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Simple and Precise UV Spectrophotometric Method Development for Estimation of Albendazole for Dissolution Study

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ABSTRACT
Albendazole is a class II drug in biopharmaceutical classification system, so its dissolution study is very difficult because of its low solubility and difficulty during estimation of drug in bulk. The present study deals with UV spectrophotometric method development and validation for estimation of albendazole in bulk form. Albendazole is a benzimidazole derivative with an oral broad spectrum of activity against human and animal helminthes parasites. The drug obeyed the Beer's law and showed good correlation. It showed absorption maxima at 229nm in 0.1 N HCL with 0.05% sodium lauryl sulphate (SLS). The linearity was observed between 4-20µg/ml. The method was applied for the analysis of the drug in the pure, tablet and suspension forms. The slope and intercept of the equation of the regression line are 0.009 and 0.017 respectively. Correlation coefficient was found to be 0.9996. The results of analysis were validated by recovery studies. The recovery was more than 97%. The method was found to be simple, reliable, rapid, precise, specific and reproducible and can be applied for routine analysis of albendazole in different dosage form and dissolution studies.

Keywords: Albendazole, UV-Vis Spectrophotometer, Recovery, Validation.

INTRODUCTION

methyl -[5-thio) -1-*H*-benzimidazol-2yl] carbamate is a benzimidazole derivative with an oral broad spectrum of activity against human and animal helminthes parasites. [1] Albendazole is the drug of choice and is approved for treatment of ascariasis, pinworm and hookworm infections etc. [2-4] *Ascaris lumbricoides* is an intestinal parasite cosmopolitan in distribution with an overall infestation incidence of a quarter of the total population. [4] Patients in the pediatric age group with moderate to severe intestinal ascariasis were treated with various anthelmintic drugs like albendazole, pyrantel pamoate and levamisole. Comparison of the percentage cure rate was made and albendazole was found to be the most effective in 92.26% of patients followed by pyrantel pamoate and levamisole in 80.82% and 64.70% of the patients respectively. [5] Albendazole have bicyclic ring structure in which a benzene ring is fused to the 4- and 5- positions of an imidazole ring and metabolite in the liver to the albendazole sulfoxide which is active part for the treatment. Chemical structure of albendazole is given in Figure 1. Smith Kline & French Animal Health was

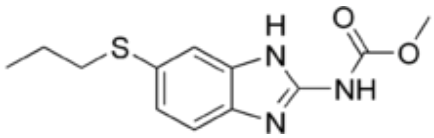

Fig. 1: Structure of Albendazole.

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working on albendazole, which was first marketed as Valbazen, an animal anthelminth, in the UK in November of 1977. It was eventually approved for human use and marketing in 1987. [6] Several techniques such as HPLC, HPLC with fluorescence detention, LC-MS, capillary electrophoresis, spectrophotometric, titrimetric and flow injection analysis for the estimation of albendazole alone and with its major metabolites had been reported. This methods used for the estimation are bit time consuming, tedious and expensive. The aim of the present study is to develop a new simple, rapid, reliable and precise UV spectrophotometric method of albendazole for routine analysis from bulk, pharmaceutical formulation and *in-vitro* dissolution studies. The developed methods were validated as per ICH guidelines and USP requirements. [7-8] Suitable statistical tests were performed on validation data. [9-10]

MATERIALS AND METHODS

Instrument used

UV visible (Lab India-3200) double beam spectrophotometer with matched pair quartz cells corresponding to 1 cm path length and spectral bandwidth of 1 nm, Vortex and Analytical balance.

Materials

Albendazole was obtained as a gift sample by Unicure Pvt.ltd (Noida. U.P) and 0.1 N HCl with 0.05% SLS (Torrent Pharma) was used as a solvent. Glass triple distilled water was used throughout the experiment.

Methods

Stock Solution

Standard stock was prepared by dissolving 10 mg of Albendazole in 10 ml of 0.1 N HCl with 0.05% w/v SLS solution to get concentration of 1000µg/ml after filtration.

Method Development

Aliquots of stock solution were further diluted with 0.1 N HCl with 0.05% SLS solution to get working solution of 4, 8, 12, 16, 20µg/ml and the working standards were scanned through UV spectroscopy which shows the maximum absorbance at 229 at nm (Figure 2).

Procedure for Calibration Curve

Aliquots of stock solution were further diluted with 0.1 N HCl with 0.05% SLS solution to get working solution of 4, 8, 12, 16, 20µg/ml. Subsequently, the prepared standard was measured after standing for 5 min at 229nm. Statistical parameters like the slope, intercept, coefficient of correlation, standard deviation, Relative standard deviation, and error was determined.

Validation method

The precision of the method for the drug was found by measuring the absorbance of 6 separate samples containing known amount of drug. The method was validated by studying the following parameters as ICH guidelines (ICH guidelines., 1995) for method validation. The slope, Intercept, correlation coefficient and optical characteristic are summarized in Table 1.

Precision

Inter-day precision: This was done by analyzing formulation for six days subsequently. The %RSD values are shown in Table 3

Intra-day Precision: This was done by analyzing formulation in same day for six times. The %RSD and data are shown in Table 3.

Recovery studies: Recovery studies were performed to judge the accuracy of the method. Recovery studies were carried out by adding a known quantity of pure drug to the pre-analyzed formulation and the proposed method was followed.

From the amount of drug found, percentage recovery was calculated. Recovery study was carried out at three levels 80%, 100% and 120%

$$\% \, Recovery = \frac{Mean\ Observed\ Concentration}{Theoretical\ Concentration} \, x\ 100$$

Limit of Detection (LOD) and Limit of Quantification (LOQ): The LOD and LOQ of albendazole were determined by using standard deviation of the response and slope approach as defined in International Conference on Harmonization (ICH) guidelines 7. The LOD and LOQ were found to be as in Table 1. Limit of detection (LOD) and limit of quantification (LOQ) were calculated. [11-12]

Table 1: Optical Parameters

S. No	Parameters	Results
1	Absorption maxima(nm)	229 nm
2	Linearity range (µg/ml)	4-20µg/ml
3	Standard Regression equation	Y=0.009x+0.017
4	Correlation coefficient	0.9996
5	Limit of Detection (µg/ml)	0.4337
6	Limit of Quantification (µg/ml)	1.3

Table 2: Recovery Study

Drug	Drug Amount (µg/ml)	Level Addition (%)	Amount Added (µg/ml)	Drug Found (µg/ml)	% Recovery	Average % Recovery
Albendazole	8	80	6.4	14.1376	98.5	97.97
	8	100	8	15.7035	97.96	
	8	120	9.6	17.1290	97.47	

Table 3: Intraday and Interday study

S. No	Concentration (µg/ml)	Intraday	%RSD	Interday	%RSD
1.	12	0.126033 ± 0.001002	0.795	0.1277 ± 0.001609	0.20
2.	20	0.186267 ± 0.000907	0.487	0.1934 ± 0.001919	0.992

RESULTS

The standard solution of albendazole was prepared and scanned for UV spectrum which had shown absorption maxima at 229nm as shown in Fig. 2. The Beer's law was verified from the calibration curve by plotting a graph of concentration versus absorbance. The plot is shown in Fig. 2. Regression analysis showed very good correlation. The calibration plot revealed zero intercept which is clear by the regression analysis equation y = m x + c. (Where y is absorbance, m is the slope and x is the concentration of albendazole in mg/ml) as obtained by

the least square method. The results of the optical parameters thus obtained are depicted in Table 1. The results of analysis for assay and recovery studies were studied and are shown in Table 2. Results for intraday and interday precision studies are illustrated in Table 3. No significant variations were observed on interday and intraday analysis.

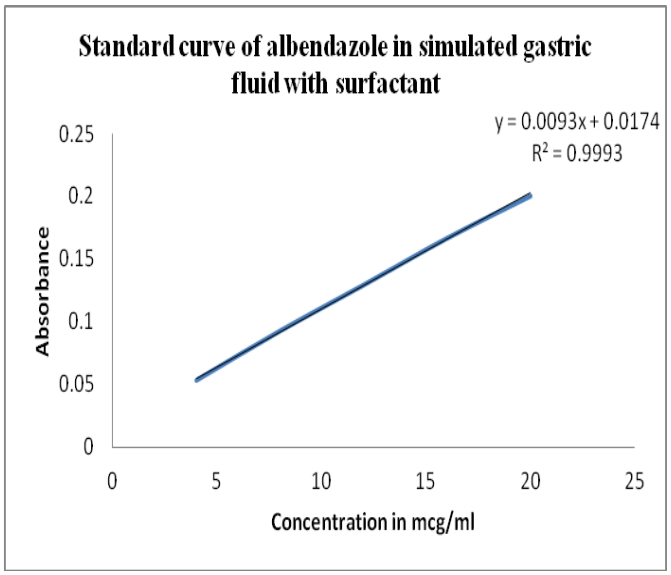

Fig. 2: Standard curve of albendazole in simulated gastric fluid with 0.05% w/v SLS at 229nm.

DISCUSSION

The spectrum of albendazole in 0.1 N HCl with 0.05% SLS showed the absorption maxima at 229nm. Effect of dilution was not observed on the maxima. The statistical analysis of data obtained for the calibration curve of albendazole in pure solution indicated a high level of precision for the proposed method, as evidenced by low value of coefficient of variation. The coefficient of correlation was highly significant. The linearity range was observed between 4 - 20µg/ml. The plot clearly showed a straight line passing through origin (y=0.009x+0.017). The limit of detection (LOD) and limit of quantification (LOQ) were found to be 0.4337µg/ml and 1.3µg/ml respectively. The assay method was validated by using recovery studies and carried out at their different level 80%, 100% and 120%. The Excellent percentage recovery value indicates that there is no interference from the excipients present in formulation, which proves the accuracy of the method. Hence this method is useful to study dissolution of drug in different formulation.

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