Asian Journal of Chemistry Vol. 18, No. 2 (2006), 1309–1312

High Pressure Liquid Chromatography Estimation of Glipizide in Pharmaceutical Dosage Forms

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A reverse phase high pressure liquid chromatographic method has been described for the estimation of glipizide in its pharmaceutical formulations using C-8 column. The mobile phase consisted of acetonitrile, methanol and buffer (7.0 mL of triethyl amine in 1000 mL of water, pH adjusted to 3.0 ± 0.1 with orthophosphoric acid) in the ratio of 35 : 50. The detection was carried out at 230 nm and the linearity was found to be in the range of 0.1 to 10 μg/mL. The method is simple, precise, specific, less time consuming and accurate for the estimation of glipizide in pharmaceutical dosage forms.

Key Words: HPLC estimation, Glipizide.

INTRODUCTION

Glipizide[1] chemically is N-[2-[[[cyclo hexyl amino] carbonyl] amino] sulphonyl] phenyl] ethyl]-5-methyl pyrazine carboxamide. It is an antidiabetic drug with minimal side effects. Several analytical methods have been reported for the estimation of glipizide in pharmaceutical dosage forms by colorimetry[2], UV spectrophotometry[3], GC-MS[4] and HPLC[5–12]. In the present study a sensitive, specific, precise and accurate HPLC method has been developed for the estimation of glipizide in pharmaceutical dosage forms.

EXPERIMENTAL

Glipizide was a gift sample from local pharmaceutical industry. The acetonitrile and methanol used were of HPLC grade (Qualigens), and triple distilled water was used. All other reagents (triethyl amine and orthophosphoric acid) used in the study were of AR quality (Qualigens).

A gradient high pressure liquid chromatograph (Shimadzu HPLC class VP series) with two LC-10 AT VP pumps, variable wavelength programmable UV-Visible detector SPD-10 A VP, SCL-10A VP system controller (Shimadzu) and C-8 column was used. The HPLC system was equipped with the software class VP series version 5.03 (Shimadzu).

Chromatographic Conditions

Acetonitrile, methanol and buffer (7 mL of triethyl amine in 1000 mL water, pH adjusted to 3.0 ± 0.1 with orthophosphoric acid) were filtered before use through 0.4 μm membrane filter. The flow rate of the mobile phase was maintained at 1

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mL/min in the ratio of 15 : 35 : 50. [acetonitrile : methanol : buffer [7 mL of triethyl amine in 1000 mL water, pH adjusted to 3.0 ± 0.1 with orthophosphoric acid)]. The detection was carried out by UV detector at 230 nm. The data were acquired, stored and analyzed with the software class VP series version 5.03 (Shimadzu).

Procedure

About 100 mg of glipizide was accurately weighed and dissolved in mobile phase so as to give a 1 mg/mL solution. Subsequent dilution of this solution was made to obtain 100 μg/mL. The standard solution prepared above was injected five times into the column at a flow rate of 1 mL/min. The peak area for each of the drug concentrations was calculated.

Glipizide solution containing 20 μg/mL and 40 μg/mL were subjected to the proposed HPLC analysis for finding out the intra- and inter-day variations. The recovery studies were carried out by adding a known amount of glipizide to the pre-analyzed samples and subjecting them to proposed HPLC method.

Estimation of Glipizide in Pharmaceutical Dosage Forms

Twenty tablets were weighed and powdered. An accurately weighed portion of the powder equivalent to 100 mg of glipizide was transferred to a 100 mL volumetric flask containing about 50 mL of mobile phase. The contents of the flask were sonicated to dissolve glipizide, made up to volume with mobile phase and the resulting mixture was filtered through 0.45 μ filter. 1 mL of this solution was added to a 100 mL volumetric flask and made up to volume with mobile phase. 20 mL of this solution was injected five times into the column. The mean value of the peak area was calculated and the drug content in each tablet was quantified using the regression equation. The same procedure was followed for the estimation of glipizide in six different brands of tablet dosage forms.

RESULTS AND DISCUSSION

The present study was carried out to develop a specific, sensitive, precise and accurate HPLC method for the analysis of glipizide in pharmaceutrical dosage forms. A typical chromatogram is shown in Fig. 1. The retention time for glipizide was 15.748 min. Each of the samples was injected five times and the same retention time was observed in all cases. The peak areas for different concentrations are shown in Table-1.

TABLE-1
STANDARD GRAPH FOR THE ESTIMATION OF GLIPIZIDE

Concentration of Glipizide (μg)	Peak area
20	291614
40	583229
60	874842
80	1166456
100	1458073

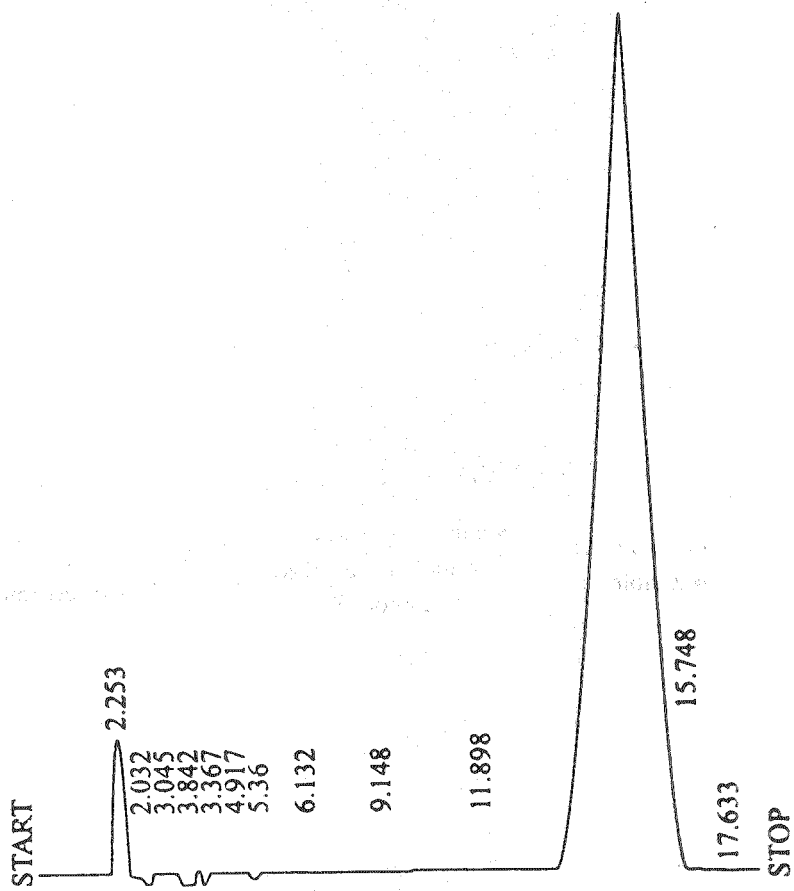

Fig. 1. Chromatogram for Glipizide

The peak areas for glipizide were reproducible as indicated by a low coefficient of variation (2.55). A good linear relationship (r = 0.9998) was observed between the concentrations of glipizide and the respective peak areas. When glipizide solutions containing 20 µg/mL and 40 µg/mL were analyzed by the proposed HPLC method for finding out intra- and inter-day variations, a low coefficient of variation was observed (Table-2). This shows that the present HPLC method is highly precise. The amounts of glipizide from the pre-analyzed samples containing known amounts of the drug are shown in Table-3. About 99.97% of glipizide could be recovered from the pre-analyzed samples indicating a high accuracy of the proposed HPLC method.

TABLE-2
PRECISION OF THE PROPOSED HPLC METHOD

Glipizide concentration (µg/mL)	Concentration of glipizide (µg/mL) found on			
	Intra-day		Inter-day	
	Mean (n = 5)	% CV	Mean (n = 5)	% CV
20	20.21	1.89	20.14	2.50
40	40.12	1.25	40.08	1.88

TABLE-3
RECOVERY OF GLIPIZIDE

Amount of drug added (μg)	Mean (± s.d.) amount (μg) found (n = 5)	Mean (± s.d.) % of recovery (n = 5)
20	20.03 ± 0.05	100.15 ± 0.30
40	39.90 ± 0.09	99.95 ± 0.40

The drug content in the tablet was quantified using the proposed analytical method. The mean amount of glipizide in six different brands of tablet dosage forms is shown in Table-4.

TABLE-4
ASSAY OF GLIPIZIDE IN TABLET DOSAGE FORMS

Brand	Labelled amount (mg/tablet)	Mean (± s.d.) amount (mg) found by the proposed method (n = 5)	Mean (± s.d.) % labelled amount (n = 5)
I	2.5	2.49 ± 0.02	99.60 ± 0.05
II	2.5	2.51 ± 0.01	100.10 ± 0.01
III	5.0	4.99 ± 0.04	99.80 ± 0.06
IV	5.0	4.98 ± 0.06	98.60 ± 0.05
V	10.0	9.99 ± 0.13	99.99 ± 0.07

The absence of additional peaks indicates no interference of the excipients used in the tablets. The tablets were found to contain 99.98 to 100.1% of the labllled amount. The low % CV indicates the reproducibility of the assay of glipizide in the tablet dosage form. The proposed HPLC method was found to be simple, precise, highly accurate, specific and less time consuming. Hence it is a preferred method over the reported methods for the estimation of glipizide in pharmaceutical dosage forms.

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(*Reccived*: 25 June 2005; *Accpeted*: 22 December 2005) AJC- 4569