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.
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].

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 \( \lambda \) max [10, 12]:**

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

![Figure 2: Calibration Curve](image)

**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 \( \mu \)g/ml.

**Standard Solution:**

Pipette out 1 ml from standard stock solution and diluted up to 100 ml with DMF to get concentration of 10 \( \mu \)g/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.

| Sr. No. | Sample   | Absorbance |
|---------|----------|------------|
| 1       | Blank    | 0.0001     |
| 2       | Standard | 0.7654     |
| 3       | Sample   | 0.7476     |

**Table 1: Absorbance of Dosage Form**

| Mankind Phrama LTD (Bandy 400 mg) |
|---|---|
| Sample | Absorbance |
| Blank   | 0.0001 |
| Standard | 0.7654 |
| Sample   | 0.7476 |

**Table 2: Assay Results**

| Type | Company               | M.D.  | E.D.  | Batch No. | Average weight (g) | Assay (%) |
|------|-----------------------|-------|-------|-----------|--------------------|-----------|
| 1    | Mankind Pharma LTD (400 mg) 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  | 0.7503| 98.02   | 0.1729|
|         |               | 0.7584  |       |         |       |
| 2       | Analyst 2     | 0.7564  | 0.7521| 98.26   |       |
|         |               | 0.7478  |       |         |       |
RESULTS AND DISCUSSION

Identification:
Solubility of Albendazole:
Solubility test was passed as per criteria.

| 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](image)

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.

ABBREVIATIONS

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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