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RESEARCH ARTICLE

FTIR SPECTROSCOPIC METHOD FOR QUANTITATIVE ANALYSIS OF GLICLAZIDE IN TABLETS

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ABSTRACT

A rapid FTIR spectroscopic method has been proposed for the estimation of Gliclazide in bulk drug and pharmaceutical dosage form. The method involves the measurement of the area of the infrared band corresponding to the amide stretching centered at 3317cm^{-1}. The excipients in the commercial tablet preparation did not interfere with the assay. The linearity range was found to be 4-24µg/ml. The technique is reliable and useful for quality control for monitoring the adulteration of pure drug. The proposed method is statistically validated and found to be useful for the routine determination of gliclazide in tablets.

Keywords: Gliclazide, FTIR, Tablets, Validation.

INTRODUCTION

Gliclazide(GCZ) is a specific type of an anti-diabetic drug most commonly used fortype2 diabetes mellitus.[1]Chemically it is 1-(1-azabicyclo(3,3,0) octyl)-3-p-tolylsulphonylurea[2]. Literature review revealed very few analytical methods includingRadioimmunoassay[3], Gas chromatography[4], HPLC[5,6] Evaporative Light Scattering Detection[7],LC-MS[8]and Mass spectroscopy[9] for quantification of GCZ in pharmaceutical dosage forms. In the present work, a rapid FTIR spectroscopic method[10,11] has been developed for the estimation of GCZ in bulk drug and pharmaceutical dosage form. To develop the quantitative analysis method, a standard solution of known concentration is prepared and spectra are collected from aliquots of the standard. Specified absorption band is identified and the peak area is calculated.

MATERIALS AND METHODS

Instrument

All spectral and absorbance measurements were made on FTIR-Model ABB MB 3000.

Standard solution of GCZ

A 1mg/ml stock solution of GCZ was prepared by dissolving 50mg of drug in 50ml of methanol.

Sample preparation

Twenty tablets were weighed. A quantity equivalent to 50mg of GCZ was weighed accurately, transferred to a beaker, dissolved in methanol, filtered through whatmann filter paper No.1 into a 50ml volumetric flask and made up to volume with methanol to get a concentration of 1mg/ml.

Method

The stock solution was diluted suitably with methanol to give a series of concentration ranging from 4-24µg/ml of GCZ. The IR spectrum was recorded for the various concentrations. The absorbance of the band due to amide stretching at 3317cm^{-1} was measured. The IR spectra for GCZ are shown in fig-1. The calibration curve of GCZ was obtained by plotting the peak area (Amide stretchingcentered at 3317cm^{-1}) versus concentration.

Sample analysis

Pharmaceutical formulation of GCZ was successfully analyzed by the proposed method. Appropriate aliquots were subjected to the above method and the amount of GCZ was determined.

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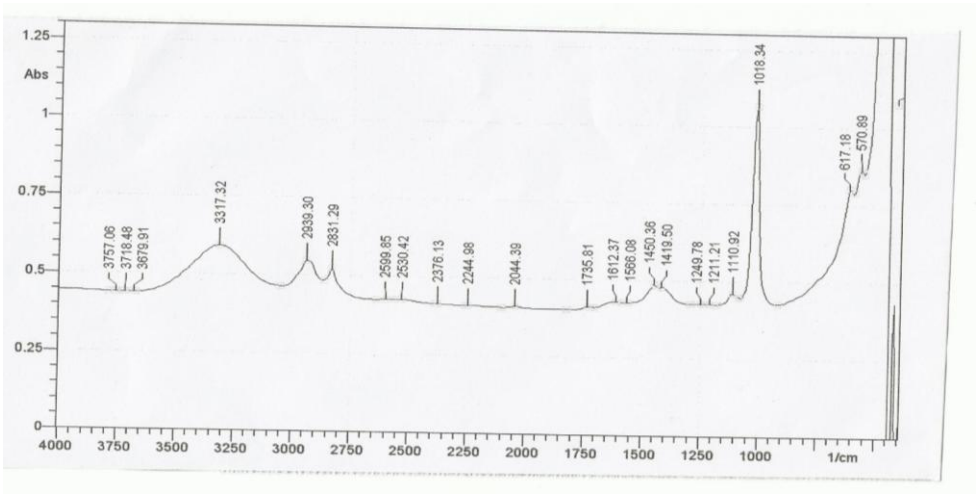

Fig 1: IR spectrum of GCZ

RESULTS AND DISCUSSION

The proposed method is statistically validated and found to be useful for the routine determination of GCZ in tablets. The regressions characteristics like slope (m), intercept(c), correlation coefficient(r), percent relative standard deviation (%RSD) and standard error (SE) were calculated and the results are summarized in Table-1. All validation parameters were found to be highly satisfactory. The results of sample analysis showed that the drug determined by the proposed method was in good agreement with the label claim proving the accuracy of the proposed method.

To study the accuracy and reproducibility of the proposed method, recovery experiments were carried out by adding a known amount of drug to pre-analyzed sample and the percentage recovery calculated.The results are furnished in Table-2. The results indicate that there is no interference of other ingredient present in the formulation.

Thus the proposed method is rapid, sensitive, accurate and reproducible and useful for the routine determination of GCZ in bulk drug and its pharmaceutical dosage form.

Table1: Statistical parameters

Parameters	Results
Linearity range(µg/ml)	4-24
Correlation coefficient (r)	0.9989
Standard deviation	0.1965
Standard error	0.0878
%RSD	0.4928
Regression equation y=mx+c	0.2825x+0.1793
Intercept	0.1793
Slope	0.2825
LOD (µg/ml)	2
LOQ(µg/ml)	4

Table2: Assay and recovery of GCZ in dosage form

Drug	Labelled amount(mg)	Amount present (mg)*	Percentage recovery*
Gliclazide	40	39.87	100.03

**Average of 6 determinations*

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