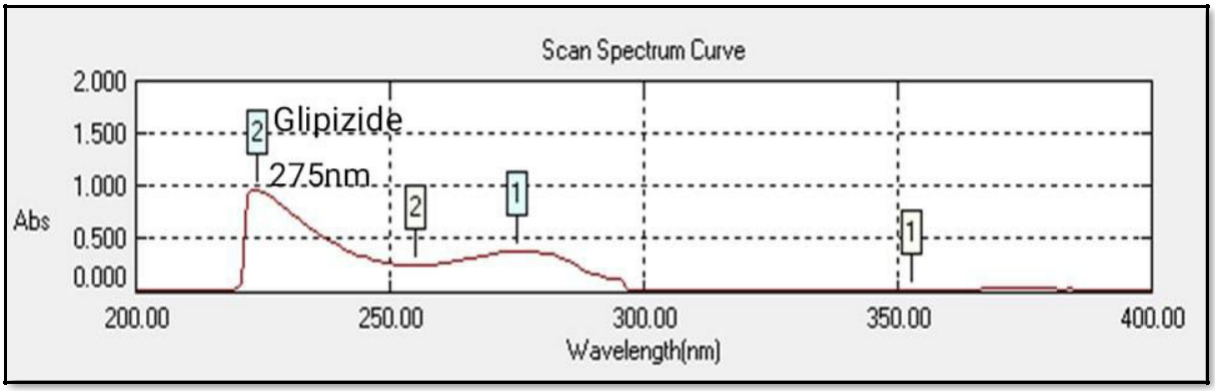

Fig.2 Wavelength of Glipizide

METHOD VALIDATION:

Linearity:

Appropriate volume of adequate from standard Glipizide stock solution was transferred to different volumetric flask of 10 ml capacity. The volume was adjusted to the mark with 0.5N NaOH to obtain concentration of 10, 15, 20, 25 and 30µg/ml. An absorbance at 275 nm was measured and the plot of absorbance vs. concentrations was plotted. The straight-line equation was determined.

Precision:

Intermediate precision (n=3): Intermediate precision expresses within- laboratories variation different days, different analysts, different equipment, etc. The intermediate precision of the method was confirmed by intraday (variation of results within the same day) and Interday (variation of results between days) analysis. The intraday and interlay precision of the proposed methods were performed by analyzing the corresponding responses three times on the same day for intraday precision and over a period of three days for inter day with three different.

Accuracy:

The accuracy of the method will be carried out at three levels 80, 100 and 120% of the working concentration of sample. This procedure was repeated for three times for each concentration and accuracy were indicated by % RSD which was found to be less than 2%.

Ruggedness:

Ruggedness is a measure of reproducibility of test results under the variation in conditions normally expected from lab to lab and analyst to analyst.

Robustness:

The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of reliability during normal usage.

Limit of Detection:

The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value.

Limit of Quantitation:

The quantitation limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy.

RESULT AND DISCUSSION:

The Glipizide having organoleptic character are white in color and having no odor. Melting point of Glipizide was found to be 207-209ºc. Absorption maxima is 275nm. The Linearity is calculated in range 10-30µg/ml. The Correlation coefficient should be near to 0.999 and for Glipizide found to be 0.999. Precision was evaluated thrice in day SD found to be 0.0068 and %RSD is 1.490 and for Interday SD is 0.0.0046 and %RSD is 1.235. Accuracy for

Glipizide was determined for 80%, 100% and 120% level of accuracy was found to be 101.4%, 99.19%, 99.37% respectively Ruggedness was determined and RSD was found to be less than 2%.For the Robustness absorbance taken at 273,275, and 277 nm. And Relative Standard Deviation was found to be less than 2%. The Limits of Detection (LOD) evaluated 0.62 µg/ml and The Limit of Quantification (LOQ) is 1.89 µg/ml.

Linearity:

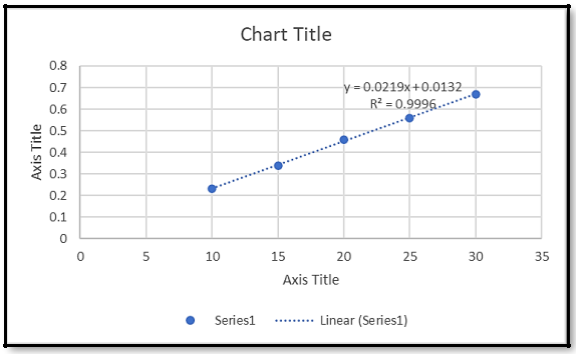

Fig.3 Linearity

Precision:

Conc. (µg/ml)	Intra-day [N=3]		Inter-day [N=3]	
	Mean Abs	% RSD	Mean Abs	% RSD
10	0.223	0.932	0.254	1.420
15	0.343	1.493	0.316	1.558
20	0.441	1.701	0.418	1.196
25	0.550	1.726	0.514	0.892
30	0.696	1.600	0.646	1.119

Accuracy:

Validation Parameter	Mean % Recovery	SD	%RSD
80%	101.4	0.005	1.281
100%	99.19	0.005	1.309
120%	99.37	0.006	1.220

Ruggedness:

Concentration	Absorbance		SD	% RSD
	Analyst-1	Analyst - 2		
10	0.263	0.259	0.0028	1.084
15	0.388	0.393	0.0035	0.905
20	0.467	0.452	0.0042	0.945
25	0.573	0.569	0.0028	0.495
30	0.708	0.698	0.007	1.006

Robustness:

Concentration	Wavelengths			SD	% RSD
	273 nm	275 nm	277 nm		
10	0.259	0.267	0.266	0.0043	1.651
15	0.320	0.328	0.329	0.0049	1.515
20	0.429	0.445	0.443	0.0087	1.986
25	0.553	0.571	0.569	0.0098	1.748
30	0.665	0.683	0.679	0.0094	1.399

Limit of Detection (LOD):

The Limit of Detection was found to be 0.62 µg/ml.

Limit of Quantification (LOQ):

The Limit of Quantification was found to be 1.89 µg/ml.

CONCLUSION:

The proposed method development and validation of UV-Vis Spectrophotometric method was to determine Glipizide. The developed method was validated in 0.5 N NaOH according to ICH guideline and shown to be accurate, precise and cost effective. It do not require expensive or sophisticated and

chemicals in contrast with chromatographic method. It can be used for the routine Quality Control analysis and quantification of the drug in the formulations.

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