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HPLC Method for the Estimation of Albendazole in Pharmaceutical Dosage Forms

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A reverse phase high pressure liquid chromatographic method (HPLC) has been described for the estimation of albendazole in its tablet dosage form using RP C-18 column. The mobile phase consisted of acetonitrile and water (containing 0.4% triethylamine adjusted to pH 3.6 with 5% orthophosphoric acid) in the ratio of 46 : 54. Mebendazole was used as internal standard. The detection was carried out at 254 nm and the linearity was found to be in the range of 0.1 to 40 μg/mL. The method is simple, precise, specific, less time-consuming and accurate for the estimation of albendazole in tablet dosage forms.

Key words: HPLC, estimation, albendazole, pharmaceutical.

INTRODUCTION

Albendazole, chemically is methyl-5-propylthio-1H-benzimidazol-2-yl-carbamate. Albendazole is active against infections with gastrointestinal nematodes including mixed infections of ascaris, trichuria and hookworms[1]. Several analytical methods have been reported for the estimation of albendazole in pharmaceutical dosage forms by colorimetry[2], UV spectrophotometry[3, 4] and non-aqueous titrations[5,6]. So far no method has been reported for the estimation of albendazole in pharmaceutical dosage forms. In the present study a sensitive, specific, precise and accurate HPLC method has been developed for the estimation of albendazole in pharmaceutical dosage forms, *i.e.*, tablets.

EXPERIMENTAL

Albendazole was a gift sample from M/s Indechemie Laboratories Limited, India and mebendazole was a gift sample from M/s CIPLA Ltd., Bangalore, India. The acetonitrile used was of HPLC grade (Qualigens), and triple distilled water (TD water) was used. All other reagents (glacial acetic acid, orthophosphoric acid and triethylamine) used in the study were of AR quality (Qualigens).

A gradient high pressure liquid chromatograph (Shimadzu HPLC Class VP series) with two LC-10AT VP pumps, variable wavelength programmable UV/VIS detector SPD-10A VP, CTO-10AS VP column oven (Shimadzu), SCL-10A VP

system controller (Shimadzu) and RP C-18 column (250 mm × 4.6 mm I.D.; particle size 5 μm; YMC, Inc., Wilmington, NC 28403, U.S.A.) was used. The HPLC system was equipped with the software "Class-VP series version 5.03 (Shimadzu).

Chromatographic conditions: Both acetonitrile and triple distilled water (consisting of 0.4% triethylamine and pH adjusted to 3.6 with 5% orthophosphoric acid) were filtered before use through 0.4 μm membrane filter. The flow rate of the mobile phase was maintained at 1.2 mL/min in the ratio of 46 : 54 (acetonitrile : water consisting of 0.4% triethylamine and pH adjusted to 3.6 with 5% orthophosphoric acid). The column temperature was maintained at 30°C and the detection was carried out by UV detector at 254 nm. The data were acquired, stored and analyzed with the software Class-VP series version 5.03 (Shimadzu).

Procedure: About 100 mg of albendazole was accurately weighed and dissolved in glacial acetic acid so as to give a 1 mg/mL solution. Subsequent dilutions of this solution were made after addition of mebendazole (20 μg/mL) as an internal standard (IS) to get concentrations of 0.1 to 40 μg/mL of albendazole and 2 μg/mL of internal standard in each dilution. The standard solutions prepared as above were injected five times into the column at a flow rate of 1.2 mL/min. The ratio of drug peak area to that of internal standard for each of the drug concentration was calculated. The regression of the drug concentration over the ratio of drug peak area to that of internal standard was obtained. This regression equation was used to estimate the amount of albendazole in pharmaceutical dosage forms.

Albendazole solutions containing 20 μg/mL and 40 μg/mL were subjected to the proposed HPLC analysis for finding out the intra- and interday variations. The recovery studies were carried out by adding known amount of albendazole to the preanalysed samples, and subjecting them to the proposed HPLC method.

Estimation of albendazole in tablet dosage forms: Twenty tablets were weighed and powdered. An accurately weighed portion of the powder equivalent to 100 mg of albendazole was transferred to a 100 mL volumetric flask containing about 50 mL of glacial acetic acid. The contents of the flask were sonicated to dissolve albendazole, made up to volume with glacial acetic acid and the resulting mixture was filtered through a 0.45μ filter. One millilitre of this solution was added to a 100 mL volumetric flask containing a solution equivalent to 200 μg of internal standard and were made up to volume with mobile phase. This solution (20 μL) was injected five times into the column. The mean values of peak area ratio of drug to internal standard of five such determinations were calculated and the drug content in the tablet was quantified using the regression equation obtained above. The same procedure was followed for the estimation of albendazole in three 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 albendazole in pharmaceutical tablet dosage forms. A typical chromatogram is shown in Fig. 1. The column pressure varied from 175–185 kgf/cm^2. The retention times for albendazole and internal

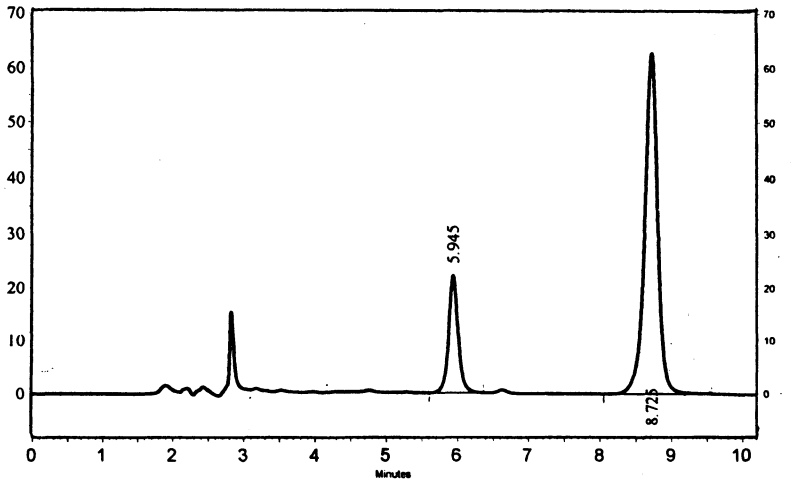

Fig. 1. Model chromatogram for albendazole

standard (mebendazole) were 8.725 min and 5.945 min respectively. Each of the samples was injected 5 times and the same retention times were observed in all cases. The ratio of peak area of albendazole to peak area of internal standard for different concentrations set up as above were calculated, and the average values for 5 such determinations are shown in Table-1. The peak areas of both the drug and internal standard were reproducible as indicated by low coefficient of variation (3.49%). A good linear relationship (r = 0.9999) was observed between

TABLE 1
CALIBRATION OF THE HPLC METHOD FOR THE ESTIMATION OF ALBENDAZOLE

Concentration of albendazole (μg/mL)	Mean (± s.d.) peak-area ratio ($n = 5$)	CV (%)
0	0	0
0.1	0.024	1.98
0.2	0.048	1.01
0.5	0.121	1.25
1	0.239	2.98
2	0.393	1.96
4	0.771	1.88
6	1.219	1.57
8	1.663	3.04
10	2.001	3.49
20	3.989	1.78
40	7.977	1.14

Regression equation (from 0.1 to 40 μg/mL)
Y = 0.0134 + 0.1998X (r = 0.9999)

the concentration of albendazole and the respective ratio of peak areas. The calibration graph was found to be Y = 0.0134 + 0.19918X (where Y = ratio of peak area of drug to that of internal standard, X = concentration of albendazole) in the range of 0.1 to 40 μg/mL. When albendazole solutions containing 20 μg/mL and 40 μg/mL were anayszed by the proposed HPLC method for finding out intra- and interday variations, a low coefficient of variation was observed (Table-2). This shows that the present HPLC method is highly precise. The amounts of albendazole from the preanalysed samples containing known amounts of the drug are shown in Table-3. About 99.97% of albendazole could be recovered from the preanalysed samples indicating the high accuracy of the proposed HPLC method.

TABLE-2
PRECISION OF THE PROPOSED HPLC METHOD

Albendazole concentration (μg/mL)	Concentration of albendazole (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	40.09	1.80

TABLE -3
RECOVERY OF ALBENDAZOLE

Amount of drug added (μg)	Mean (± s.d.) amount (μg) found (n = 5)	Mean (± s.d.) % of recovery (n = 5)
20	20.03 ± 0.06	100.15 ± 0.3
40	39.99 ± 0.08	99.97 ± 0.2

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

TABLE-4
ASSAY OF DIFFERENT BATCHES OF ALBENDAZOLE TABLET DOSAGE FORMS

Brand	Labelled amount of drug (mg)	Mean (± s.d.) amount (mg) found by the proposed method (n = 5)	Mean (± s.d.) % labelled amount (n = 5)
I	400	399.97 ± 0.01	99.98 ± 0.05
II	400	399.89 ± 0.31	99.94 ± 0.15
III	400	400.02 ± 0.02	100.10 ± 0.01

The absence of additional peaks indicates no interference of the excipients used in the tablet. The tablets were found to contain 99.98 to 100.1% of the labelled amount. The low % CV indicates the reproducibility of the assay of albendazole 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[2-6] for the estimation of albendazole in tablet dosage forms.

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