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Development and Validation of UV Spectroscopic Method for Estimation of Albendazole In Tablet Dosage Form

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ABSTRACT

Albendazole (ALB), chemically known as methyl [5-(propylthio)-1H-benzimidazol-2-yl] carbamate is widely used as an anthelmintic having a wide spectrum of activity. Numerous numbers of analytical methods are there for the simultaneous estimation of bulk and in formulation, such as spectrophotometry and liquid chromatography. As the UV spectrophotometric method is rapid, simple, accurate and economical, the method has been developed for the assay of the albendazole in pharmaceutical formulation. The wavelengths selected for the method were at 291 nm. The results of analysis have been validated by recovery studies as per ICH guidelines. The developed method was rapid, simple, accurate and economical and it can be used for routine quality control analysis. It showed absorption maxima at 291 nm in analytical grade DMF. The drug obeyed the Beer's law and showed good correlation of concentration with absorption which reflect in linearity.

Keywords: Albendazole, UV spectrophotometer, Method Development, Method Validation, ICH Guidelines.

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INTRODUCTION

Albendazole is a broad spectrum anthelmintic. It is used for the treatment of Threadworm, Hookworm and Tape- worm [1-2]. Albendazole (ALB) (Figure 1), chemically known as methyl [5-(propylthio)-1H-benzimidazol-2-yl] carbamate [3,4] is widely used as an anthelmintic having a wide spectrum of activity. Albendazole binds to the colchicines -sensitive site of β-tubulin inhibiting their polymerization into microtubules. The decrease in microtubules in the intestinal cells of the parasites decreases their absorptive function, especially the uptake of glucose by the adult and larval forms of the parasites, and also depletes glycogen storage. Insufficient glucose results in insufficient energy for the production of adenosine triphosphate (ATP) and the parasites eventually dies[4].

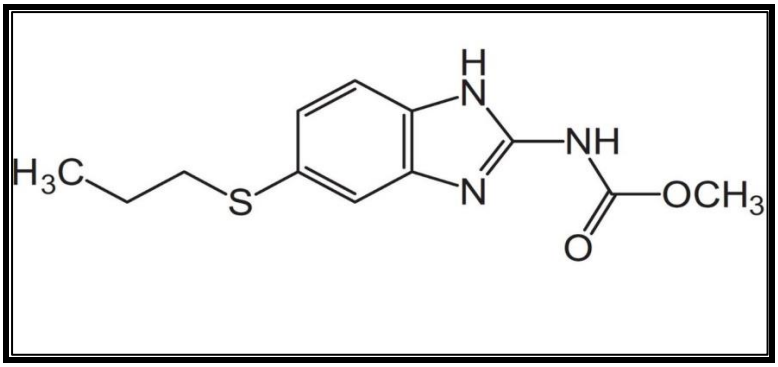

Figure 1: Chemical Structure of Albendazole

Several techniques such as spectrophotometric [6-7], titrimetric, Dissolution [8] 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 developed methods were validated as per ICH guidelines and USP requirements [3]. Suitable statistical tests were performed on validation data [4-5].

From literature review it's found that lot of work was done on UV [5, 6] method development for Albendazole in combination with other drugs. But very few methods were reported on Albendazole tablets for UV method development.

The aim of the present work is to develop and validate an economical, accurate, precise and reproducible UV Spectrophotometric method for the determination of Albendazole as in solid dosage form from different sample from Indian pharmaceutical tablet.

MATERIALS AND METHOD

Instruments

Agilent technologies Carry 60 UV-visible spectrophotometer with matched pair quartz cells

corresponding to 1 cm path length and spectral bandwidth of 1 nm, Bath Sonicator and Citizen weighing balance.

Materials

Albendazole was obtained as a gift sample. Albendazole Tablets were procured from local pharmacy. DMF used was of analytical grade. Glass double distilled water was used throughout the experiment. Doubly distilled water was used to prepare all solutions. Freshly prepared solutions were employed.

METHOD DEVELOPMENT

Determination of ƛ max [10, 12]:

100 mg Weighed amount of Albendazole was dissolved into DMF to obtain a 10 µg/ml solution. This solution was subjected to scanning between 200-400 nm and absorption maximum was determined [6-7].

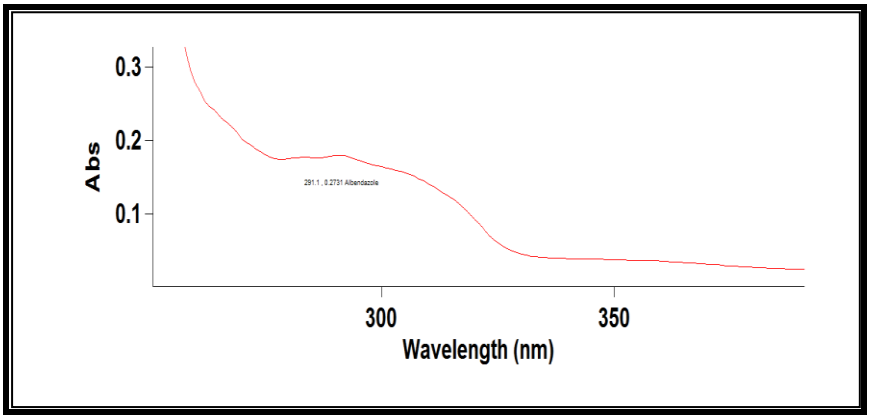

Figure 2: Calibration Curve

Working Concentration:-

Standard Stock Solution:

Standard stock was prepared by dissolving 100 mg of Albendazole in 100 ml of DMF to get concentration of 1000 µg/ml.

Standard Solution:

Pipette out 1 ml from standard stock solution and diluted up to 100 ml with DMF to get concentration of 10 µg/ml.

Procedure for UV Reading:-

Blank:

Fill the cuvette with **DMF**. Wipe it with filter paper properly then placed inside the chamber. Note down the reading.

Standard:

Fill the cuvette with **Standard** solution. Wipe it with filter paper properly then placed inside the chamber. Note down the reading.

Sample: Fill the cuvette with **Sample** solution. Wipe it with filter paper properly then placed inside the chamber. Note down the reading.

Procedure for Sample preparations:-

For analysis of commercial formulations; twenty tablets were taken and powdered. The powder equivalent to 100 mg of Albendazole was accurately weighed or measured and transferred to 100 ml volumetric flask and dissolved in 60 ml DMF, the solution was sonicated for 20 min. The resulting solution was further diluted to 100 ml with DMF and filtered through whatman filter paper no. 41. Then 1 ml of the above solution was pipette out into 100 ml volumetric flask and made up to the mark with DMF. The absorbance was measured at 291 nm. The amount of the drug in a sample was calculated from the calibration curve. The results are reported.

Table 1: Absorbance of Dosage Form

Mankind Phrama LTD (Bandy 400 mg)		
Sr. No.	**Sample**	**Absorbance**
1	Blank	0.0001
2	Standard	0.7654
3	Sample	0.7476

Table 2: Assay Results

Type	Company	M.D.	E.D.	Batch No.	Average weight (g)	Assay (%)
1	Mankind Pharma LTD (400mg) Bandy	07/2017	04/2020	BVS 0245	0.5027	97.7

Method Validation [5, 14, 15,16]

Linearity:-

The linearity of the proposed assay was studied in the concentration range 5 - 25 ppm at 291 nm. The calibration data showed a linear relationship between concentrations. The value of regression equation, regression coefficient and correlation coefficient was found 0.999.

Table 3: Linearity Results

Sr. No.	Sample solution	Absorbance
1	5 PPM	0.3797
2	10 PPM	0.7458
3	15 PPM	1.1521
4	20 PPM	1.5162
5	25 PPM	1.8953
Correlation Coefficient		**0.999**

Accuracy:-

To ensure the accuracy of the method, recovery study was performed by preparing 3 sample solutions of 80, 100 and 120 % of working concentration and adding a known amount of active drug to each sample solution and dissolved in 100 ml of volumetric flask with water and measuring the absorbance at 291 nm.

The results are reported.

Table 4: Accuracy Results

Spectrophotometric Method Accuracy (%)	Quantity weighed mg	Quantity found mg	Recovery (98-102 %)
80	0.8	0.79	98.7
100	1	1.01	101
120	1.2	1.19	99.16

Precision:

The precision were determined for five sample solution and presented as the % RSD.

Table 5: Precision Results

Sr. No.	Sample solution	Absorbance
1	Sample solution-1	0.7546
2	Sample solution-2	0.7521
3	Sample solution-3	0.7547
4	Sample solution-4	0.7589
5	Sample solution-5	0.7584
Mean		**0.7557**
SD		**0.0029**
% RSD		**0.3783**

Ruggedness:

Ruggedness is a measure of the reproducibility of a test result under normal, expected operating condition from instrument to instrument and from analyst to analyst.

Table 6: Results for Ruggedness Studies

Sr. No.	Analyst	Results	Mean	% Assay	% RSD
1	Analyst 1	0.7421 0.7584	0.7503	98.02	0.1729
2	Analyst 2	0.7564 0.7478	0.7521	98.26	

RESULTS AND DISCUSSION

Identification:-

Solubility of Albendazole:-

Solubility test was passed as per criteria.

Table 7: Albendazole Solubility Results

Sr. no.	Title	Result
1	DMF	Soluble
2	Methanol	Slightly soluble
3	Water	Practically insoluble

Melting point of Albendazole:-

209 °C (Uncorrected)

Results for linearity for Assay method of Albendazole -

The correlation coefficient value was found to be (R^2) **0.999** and it's within acceptance criteria represented in Table - 3.

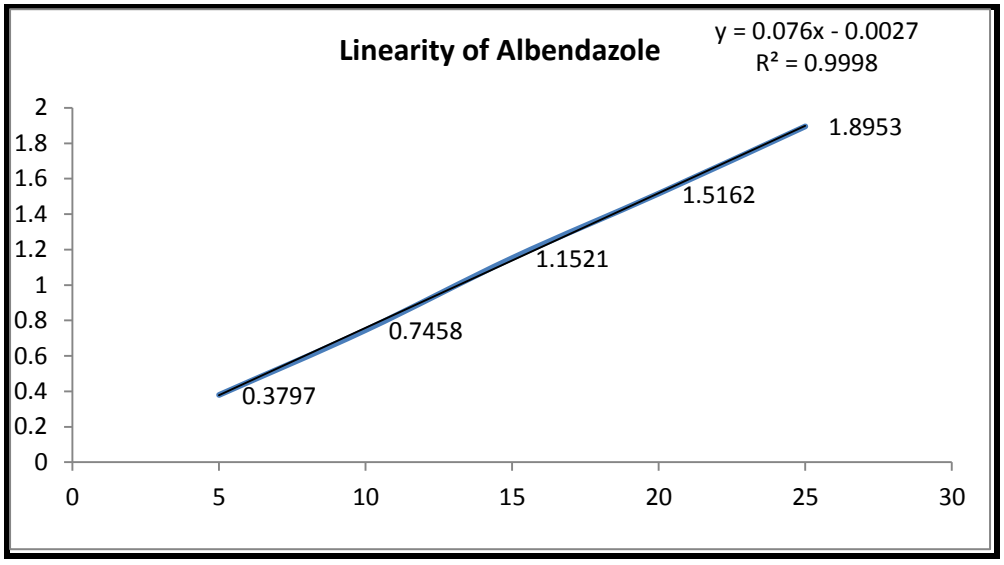

Figure 3: Calibration Curve Albendazole

Results for Accuracy for Assay method of Albendazole -

Accuracy results were found within acceptance criteria **98-102%** represented in Table - 4**.**

Results for Precision for Assay method of Albendazole –

The % RSD for different sample of precision was found to be **0.3783** and it's within acceptance criteria represented in Table - 5.

Results for Ruggedness for Assay method of Albendazole –

The % RSD for different sample of ruggedness was found to be **0.1729** and it's within acceptance criteria represented in Table - 6.

CONCLUSION

A method for the estimation of Albendazole in tablet form has been developed. From the spectrum of Albendazole, it was found that the maximum absorbance was 291 nm in DMF. A good linear relationship was observed in the concentration range of 5 - 25 µg/ml. The high percentage recovery indicates high accuracy of the method. The method shows no interference from the common excipients and additives. This demonstrates that the developed spectroscopic method is simple, accurate, precise and rugged for the estimation of Albendazole in solid dosage forms. Hence, the method could be considered for the determination of Albendazole in quality control laboratories.

The method was found to be simple, accurate, linear, precise and rugged and can be applied for routine analysis of Albendazole in different dosage form and dissolution studies.

ABBREVARTIONS

PPM - Parts per Million

nm - Nanometer

DMF- Dimehyl Formaldehyde

UV - Ultra violet

Ml - Milliliter

DNA - Deoxyribonucleic acid

HIV - Human Immunodeficiency Virus

ICH - International Council for Harmonization

RSD - Relative Standard Deviation

SD - Standard Deviation

Qty - Quantity

C - Celsius

M.D. - Manufacturing Date

E.D. - Expiry Date

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