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Original Research Article

DEVELOPMENT AND VALIDATION OF SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF ALBENDAZOLE DISSOLUTION STUDY

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Abstract: In the biopharmaceutical classification system, albendazole is a class II drug, so its dissolutio n analysis is very difficult due to its low solubility and difficulty in estimating product in bulk.
The present study deals with the design and validation of UV spectrophotometric methods to estimate albendazole in bulk form.Albendazole is a benzimidazole derivative that has an oral wide range of acti vity against parasites of human and animal helminths.The drug was obeying the law of the Beer and sh owing good correlation.It showed a peak absorption of sodium lauryl sulphate (SLS) at 229 nm in 0.1 N HCl.Linearity of 420µg / ml was observed.The method was used in the pure, tablet and suspension forms to analyze the drug. The regression line equation slope and intercept is 0.009 and 0.017 respecti vely. It was found that the coefficient of correlation was 0.9996.Restoration trials have confirmed the f indings of the study. The restoration has reached 97%. The method has been found to be simple, effect ive, fast, precise, detailed and reproducible and can be used in different dosage type and dissolution st udies for routine analysis of albendazole.

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

Introduction: Albendazole (ABZ) carbamate m ethyl-[5-(propyl thio)-1-H-benzimidazol-2yl] is a benzimidazole derivative with an oral wide range of human and animal helminth paras ite involvement.[1] Albendazole is the drug of choice and is approved to treat ascariasis, pinwo rm, hookworm, etc.[2,4]Ascaris lumbricoides is a cosmopolitan intestinal parasite in distribution with a total frequency of infestation of one quar ter of the total population.[4] Patients in the pe diatric age group are diagnosed with various ant helmintic drugs such as albendazole, pyrantel pa moate and levamisole with moderate to severe i ntestinal ascariasis. The percentage of treatment was compared and 90 percent of albendazole

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patients were found to be the most active, followed by pyrantel pamoate and levamisole in 85.82 percent and 60.70 percent respectively. [5].Albendazole has a bicyclic ring structure in which a benzene ring is fused to the 4- and 5- positions of an imidazole ring and the albendazole sulfoxide metabolite in the liver that is an important part of the treat ment.

Materials and Methods

Instrument used: UV visible (Shimadzu 1800) spectrophotometer with paired 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 Orex Pharma pvt Ltd from **India** and 0.1 N HCl with 0.05% SLS (Torrent Pharma) was used as a solvent. Glass triple distilled water was used during the whole 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 100µg/ml.

Method Development: The stock solution was further diluted with 0.1 N HCl with 0.05 per cent SLS solution in order to obtain 4, 8, 12, 16, 20µg / ml and dilutions scanned by UV spectroscopy showing the maximum absorbance at 229 nm.

Procedure for Calibration Curve: Dilutions of stock solution were further diluted with 0.1 N HCl with 0.05 percent SLS solution t o obtain 4, 8, 12, 16, 20µg / ml solution. Consequently, 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 resolute.

Validation method

Precision: Inter-day precision: This was done by analyzing formulation for 5 days subsequently. The %RSD values are shown in Table 3.

Intra-day Precision: This was performed by analyzing formulation in same day for six different times. The %RSD and data are shown in Table 2.

Recovery studies: Recovery studies were performed to analyse the accuracy of the method. The recovery studies were operated by incorporating a known quantity of pure drug to the pre-analyzed formulation and the suggested method was followed. From the amount of drug found after performance, percentage recovery was calculated. Recovery study was performed out at three different levels 80%, 100% and 120%.

% Recovery = Mean Observed Concentration/Theoretical concentration*100

Limit of Detection (LOD) and Limit of Quantification (LOQ) - The albendazole LOD and LOQ were found using standard response deviation and slope approach, as defined in guidelines 7 of the International Conference on Harmonization (ICH). [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	coefficient	0.9996
5	Limit of Detection (µg/ml)	0.4337
6	Limit of Quantification(µg/ml)	1.3

Table 2: Intraday and Interday study

S. No	Concentration (µg/ml)	Intraday	%RSD	Interday	%RSD
1	12	0.146033 ± 0.001002	0.895	0.1277 ± 0.001609	0.30
2	20	0.26267 ± 0.000907	0.487	0.1934 ± 0.001919	0.992

Table3: 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	97.97
	8	100	8	15.7035	97.96	
	8	120	9.6	17.1290	97.47	

Result -

Albendazole's standard solution was prepared a nd tested for UV spectrum which showed a pea k absorption at 229 nm .The calibration plot sho wed zero intercept, which is obvious from the e quation y = m x + c of the regression analysis. (I f y is consumed, m is the slope and x is the albe ndazole concentration in mg / ml) as the least sq uare approach is used.Table 1 shows the effects of the optical parameters thus obtained.The resu lts of the assay and recovery studies analysis have been studied and are presented in Table 3. Table 2 shows the outcomes of intraday and inte rday precision tests.On interday and intraday an alysis, no significant variations were observed.

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