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Development of UV Spectrometric Method of Glibenclamide (Glyburide) in Bulk and Pharmaceutical Formulations

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Abstract: The present research work discussed the development of a UV estimation method for Glibenclamide. A simple, accurate, cost effective and reproducible spectrophotometric method has been developed for the estimation of Glibenclamide in bulk and pharmaceutical dosage form. UV spectrophotometric method, which is based on measurement of absorption at maximum wavelength of 242nm. The percentage recovery of Glibenclamide ranged from (99.49 ± 0.1069) in pharmaceutical dosage form. The developed method was validated with linearity, accuracy (recovery), precision and specificity. Beer's law was obeyed in the concentration range of 5-30 µg/ml having line equation y = 0.0211 × -0.0114 with correlation coefficient of 0.9934. Results of the analysis were validated statistically and by recovery studies.
Keywords: Glibenclamide, UV spectrophotometry.

INTRODUCTION

Chemically Glibenclamide is 5-chloro-n-[2-[4[[[(cyclohexylamino)carbonyl]-amino]sulphonyl]phenyl]-ethyl]-2-methoxy benzamide is oral hypoglycaemic drug sulphonyl ureas - second generation) act by inhibiting ATP-sensitive potassium channels in pancreatic beta cells. This inhibition causes cell membrane depolarisation, which cause voltage dependent calcium channels to open, which causes an increase in intracellular calcium in the beta cell, which stimulates insulin release.

The literature survey reveals that Glibenclamide was analysed by RP-HPLC, spectrophotometer, LCMS was used for determination of Glibenclamide.

Analysis is an important component in the formulation development of any drug molecule. It becomes essential to develop a simple, sensitive, accurate, precise, reproducible method for the estimation of drug sample. Our main concern is development and validation of UV spectrometric method.

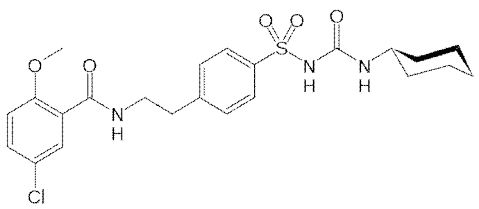

Figure no 1- Structure of Glibenclamide

MATERIALS AND METHOD:

Instruments and material:

Instrument used were Pharmaspec UV 1700 Schimadzu and AX200 analytical balance. Glibenclamide pure drug was obtained from MICRO LABS LTD as gift sample with 99.9% w/w assay value and was used without further purification. All chemical and reagent used were of analytical grade. Glyburide tablets were purchased form market.

Preparation of standard stock solution:

Standard drug solution of Glibenclamide was prepared by dissolving 10mg in 10ml chloroform (1mg/ml) and transfer 1ml of this solution to 10ml of volumetric flask, made upto mark with same solvent. For obtaining clear solution, solution was filtrated.

Preparation of calibration curve:

Aliquots of 0.5 to 3ml of portion of stock solution were transferred to a series of 10ml volumetric flask and made upto mark with solvent (chloroform). Solutions were scanned in the range of 200-400 nm against blank. The absorption maximum was found to be at 242 nm against blank (fig no:2). The caliberation curve was plotted. The optical characteristics are summerized in (table no:2).

Preparation of sample solution:

The proposed method was applied to analyse commercially available Glibenclamide tablet. Ten tablets were weighed and powdered. The amount of tablet powder equivalent to 25 mg of Glibenclamide was weighed accurately and transferred 100 ml volumetric flask. Then 20 ml chloroform was added and kept for 15 min with frequent shaking and volume was made upto mark with chloroform. The solution was then filtered through Whatmann filter paper #41. These absorbance was measured against blank.

RESULT AND DISCUSSION

Precision

Assay of method precision (intra day precision) was evaluated by carrying out three independent assays of test samples of Glibenclamide. The inter mediate precision (inter day precision) of the method was also evaluated using two different analysts, systems and different days in the laboratory. The relative standard deviation (RSD) and assay values obtained by two analysts were 0/37,99.87 and 0.33,99.60 respectively. (Table no : 4)

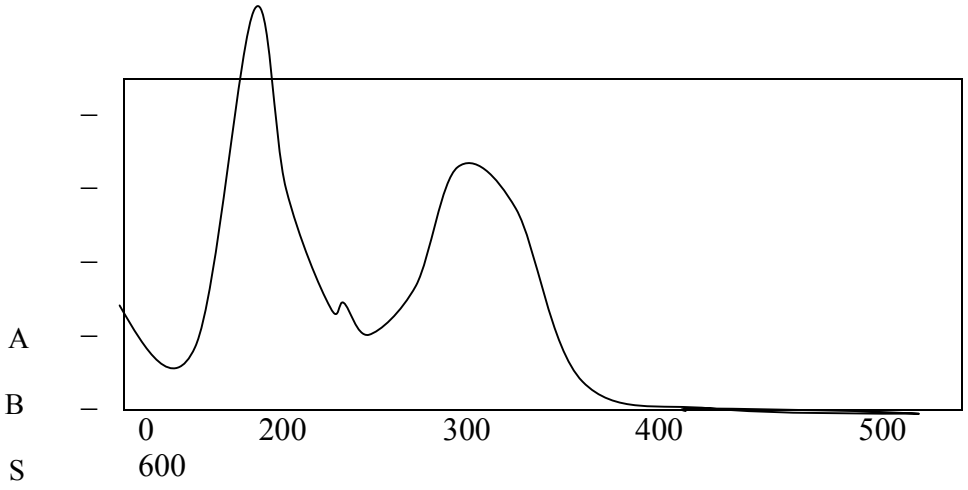

Figure no 2 – Determination of λ max of Glibenclamide by UV scanning

Table no 1-caliberation curve

Sr .no	Concentration (µg/ml)	Absorbance
1	0	0
2	5	0.066
3	10	0.207
4	15	0.302
5	20	0.432
6	25	0.535
7	30	0.598

Table no-2 validation parameters

Sl No	Parameter	Result
1	Absorption maxima (nm)	242
2	Linearity range (µg /ml)	5-30
3	Standard regression equation	Y=0.0211 x -0.0114
4	Correlation coefficient (r2)	0.9934
5	Molar absorptivity	17685.99
6	Accuracy (% recovery)	99.89
7	Precision	98.87 % (intra day precision) and 99.60 % (inter day precision)
8	Specificity	A 20 µg/ml solution of candidate drug in methanol at UV detection of 242 nm will show an absorbance value of 0.423
9	LOD (µg /ml)	0.578
10	LOQ (µg /ml)	1.926

Table no 3 Determination of accuracy by percentage recovery method

Ingredient	Tablet amount (µg/ml)	Level of addition (%)	Amount added (mg)	Drug found (mg/ml)	% recovery	Average % recovery
Glibenclamide	20	80	17.4	4.97	99.4	99.49
	20	100	20	4.98	99.6	
	20	120	22.6	4.96	99.2	

- Glibenclamide having brand name Glyburide - 5mg

Table no-4 Determination of Precision

Sample number	Assay ofglibenclamide	
	Analyst-I(intra-day precision)	Analyst-II(intra-day precision)
1	99.42	99.70
2	99.63	99.23
3	99.58	99.57
4	99.10	99.88
5	100.12	99.98
6	99.20	99.25
Mean	99.87	99.60
RSD	0.37	0.33

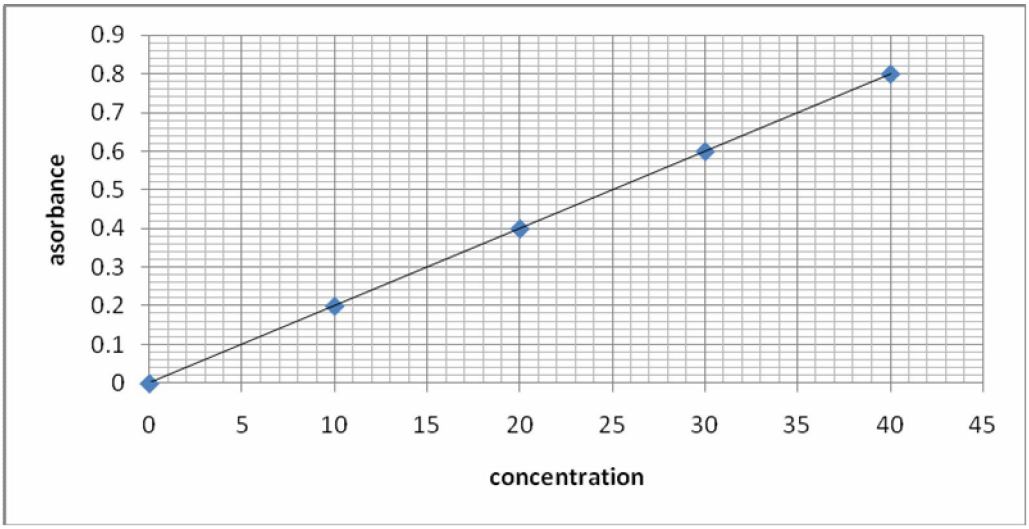

Figure no 3 - Determination of linearity of Glibenclamide by UV scanning

Accuracy (Recovery Test)

Accuracy of the method was studied by recovery experiments. The recovery experiments were performed by adding known amounts to tablet. The recovery was performed at three levels 80, 100 and 120 % of Glibenclamide standard concentration. The recovery samples were prepared in afore mentioned procedure. Three samples were prepared for each recovery level. The solutions were then analysed, and the percentage recoveries were calculated from the caliberation curve. The recovery values for Glibenclamide ranged from 99.97. (Table no:3)

Linearity:

The linearity of the response of the drug was verified at 5 to 40 µg/ml concentrations, but linearity was found to be between 5-30 µg/ml concentration. The caliberation graphs were obtained by plotting the absorbance versus the concentration data and were treated by linear regression analysis (Table no:2). The equation of the caliberation curve for Glibenclamide obtained y = 0.0211 × -0.0114, the caliberation curve was found to be linear in the afore mentioned concentrations (the correlations coefficient (r2) of determination was 0.9934).

Limit of detection (LOD) and limit of quantification (LOQ)

The LOD and LOQ of Glibenclamide were determined by using standard deviation of the response and slope approach as defined in international conference on Harmonization (ICH) guidelines . The LOD and LOQ was found to be as in Table no:2.

CONCLUSION

The developed method was found to be simple, sensitive, accurate, precise, reproducible and can be used for routine quality control analysis of Glibenclamide in bulk and pharmaceutical formulation.

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