

DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ALBENDAZOLE IN BULK, TABLET, AND ITS ORAL SUSPENSION DOSAGE FORM

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ABSTRACT

Aim: A method for the simultaneous estimation of albendazole in bulk, tablets, and oral suspension dosage form is developed and validated using reversed phase high performance liquid chromatography (RP-HPLC). **Objective:** This attempt is made because there isn't a single RP-HPLC method that can simultaneously estimate albendazole in bulk, tablet, and oral suspension dosage form. **Materials and Methods:** The chromatography was performed using an instrument Thermo Scientific Fischer model number Dionex Ultimate 3000, with column ODS Nucleodur C₁₈, having dimension 250 mm × 4.6 mm i.d, 5µm particle size, mobile phase OPA (0.1%) in water: Acetonitrile 60:40 (v/v) with a flow rate of 1.0ml/min. The injection volume was fixed at 10 µl. The detection was done using PDA detector at a λ_{max} of 308 nm. The diluent used for making

dilutions was 1% (v/v) solution of sulphuric acid in Methanol: Water in 50:50(v/v) ratio. The method was validated in accordance with ICH guidelines by studying the parameters like specificity, linearity, accuracy, precision, robustness, system precision. **Result:** The albendazole was eluted with the retention time of about 3.90 minute. The linearity was achieved in the concentration ranges 50 µg/ml – 150µg/ml and the observed regression coefficient (R^2) value was found as 0.9941 for this linearity. The percentage recovery for albendazole was found in between 99.19% to 100.01 for bulk, 99.17% to 99.83% for Tablet, 99.54% to 100.80% for oral suspension. **Conclusion:** The method's suitability for the simultaneous determination of albendazole in bulk, tablet, and oral suspension dosage form is confirmed by the high recovery values.

KEYWORDS: Albendazole, RP-HPLC, Oral Suspension, Method Development, Validation, Nucleodur.

INTRODUCTION

Chemically speaking, albendazole is methyl-5-propylthio-1H-benzimidazol-2-yl carbamate^[1] (Figure 1). It has a broad spectrum of activity and is frequently used as an anthelmintic.^[2] According to the Indian Pharmacopoeia^[2], albendazole has the chemical formula $C_{12}H_{15}N_3O_2S$ and a molecular weight of 265.3 g/mol. Its bulk form is assayed by titrating anhydrous glacial acetic acid with 0.1 M perchloric acid using crystal violet solution as an indicator, its oral suspension is assayed by liquid chromatography, and its tablet dosage form is assayed by UV Titrimetry in non-aqueous medium^[3], redox titrimetry^[4,5], UV spectrophotometry^[6-9], spectrofluorimetry^[10], visible spectrophotometry^[11-13], voltammetry^[14,15], and high performance liquid chromatography (HPLC)^[16-20] are a few of the methods that can be used to quantify albendazole.

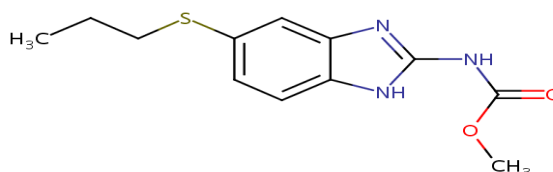


Figure 1: Chemical Structure of Albendazole.

A review of the literature reveals that while there are several methods for estimating albendazole in bulk, tablet, and oral suspension dosage form separately, there isn't a single

method for estimating albendazole in bulk, tablet, and oral suspension dosage form all at once. Therefore, efforts have been made to develop a novel, quick, easy, precise, and reliable method that can simultaneously estimate the dosage form of albendazole in tablet, liquid, and bulk forms using an RP-HPLC method and be validated in accordance with ICH guidelines.

MATERIALS AND METHODS

Chemicals and Reagents

Albendazole reference standard was procured from IPC Ghaziabad as a gift sample and albendazole test samples (i.e., albendazole tablet and oral suspension) was purchased at a nearby pharmacy.

All the chemicals were of the HPLC grade and were bought from reliable sources

Table 1: List of Chemicals used in Research Work.

S. No.	Name of Chemical	Provider of Chemical
1.	Albendazole reference standard	Indian pharmacopoeia commission Ghaziabad
2.	Albendazole test samples	Local Pharmacy Store
3.	Acetonitrile	Rankem Chemical Corporation
4.	Ortho-phosphoric Acid	Rankem Chemical Corporation
5.	Milli-Q Water	Bio Millipore Co., Bedford, USA
6.	Methanol	Rankem Chemical Corporation
7.	Suphuric Acid	Fisher scientific

Chromatographic conditions

HPLC Thermo scientific fisher and ODS Nucleodur C₁₈ (250mm×4.6mm, particle size 5µm) column used for the study. The apparatus had a PDA detector, a binary pump, an autosampler, a temperature-controlled sample chamber, and a column oven.

Table 2: Chromatographic Conditions.

HPLC system	Thermo scientific fisher, Dincox ultimate 3000
Software used	Chromeleon
Column	C ₁₈ , 250 mm × 4.6 mm, 5 Micron
Mobile Phase	60:40 v/v (0.1% OPA in water:ACN)
Flow Rate	1.0 mL/min
Injection Volume	10 µL
Detector	PDA
Wavelength	308 nm
Run Time	10 min
Column Temperature	25°C

Instruments

Table 3: List of Instruments used in Research Work.

S.NO.	Name of the Instrument	Model	Instrument's Manufacturer
1.	HPLC system	Dinox ultimate 3000	Thermo scientific fisher
2.	Analytical column	C ₁₈ , 250 mm × 4.6 mm, 5 Micron	Nucleodur
3.	UV-Visible Spectrophotometer	Lamda max 308	Perkin Elmer
4.	Analytical Weighing Balance	XP-205	Mettler Toledo
5.	Sonicator	Branson Sonicator	Mettler Toledo
6.	Milli-Q Water purification system	Integral 3 Q-POD	Millipore Co., Bedford, USA
7.	Syringe filter	RanDisk	Rankem

Preparation of Mobile Phase- Precisely measured 1ml of OPA was taken and put into a volumetric flask with 1000 millilitres. HPLC grade water was used to make up the volume (0.1% OPA). For ten minutes, the solution was sonicated. In a ratio of (60:40), 0.1% OPA in water and ACN were used as the mobile phase.

Preparation of Diluent- The diluent was made up of a 50:50 mixture of water and a 1% v/v solution of sulfuric acid in methanol.

Preparation of stock solution (Albendazole standard stock solution)- Albendazole, accurately weighed at 50 mg, was transferred into a 50 ml volumetric flask. 20 ml of diluent should be added; sonicate to dissolve. Add diluents up to the mark, then thoroughly mix. (About 1000 g/ml of concentration).

Preparation of Standard solution- A 100 ml volumetric flask was filled with precisely measured 10 ml of albendazole standard stock solution, which was then topped off with diluent and thoroughly mixed.

(Albendazole standard solution concentration is approximately 100 g/ml.)

Preparation of Sample solution (Albendazole tablet sample solution)- A 252 mg albendazole tablet, which is the equivalent of 100 mg of albendazole, was accurately weighed and added to a volumetric flask with 30 ml of diluents. The mixture was then sonicated to dissolve, and the remaining diluent was used to bring the volume up to the 100 ml mark.

A 100 ml volumetric flask was filled with 10 ml of this solution, which was then diluted to the proper level with diluents to achieve a concentration of 100 g/ml and filtered through a 0.45 filter.

Albendazole Oral Suspension- A 100 ml volumetric flask was filled with an accurately weighed 6.15 g of well-mixed sample (albendazole oral suspension containing 200 mg/ 5 ml) and the required amount of diluents. A 50 ml volumetric flask was used to transfer 2.5 ml of the above solution and add diluent to bring the volume up to the required level. (Albendazole concentration is approximately 100 g/ml.) After that, it was put through a 0.45mm nylon syringe filter.

Optimization of the Chromatographic Conditions - To create a simultaneous assay method for albendazole in its bulk, tablet, and oral suspension dosage forms, the RP-HPLC method was improved. Firstly, the solubility of Albendazole is checked in different solvents like HPLC grade water, Acetic acid, formic acid, methanol, acidic methanol, ACN, acetone and the best suitable solvent among them was found to be 1% v/v solution of sulphuric acid in methanol which is further diluted with water in 50:50 ratio. The best mobile phase for Albendazole based on polarity, stability, retention time was selected as 0.1% OPA in water: ACN in 60:40 ratio. Columns with different lengths, particle size of stationary phase and internal diameter was also tried to check the parameters of the system's suitability, such as asymmetry, theoretical plates, peak to valley ratio, peak purity and the best column selected as Nucleodur (C₁₈, 250 mm × 4.6 mm, 5 Micron). The suitable flow rate for this method was found to be 1.0 ml/min. 10ml was used as the injection volume. The sample compartment and column oven temperature were adjusted at 25°C.

Method Validation

The following factors, including, were studied to validate the provided method such as Linearity, Accuracy, Precision, Specificity, System Suitability, Robustness, Force Degradation Study and Solution Stability Testing as per the ICH guidelines.

System suitability

Six replicates of a standard albendazole 100 ppm solution were injected to study it and after the completion of the run it was assessed for retention time, area, theoretical plates, and asymmetry.

Specificity

The ability to clearly identify the analyte in the presence of other substances that may be present in the sample is known as specificity. The method's specificity was established by studying whether there is any kind of interference of the albendazole drug peak with the diluent and mobile phase components.

Linearity

Linearity is the ability of the analytical process to produce results that are directly proportional to the analyte concentration in the given sample and fall within a certain range. The linearity of albendazole was observed in the concentration ranges from 50 ppm to 150 ppm and these solutions were prepared in triplicate from the standard stock solution (concentration about 1000 µg/ml). The calibration curve, regression equation, and regression coefficient (R^2) were all calculated based on the linearity results.

Precision

When a method is applied to multiple sampling of a homogeneous sample, precision is the factor that provides an idea of how closely test results will agree. To verify accuracy, the following parameters were examined:

Repeatability: It conveys the precision over a brief period while operating under the same conditions. In this parameter 3 concentrations of standard albendazole solution (i.e., 50 ppm, 100 ppm, 150 ppm) are injected in triplicate and the observation was recorded. The RSD for the same should not be more than 2%.

System precision: This parameter was studied for checking the suitability of the system for the current method. It was studied by injecting a blank solution followed by 6 injections of the standard solution of concentration 100 ppm. The following parameters were studied in system precision are as theoretical plates (it should be more than 2000), asymmetry (it should be in range 0.8 to 1.2) and RSD was calculated for each one parameter, and it should not be more than 2%.

Method precision: This parameter was studied for the checking the suitability for the current developed method for assessing the analyte in the given sample. . It was studied by injecting a blank solution followed by 5 injections of the standard solution of concentration 100 ppm followed by 6 injections of the test sample (concentration is about 100 ppm) in replicates.

Intermediate precision: It conveys variation within laboratories, such as different days, equipment, or analysts. This parameter was studied by injecting 5 injections of bulk solution in replicate of 100 ppm and test solution 6 injections in replicate of 100 ppm and RSD was calculated for each one parameter and it should not be more than 2%.

Accuracy

It conveys how closely two values agree, whether they are used as accepted reference values or as conventional true values. The accuracy study involved injecting a known quantity of placebo into an albendazole standard solution at concentration levels of 80%, 100%, and 120% (each level was injected three times), submitting them to the proposed HPLC method, and calculating the percentage recovery at each level.

Robustness

It refers to the analytical method's ability to be unaffected by small but intentional changes to the method parameters. It gives a sign of how reliable a method is under typical conditions. It was done by changing some of the chromatographic conditions such as wavelength (± 2), flow rate ($\pm 20\%$), column temperature ($\pm 10^\circ\text{C}$), and mobile phase composition ($\pm 5\%$). The standard solution (concentration is about 100 ppm) was injected in duplicate to study this parameter.

Force Degradation Study

To determine the stability of the standard solution and test solution under the conditions listed below, a force degradation study was conducted.

Acid Degradation: In this the blank, standard and test solution was treated with 0.1N hydrochloric acid, 1N hydrochloric acid solution and then injected in the HPLC after 1 hour to observe the % degradation of the drug by calculating % assay of the drug.

Alkali Degradation: In this the blank, standard and test solution was treated with 0.1N sodium hydroxide, 1N sodium hydroxide solution and then injected in the HPLC after 1 hour to observe the % degradation of the drug by calculating % assay of the drug.

Oxidation Degradation: In this the blank, standard and test solution was treated with 10 % w/v Hydrogen peroxide solutions and then injected in the HPLC after 1 hour to observe the % degradation of the drug by calculating % assay of the drug.

Thermal Degradation: In this the standard and test solutions were subjected to thermal degradation by keeping them at 80°C for 1 hours, followed by analysis in HPLC by studying % degradation of the drug by calculating % assay of the drug.

Solution Stability Testing

This test is performed for checking the stability of the albendazole standard and test solutions in normal day light condition for an interval of 24 hours. For performing this test, a 100 ppm concentration of albendazole standard and test solutions was prepared and it was injected at different time interval in HPLC ranging from initial 0 hours upto 24 hours to see the % degradation of the drug in solution form at different time interval.

RESULT AND DISCUSSION

A straightforward, quick, accurate, precise, and repeatable method for simultaneously estimating albendazole in bulk, tablet, and its oral suspension dosage form was developed and validated after all chromatographic conditions were optimized. The mobile phase optimized for this method was a ratio of (0.1% OPA: ACN) in 60:40 v/v proportion. The chromatogram of albendazole obtained in this method gives a sharp peak of albendazole with the retention time of about 3.9 minutes at a flow rate of 1 ml/min with a UV range at about 308 nm. The run time for this method is 10 minutes.

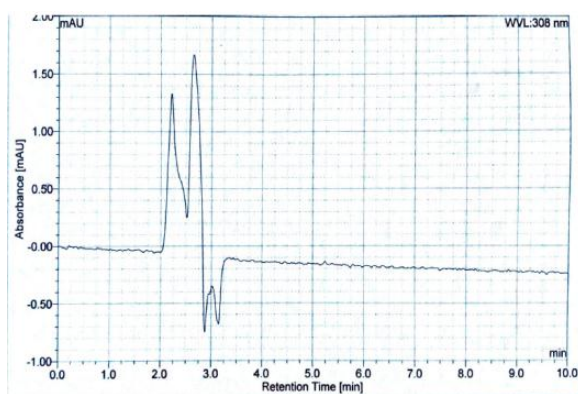


Figure 2: Chromatogram of Blank

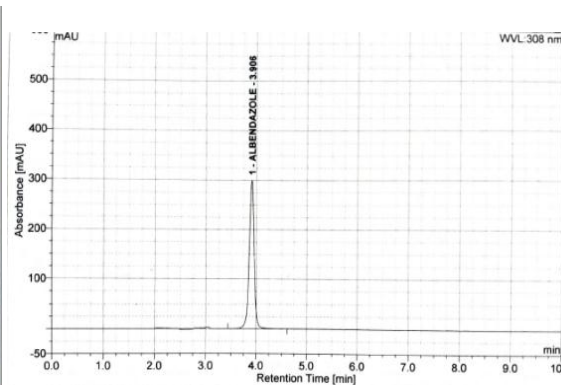


Figure 3: Chromatogram of Albendazole Bulk

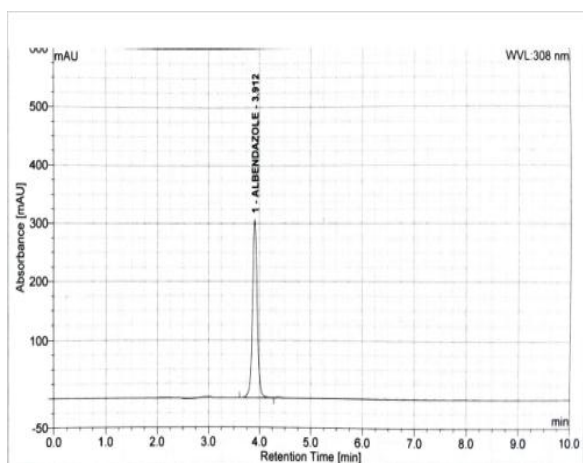


Figure 4: Chromatogram of Albendazole Tablet

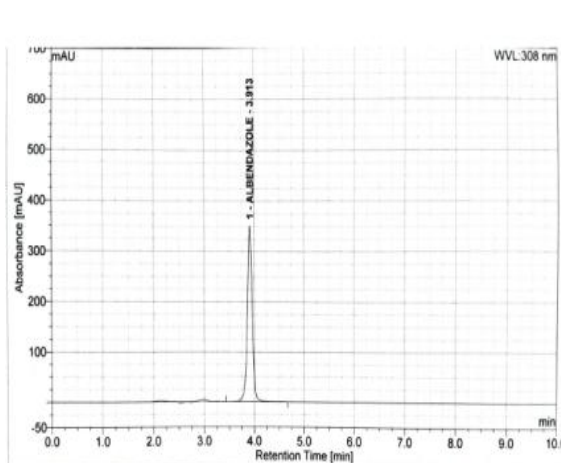


Figure 5: Chromatogram of Albendazole Oral Suspension

System Suitability

The results for all the system suitability parameters were optimal for performing the method validation and are as follows:

Table 4: System suitability parameters for Albendazole.

SYSTEM SUITABILITY PARAMETERS				
S.NO.	Retention Time	Theoretical Plates	Asymmetry	Area
1	3.906	8684	0.990	33.738
2	3.907	8628	0.990	33.695
3	3.908	8633	1.000	33.716
4	3.908	8722	1.000	33.690
5	3.910	8761	1.000	33.740
6	3.910	8820	1.000	33.714
Mean	3.908	8708	0.997	33.715
SD	0.002	75.03	0.005	0.021
%RSD	0.041	0.861	0.518	0.062

Specificity

Since the analyte could be clearly distinguished from other components in the sample solution, the method was determined to be specific. For this the sample solution is injected along with the 0.1% OPA, ACN, and diluents. The peak purity was also determined for the same and it was found to be 1. The chromatogram for the same are attached below:

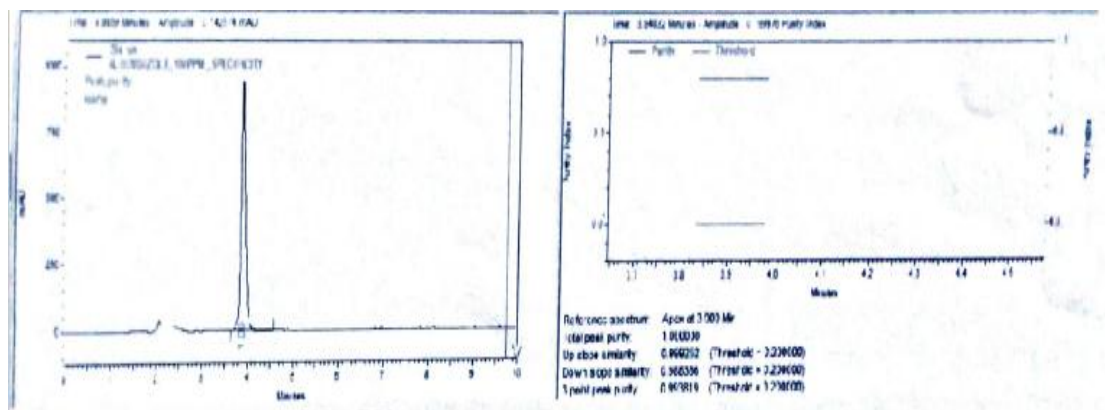


Figure 6: Specificity of Albendazole with peak purity.

Linearity

The linearity was determined from the standard stock solution by diluting it to different concentration ranging from 50 ppm to 150 ppm. It was performed by injecting 3 replicates of each concentration and then the mean of them was obtained and using these values a calibration curve is plotted to determine the correlation coefficient, y-intercept, and slope of the regression line and the result for the same are given below:

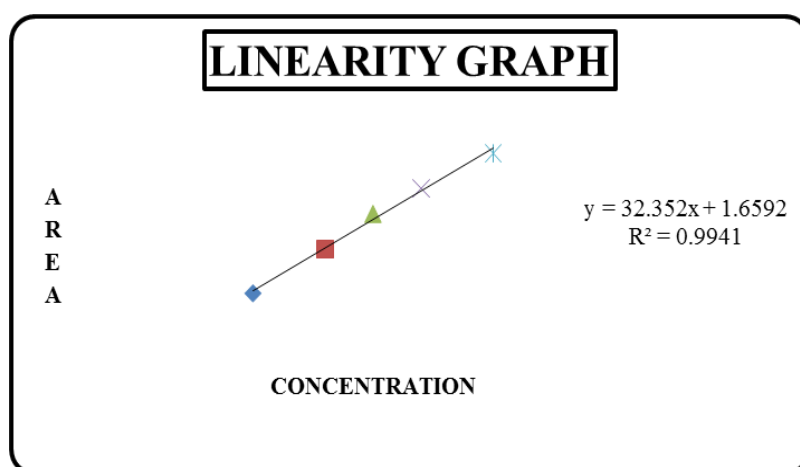


Figure 7: Linearity graph of Albendazole.

Table 5: Linearity range of Albendazole.

S.No.	Concentration	ALBENDAZOLE		
		Concentration (mcg/ml)	Area	AVERAGE
1	50%	51.6	17.195	17.186
	50%	51.2	17.177	
2	80%	82.5	27.249	27.267
	80%	82.0	27.286	
3	100%	103.2	35.407	35.291
	100%	102.5	35.175	

4	120%	123.0	41.143	41.149
	120%	123.5	41.156	
5	150%	153.7	49.160	49.161
	150%	153.4	49.161	
Slope	32%			
Intercept	1.65			

Precision

In this study, system precision, method precision, intermediate precision, and repeatability studies are used to assess precision. Each test's findings are within the limits as per ICH guidelines and the value of % RSD is not more than 2% in any case. The result for the same are tabulated below:

System Precision

Table 6: System precision result.

SYSTEM PRECISION BULK				
S.NO.	Retention Time	Theoretical Plates	Asymmetry	Area
1	3.906	8684	0.990	33.738
2	3.907	8628	0.990	33.695
3	3.908	8633	1.000	33.716
4	3.908	8722	1.000	33.690
5	3.910	8761	1.000	33.740
6	3.910	8820	1.000	33.714
Mean	3.90	8708	0.997	33.715
SD	0.001	75.03	0.005	0.020
%RSD	0.040	0.861	0.518	0.061

Method Precision

Table 7: Method precision result.

Method Precision			
S.NO.	Bulk	Tablet	Oral Suspension
1	33.55	35.33	50.74
2	33.60	35.26	50.65
3	33.53	35.27	51.19
4	33.70	35.34	52.10
5	33.54	35.22	51.19
6	33.71	36.13	50.83
MEAN	33.60	35.42	51.11
SD	0.08	0.35	0.53
% RSD	0.24	0.99	1.05

Intermediate Precision**Table 8: Intermediate precision result.**

INTERMEDIATE PRECISION						
S.NO.	Bulk		Tablet		Oral Suspension	
	Analyst I	Analyst II	Analyst I	Analyst II	Analyst I	Analyst II
1	33.74	35.14	35.33	35.53	40.09	37.45
2	33.70	34.74	35.26	35.64	40.13	37.45
3	33.72	34.93	35.27	35.60	40.14	37.43
4	33.69	34.87	35.34	35.63	40.17	37.47
5	33.74	35.02	35.22	35.60	40.24	37.43
6	33.71	35.22	36.13	35.63	40.03	37.46
MEAN	33.72	35.08	35.42	35.61	40.13	37.45
SD	0.02	0.37	0.35	0.04	0.07	0.02
% RSD	0.06	0.50	0.99	0.11	0.18	0.04

Repeatability**Table 9: Repeatability result for albendazole standard.**

ALBENDAZOLE REPEATABILITY					
S.NO.	Concentration	Area	Mean	SD	% RSD
1	50	17.134	17.147	0.026	0.152
	50	17.130			
	50	17.177			
2	100	35.150	35.212	0.054	0.153
	100	35.245			
	100	35.241			
3	150	49.422	49.343	0.089	0.181
	150	49.362			
	150	49.246			

Accuracy

The accuracy was determined for the given albendazole tablet and oral suspension dosage form at 80%, 100%, 120% level and the % recovery was found to be within the limit i.e. 98% to 102%.

Table 10: Accuracy result for Albendazole Bulk.

ACCURACY: STANDARD							
DRUG	CONCENTRATION % OF SPIKED LEVEL	AMOUNT ADDED (ppm)	AMOUNT FOUND (ppm)	MEAN	% SD	% RSD	% RECOVERY
ALBENDAZOLE	80%	80	79.24	79.35	0.23	0.29	99.19
		80	79.20				
		80	79.62				
	100%	100	101.22	100.01	1.05	1.05	100.01
		100	99.56				

		100	99.26				
	120%	120	119.24	119.11	0.13	0.10	99.25
		120	119.10				
		120	118.98				

Table 11: Accuracy result for Albendazole Tablet.

ACCURACY: MANKIND TABLET							
DRUG	CONCENTRATION % OF SPIKED LEVEL	AMOUNT ADDED (ppm)	AMOUNT FOUND (ppm)	MEAN	% SD	% RSD	% RECOVERY
ALBENDAZOLE	80%	80	80.29	79.34	0.82	1.03	99.17
		80	78.90				
		80	78.84				
	100%	100	100.82	99.83	0.90	0.90	99.83
		100	99.63				
		100	99.05				
	120%	120	118.77	119.20	0.73	0.61	99.33
		120	120.05				
		120	118.79				

Table 12: Accuracy result for albendazole Oral Suspension.

ACCURACY: MANKIND ORAL SUSPENSION							
DRUG	CONCENTRATION % OF SPIKED LEVEL	AMOUNT ADDED (ppm)	AMOUNT FOUND (ppm)	MEAN	% SD	% RSD	% RECOVERY
ALBENDAZOLE	80%	80	80.45	80.65	0.20	0.254	100.80
		80	80.86				
		80	80.63				
	100%	100	99.46	99.54	0.07	0.070	99.54
		100	99.57				
		100	99.59				
	120%	120	119.51	119.54	0.05	0.043	99.61
		120	119.60				
		120	119.51				

Robustness

The robustness was studied by deliberately changing the following parameters mobile phase composition, flow rate, column temperature, and wavelength. The result obtained from these are listed below:

Table 13: Robustness result for albendazole standard.

DRUG	PARAMETERS	VARIANCE	% SD	% RSD
ALBEDAZOLE	Wavelength	+2 nm	0.032	0.097
	Wavelength	- 2 nm	0.025	0.072
	flow rate	0.8 ml/mim	0.166	0.362
	flow rate	1.2 ml/min	0.302	0.989
	column temperature	+ 10%	0.018	0.054
	column temperature	- 10%	0.097	0.288
	mobile phase composition	+ 5 %	0.016	0.042
	mobile phase composition	5	0.298	0.814

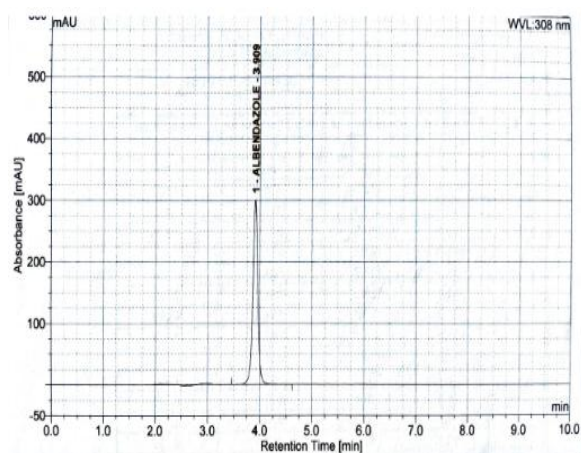


Figure: 8 Wavelength plus 2

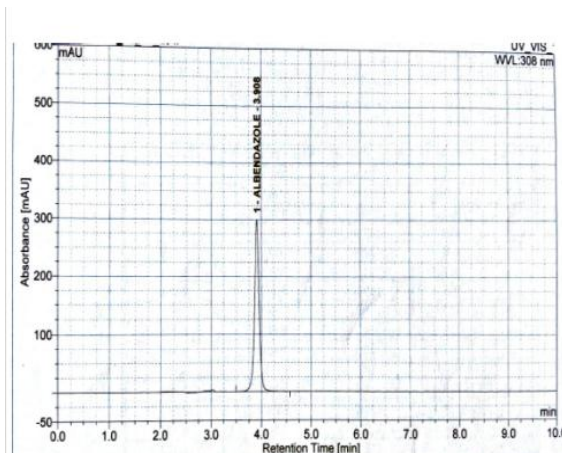


Figure: 9 Wavelength minus 2

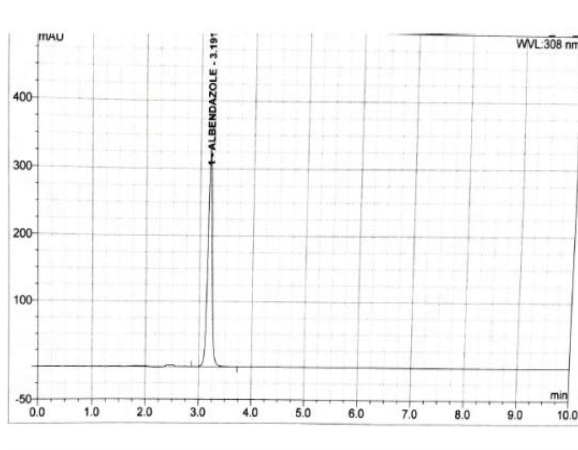


Figure: 10 Flow rate plus 2

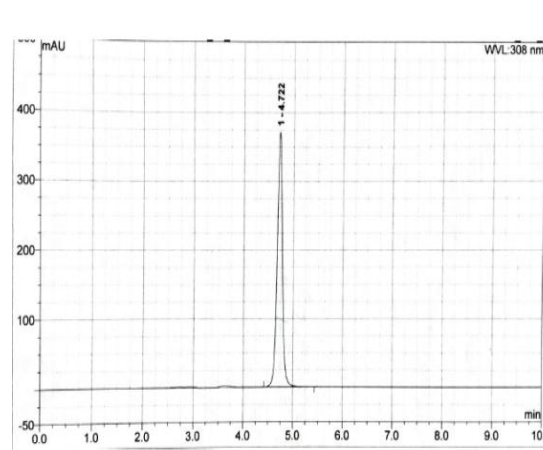


Figure: 11 Flow rate minus2

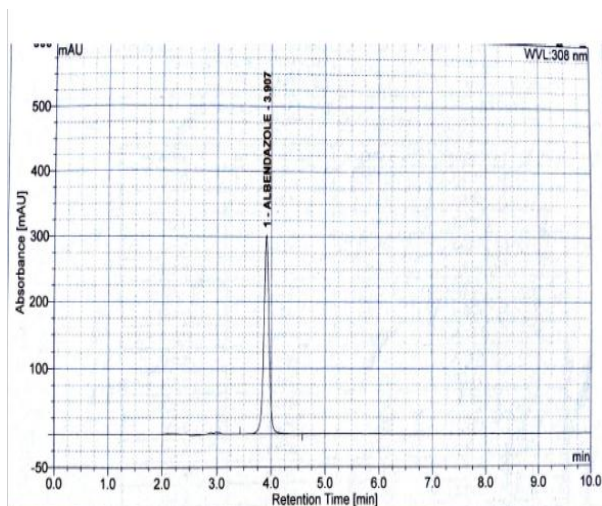


Figure: 12 Column temperature plus 10

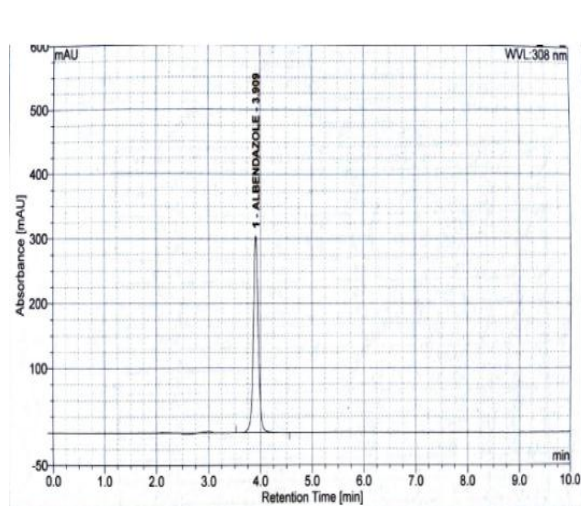


Figure: 13 Column temperature minus 10

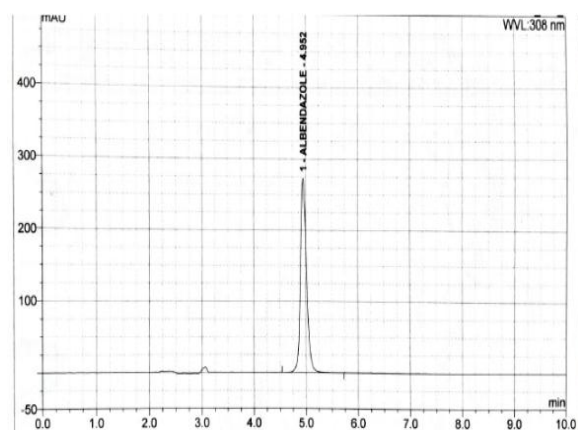


Figure: 14 Mobile Phase composition plus

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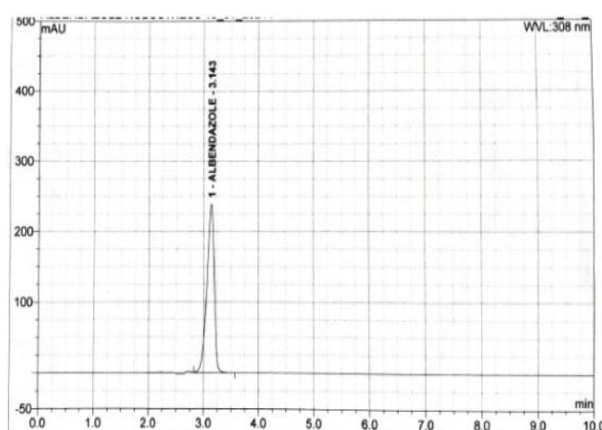


Figure: 15 Mobile Phase composition minus

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Force Degradation Study

To conduct the Force Degradation Study, sample solutions were subjected to thermal, oxidative, photolytic, oxidative, and basic degradation. The outcome was as follows, which shows that all the data was determined to be within the limit:

Table 14: FDS result for Albendazole Bulk.

FORCE DEGRADATION STUDY OF ALBENDAZOLE BULK		
Condition	Assay (%)	% Degradation
0.1 M HCl (Acid)	99.19	0.81
1 M HCL (Acid)	98.23	1.77
0.1 M NaOH (Alkaline)	98.40	1.6
1 M NaOH (Alkaline)	98.53	1.47
10 % H ₂ O ₂ (Oxidation)	98.60	1.40
Thermal Stability	98.84	1.16

Table 15: FDS result for Albendazole Tablet.

FORCE DEGRADATION STUDY OF ALBENDAZOLE TABLET		
Condition	Assay (%)	% Degradation
0.1 M HCl (Acid)	98.55	1.45
1 M HCL (Acid)	98.24	1.76
0.1 M NaOH (Alkaline)	99.46	0.54
1 M NaOH (Alkaline)	99.32	0.68
10 % H ₂ O ₂ (Oxidation)	98.13	1.87
Thermal Stability	98.29	1.71

Table 16: FDS result for Albendazole Oral Suspension.

FORCE DEGRADATION STUDY OF ALBENDAZOLE ORAL SUSPENSION		
Condition	Assay (%)	% Degradation
0.1 M HCl (Acid)	99.05	0.95
1 M HCL (Acid)	99.26	0.74
0.1 M NaOH (Alkaline)	98.35	1.65
1 M NaOH (Alkaline)	98.72	1.28
10 % H ₂ O ₂ (Oxidation)	98.83	1.17
Thermal Stability	98.53	1.47

Stability of Solution

The stability of albendazole tablet and its oral suspension dosage form was studied and from the observed value of result it was found that the sample solution remained stable for a minimum of 24 hours. The data for the same is tabulated below:

Table 17: Stability result for Albendazole Bulk solution.

SOLUTION STABILITY OF ALBENDAZOLE REFERENCE		
TIME (HOURS)	AREA	RELATIVE AREA
0	34.082	0.000
1	33.975	0.107
2	33.949	0.133
4	33.924	0.158
8	33.899	0.183
15	33.825	0.257
24	33.536	0.546
MEAN	33.884	
SD	0.172	
%RSD	0.508	

Table 18: Stability result for Albendazole Tablet solution.

SOLUTION STABILITY OF ALBENDAZOLE TABLET		
TIME (HOURS)	AREA	RELATIVE AREA
0	35.770	0.000
1	35.218	0.552
2	35.205	0.565
4	34.837	0.933
8	34.837	0.933
15	34.799	0.971
24	34.762	1.008
MEAN	35.061	
SD	0.367	
% RSD	1.046	

Table 19: Stability result of Albendazole Oral Suspension.

SOLUTION STABILITY OF ALBENDAZOLE ORAL SUSPENSION		
TIME (HOURS)	AREA	RELATIVE AREA
0	40.241	0.000
1	40.098	0.143
2	40.070	0.171
4	39.999	0.242
8	39.971	0.270
15	39.700	0.541
24	39.766	0.475
MEAN	39.98	
SD	0.189	
% RSD	0.473	

CONCLUSION

Albendazole, methyl-[5-(propylthio)-1*H*-benzimidazol-2-yl]carbamate is also made by the heterocyclization of a derivative of phenylenediamine to a derivative of benzimidazole, an anthelmintic drug which is simultaneously estimated by a simple, rapid, sensitive, precise and accurate RP-HPLC (Reverse Phase High Performance Liquid Chromatography) method was developed as per ICH guidelines for the simultaneous estimation of albendazole in bulk, tablet and oral suspension dosage form. This method is so easy and simple that it can be used for routine quality control analysis of Albendazole. Through this method one can easily and quickly quantify Albendazole in bulk and pharmaceutical dosage form i.e. (tablet and oral suspension) with a run time of about 10 minutes.

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CONFLICT OF INTEREST

The authors declared that they have no conflict of interest found in this research paper.

Abbreviations

RP-HPLC: Reverse Phase High Performance Liquid Chromatography, **ICH:** International Council on Harmonization, **SD:** Standard Deviation, **RSD:** Relative Standard Deviation, **IPC:** Indian Pharmacopoeia Commission, **OPA:** Ortho Phosphoric Acid, **ACN:** Acetonitrile, **ODS:** Octadecyl-Silica, **C₁₈:** Octadecyl, **mm:** Millimeter, **i.d.:** Internal Diameter, **μl:** Microliter, **ml:** Milliliter, **v/v:** Volume/ Volume, **min(s):** Minutes, **λ:** Wavelength, **μ:** Micron, **°C:** degree Celsius, **hr(s):** Hours, **HPLC:** High Performance Liquid Chromatography, **UV:** Ultraviolet, **PDA:** Photo diode array.

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