DEVELOPMENT AND VALIDATED UV SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF ALBENDAZOLE IN TABLET DOSAGE FORM.

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ABSTRACT
Albendazole (ABZ) is an oral broad-spectrum anthelmintic, antiparasitic agent generally prescribed for the treatment of tissue infections caused by a variety of nematodes, Threadworm, Hookworm and Tapeworm. Several techniques such as HPLC, HPLC with fluorescence detection, LC-MS, capillary electrophoresis, spectrophotometric, titrimetric and flow injection analysis for the estimation of albendazole alone and with its major metabolites had been reported. **Objective:** To developed simple, reliable, rapid, precise, specific and reproducible UV spectroscopic method for routine analysis of Albendazole in tablet Form. **Method:** Aliquots of stock solution were further diluted with DMF to get working solution of 5, 10, 15, 20, 25 μg/ml and the working standards were scanned between 200 - 400 nm which shows the maximum absorbance at 295 nm. **Result:** The drug obeyed the Beer’s law and showed good correlation. It showed absorption maxima at 298 nm in Dimethyl Formamide (DMF). The linearity was observed between 5-25 μg/ml. The results of analysis were validated by recovery studies. The recovery was found to be 99.43-101.55%. **Conclusion:** 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, Threadworm, hookworm, spectrophotometry, Beer’s law, recovery study.
INDRODUCTION

Albendazole is a broad spectrum anthelmintic. It is used for the treatment of Threadworm, Hookworm and Tape-worm [1-3]. Albendazole (ALB) (Figure 1), chemically known as methyl [5-(propylthio)-1H-benzimidazol-2-yl] carbamate [3-5] is widely used as an anthelmintic having a wide spectrum of activity. The drug is official in British Pharmacopoeia [4], which describes a potentiometric titration with perchloric acid in formic acid–acetic acid medium. The development of reliable and affordable procedures for assay of drug substances either as pure drug or in combination remains a major research area in today’s Pharmaceutical care and practice [6]. To the best of our knowledge, the estimation of the drug in pure form using non-aqueous titration is described in British Pharmacopoeia. The aim of the present work was to develop simple, rapid, accurate and sensitive spectrophotometric method for the estimation of Albendazole in tablet. Chemical structure of albendazole is given in Fig 1. ABZ is effective in the treatment of echinococcosis, hydrated cysts and neurocysticercosis. Several techniques such as HPLC, HPLC with fluorescence detection, LC-MS, capillary electrophoresis, spectrophotometric, titrimetric and flow injection analysis for the estimation of albendazole alone and with its major metabolites had been reported [7]. 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 [8]. Suit-able statistical tests were performed on validation data [9, 10]. The aim of the present work was to develop simple, rapid, accurate and sensitive spectrophotometric method for the estimation of Albendazole in bolus, tablet and suspension forms respectively.

![Figure1-Chemical Strucure of Albendazole.](image-url)
MATERIALS AND METHODS

Instrument used: Shimadzu double beam UV-visible spectrophotometer 1700 Ultra 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.

EXPERIMENTAL

Determination of $\lambda_{\text{max}}$: 10 mg Weighed amount of albendazole was dissolved into DMF to obtain a 100 µg/ml solution. This solution was subjected to scanning between 200-400 nm and absorption maximum was determined.

Standard Stock Solution: Standard stock was prepared by dissolving 10 mg of Albendazole in 100 ml of DMF to get concentration of 100 g/ml.

Method Development: Aliquots of stock solution were further diluted with DMF to get working solution of 5,10,15,20, 25 g/ml and the working standards were scanned between 200 - 400 nm which shows the maximum absorbance at 295 nm. Figure 2

Procedure for calibration curve: Aliquots of stock solution were further diluted with DMF to get working solution of 5, 10,15,20,25 g/ml. Subsequently, the prepared standards were measured after standing for 5 min at max as recorded in each case against a solvent blank similarly prepared. A calibration curve of the absorbance against the concentration of the drug was plotted. Figure 3
Procedure for pharmaceutical preparations
For analysis of commercial formulations; twenty tablets or bolus were taken and powdered. The powder or suspension equivalent to 100 mg of albendazole was accurately weighed or measured and transferred to 100 ml volumetric flask and dissolved in 20 ml DMF. Then the solution was shaken for 20 min. The resulting solution was further diluted to 100 ml with DMF and filtered through whatman filter paper no. 41. 1 ml of the above solution was pipetted out into 100 ml volumetric flask and made up to the mark with DMF. The absorbance was measured at 248 nm against the blank. The amount of the drug in a sample was calculated from the calibration curve. The results are reported in Table 1.

Table 1 - Results of assay of Albendazole tablet

<table>
<thead>
<tr>
<th>Brands</th>
<th>Forms</th>
<th>Label mg, mg/ml</th>
<th>Label claim</th>
<th>*Found (mg, mg/ml) ±S.D</th>
<th>% RSD</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>TABLET</td>
<td>200</td>
<td>200</td>
<td>194.24 ± 0.553</td>
<td>0.206</td>
</tr>
</tbody>
</table>

VALIDATION OF 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 [11] for method validation. The correlation coefficient and optical characteristic are summarised in Table 2.

Table 2 - Optical characteristic of the proposed method.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>λ_max nm</td>
<td>295nm</td>
</tr>
<tr>
<td>Beer’s law limit, μg/ml</td>
<td>5-25μg/ml</td>
</tr>
<tr>
<td>Correlation coefficient (r²)</td>
<td>0.99752</td>
</tr>
<tr>
<td>Standard Regression equation</td>
<td>Y=0.03639X+0.05443</td>
</tr>
</tbody>
</table>
a. **Precision**

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

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

**Table 3- Assay results and precision studies.**

<table>
<thead>
<tr>
<th>SAMPLE</th>
<th>LABEL CLAIM mg/tab</th>
<th>Found(mg)</th>
<th>Label claim ±S.D</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALB tablet</td>
<td>200</td>
<td>200</td>
<td>100.54 ± 0.293</td>
<td>Repetability</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.471</td>
</tr>
</tbody>
</table>

b. **Stability**

Standard stock solutions of Albendazole were stored in two different conditions at ± 4°C and at ambient temperature for one month. During this period the solutions were analyzed with UV spectrophotometric method, the spectrum was compared with the spectrum of freshly prepared standard solution.

c. **Accuracy**

The proposed method was compared with non - aqueous method for the estimation of Albendazole pure drug. The results are reported in Table 4.

**Table 4 – Accuracy study of ALB**

<table>
<thead>
<tr>
<th>SPECTROPHOTOMETRIC METHOD</th>
<th>Quantity weighed mg</th>
<th>Quantity found mg</th>
<th>Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100</td>
<td>99.13</td>
<td>99.13 ± 0.324</td>
</tr>
<tr>
<td></td>
<td>200</td>
<td>197.34</td>
<td>98.67 ± 0.245</td>
</tr>
<tr>
<td></td>
<td>300</td>
<td>294.12</td>
<td>98.04 ± 0.256</td>
</tr>
<tr>
<td></td>
<td>400</td>
<td>394.32</td>
<td>98.58 ± 0.364</td>
</tr>
</tbody>
</table>

d. **Ruggedness:** Ruggedness is a measure of reproducibility of test results under the variation in conditions normally expected from laboratory to laboratory and from analyst to analyst. Ruggedness of the proposed method is determined by analysis of aliquots from homogenous slot by two analyst using same operational and environmental conditions [12].

Table 5
Table 5- Ruggedness study

<table>
<thead>
<tr>
<th>Sr.no</th>
<th>Analyst I Amt. found %</th>
<th>% R.S.D</th>
<th>Analyst II Amt. found %</th>
<th>% R.S.D</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>99.99±0.74</td>
<td>0.74</td>
<td>100.60±0.73</td>
<td>0.72</td>
</tr>
</tbody>
</table>

RESULTS AND DISCUSSION
It can be seen from Figure 2 that the spectrum of Albendazole has a maximum absorbance at 295 nm in DMF. The method obeys Beer - Lambert law within the range of 5 - 25 µg/ml and the calibration curve showed linearity as shown in Figure 3. Correlation coefficient was found to be 0.99752 and the Standard Regression equation was y=0.03639X+0.05443.

CONCLUSION
A method for the estimation of Albendazole in tablet form has been developed. From the spectrum of Albendazole as shown in Figure 2, it was found that the maximum absorbance was 295 nm in DMF. A good linear relationship (0.997) 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 selective for the estimation of Albendazole in solid and suspension dosage forms. Hence, the method could be considered for the determination of Albendazole in quality control laboratories.

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