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Full Length Research Paper

Developing a Spectrophotometric method for the estimation of Albendazole in solid and suspension forms

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A Spectrophotometric method has been developed for the determination of Albendazole in bulk, tablet and suspension dosage forms. Solution of Albendazole in methanolic glacial acetic acid solution shows maximum absorbance at 235 nm. Beer's law was obeyed in the concentration range of 2.5 - 20 µg/ml with molar absorptivity of 1.0815 x 10^4 mol^{-1} cm^{-1}. The method was applied for the analysis of the drug in the pure, tablet and suspension forms. The slope and intercept of the equation of the regression line are 0.0310 and 0.00067 respectively. Correlation coefficient was found to be 0.9998. Results of percentage recovery showed that the method was not affected by the presence of common excipients. The proposed method is simple, sensitive, rapid, economical and could find application as an in - process quality control method for Albendazole.

Key words: Albendazole, spectrophotometry, Beer's law.

INTRODUCTION

Albendazole is a broad spectrum anthelmintic. It is used for the treatment of Threadworm, Hookworm and Tapeworm (Jaime and William, 1988, Rang et al, 1999, International Pharmacopoeia, 1987). Chemically, Albendazole is Methyl 5-propylthio-1H-benzimidazol-2-yl carbamate (British Pharmacopoeia, 2001). The preparation and synthesis of the drug was reported by Gujunk and Theorides, (1975).The anthelmintic activity of the drug was reported by Theorides (1975). 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 (Esimone et al., 2008). Extensive literature survey revealed that the estimation of the Albendazole in dosage and suspension forms are not available in Pharmacopoeia and therefore, require much more investigation. To the best of our knowledge, the estimation of the drug in pure form using non - aqueous titration is described in British Pharmacopoeia. The drug is readily available in Nigeria market in tablet, bolus (Veterinary preparation) and suspension forms. The need to come up with a simple and sensitive method of analysis for the estimation of drug in pharmaceutical preparations therefore arises. 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.

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EXPERIMENTAL

Materials

Pharmaceutical grade of Albendazole (Figure 1) was obtained as gift from Sam Pharmaceutical Ltd, Ilorin, Nigeria. All the chemicals were of analytical reagent grade of Merck (Germany) unless otherwise specified. Doubly distilled water was used to prepare all solutions. Freshly prepared solutions were employed. Different brands Albendazole tablet, Bolus and Suspensions were purchased from Pharmacies. Lactose B.P, Talcum powder, Maize starch (Pharmaceutical grade) and Magnesium stearate, Propylene glycol, Carboxylmethyl cellulose, Tween 80, Titanium Dioxide were obtained from Tuyil Pharmaceutical Industries Ltd. Ilorin, Nigeria. UV/Vis

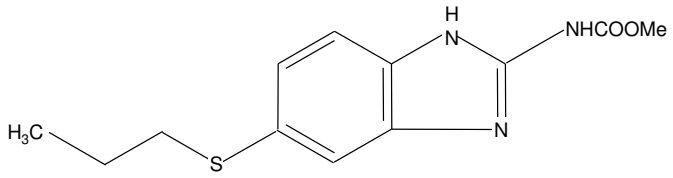

Figure 1. Structure of Albendazole.

Spectrophotometer (model V460) was employed for spectra measurements.

Methods

Albendazole stock solution.

Standard stock was prepared by dissolving 50 mg of Albendazole in 100 ml of methanolic glacial acetic acid to get concentration of 500 µg/ml.

Method Development

Aliquots of stock solution were further diluted with methanolic glacial acetic acid to get working solution of 2.5, 5.0, 7.5, 10.0, 12.5, 15.0, 17.5, 20.0 and 22.5 µg/ml and the working standards were scanned between 150 - 300 nm which shows the maximum absorbance at 235 nm. (Figure 2)

Procedure for calibration curve.

Aliquots of stock solution were further diluted with methanolic glacial acetic acid to get working solution of 2.5, 5.0, 7.5, 10.0, 12.5, 15.0, 17.5, 20.0 and 22.5 µg/ml. Subsequently, the prepared standards were measured after standing for 5 min at λ_{max} as recorded in (Table 1) in each case against a solvent blank similarly prepared. A calibration curve of the absorbance against the concentration of the drug was plotted. This was shown in 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 methanolic glacial acetic acid. Then the solution was shaken for 20 min. The resulting solution was further diluted to 100 ml with methanolic glacial acetic acid 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 methanolic glacial acetic acid. The absorbance was measured at 235 nm against the blank. The amount of the drug in a sample was calculated from the calibration curve. The results are reported in Table 2.

Validation 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 (ICH guidelines., 1995) for method validation. The slope, Intercept, correlation coefficient and optical characteristic are summarised in Table 1.

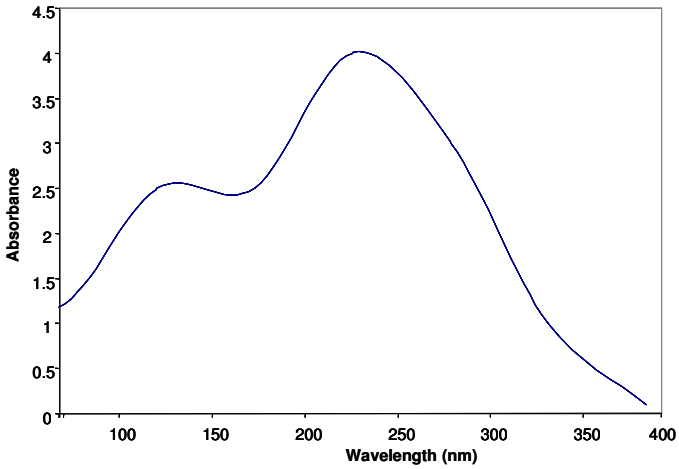

Figure 2. UV spectrum of Albendazole.

Table1. Optical characteristic of the proposed method.

Parameters	Values
λ max, nm	235
Beer's law limit, µg/ml	2.5-20
Molar absorptivity, $Lmol^{-1}cm^{-1}$	1.0820×10^4
Range of errors, %	-0.25-0.36
Regression equation, slope(b)	0.0310
Intercept(a)	0.00067
Correlation coefficient (r)	0.9998
T - value(2.55)[b]	1.29
F - value	2.68(2.55)

[a] Y= a + bc c is the concentration in µg/ml [b] . Values in parentheses are the theoretical values for t and F values at 95% confidence and five degree of freedom

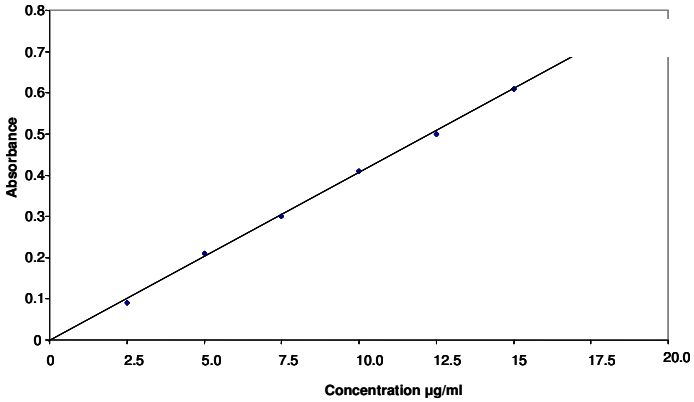

Figure 3. Calibration curve of Albendazole

Precision

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

Table 2. Results of assay of Albendazole of the different brands in solid dosage and suspension forms.

Brands	Forms	Label Claim(mg, mg/ml	*Found(mg, mg/ml) ±S.D	%RSD
A	Tablet	200	194.24 ± 0.553	0.206
B	Bolus	250	243.07 ± 0.512	0.150
C	Bolus	500	497.6 ± 0.272	0.180
D	Suspension	25	25.11 ± 0.386	0.167
E	Suspension	25	24.60l ± 0.245	0.170

*Average of 3 different concentration levels.

Table 3. Assay results and precision studies.

Sample	Label amount mg/tab	Found (mg)	%Label claim* ± S.D	Precision**		
				Repeatability	Interday	Intraday
Albendazole tablet	200	200	100.54 ± 0.293	0.471	0.034	0.028

*Average of six determinations
** S.D of five determinations

Table 4. Results of recovery studies.

Weight of Albendazole taken(mg)	Total weight of excipients weighed (mg)	Recovery (mg) ± S.D	%RSD
100	10	98.23 ± 0.334	0.204
200	20	199.45 ± 0.225	0.180
300	40	292.26 ± 0.178	0.344
400	80	394.56 ± 0.392	0.432
500	100	489.34 ± 0.278	0.423

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

Interference

The effect of commonly utilized excipients in drug formulation was studied. The specificity of the method was conducted to prove that the drug is free from interference of commonly used tablet excipients. The drugs were studied in the presence of various excipients e.g. lactose, talcum powder, corn starch, magnesium stearate which were prepared in the proportion corresponding to those which are used in the final dosage form and in the mixture containing Albendazole. Suspension containing various amount of Albendazole and common suspending agents e.g. propylene glycol, Carboxylmethyl cellulose, Tween 80, Titanium dioxide were prepared in proportion corresponding to those which are used in the final suspension. The results are reported in Table 4.

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.

Accuracy

The proposed method was compared with non - aqueous method for the estimation of Albendazole pure drug. The results are reported in Table 5.

RESULTS AND DISCUSSION

It can be seen from Figure 2 that the spectrum of Albendazole has a maximum absorbance at 235 nm in methanolic glacial acetic acid. The method obeys Beer - Lambert law within the range of 2.5 - 20 µg/ml and the calibration curve showed linearity as shown in Figure 3. It can be observed from Table 1 that the slope and intercept of the equation of the regression line are 0.0310 and 0.00067 respectively. Correlation coefficient was found to be 0.9998.

The results obtained from analysis of different brands of Albendazole tablets, bolus and suspension were in good agreement with the label claims as shown in Table 2. The little difference might be due to batch variation of medicaments in tablets, bolus and suspension, instrumental errors or degradation of active ingredients with time. The precision of the method was investigated by repeatability. The accuracy and precision of the proposed method were established by performing intraday and interday assays by analysing formulation for six days subsequently and six times in same day. The standard deviations obtained by both methods (Table 3) are acceptable (that is within the permissible bias range) and

Table 5. Comparison of proposed method with non - aqueous titration method in determination of Albendazole pure drug.

SPECTROPHOTOMETRIC METHOD			NON - AQUEOUS TITRATION METHOD	
Quantity weighed mg)	Quantity Found(mg)	Recovery (%)	Quantity Found (mg)	Recovery (%)
100	99.13	99.13 ± 0.324	98.56	98.56 ± 0.456
200	197.34	98.67 ± 0.245	194.32	97.16 ± 0.256
300	294.12	98.04 ± 0.256	292.32	97.44 ± 0.544
400	394.32	98.58 ± 0.364	399.34	99.83 ± 0.311

therefore considered to be satisfactory (Annapurna et al., 2009). The high percentage recoveries obtained in Table 4 for various amounts of Albendazole in formulated mixture with excipients suggested that there is no interference from any of the excipients (such as starch, lactose, titanium dioxide and magnesium stearate) as evidenced by the lack of absorbance at the specified λ_{max} for the excipients and blank solutions. It was observed that the % recovery increased with concentration which can be attributed to the detector (Williams, 1977) and the usual variation of absorbance with concentrations (Abdou, 1990). The results obtained were reproducible with low % RSD values.

The results reported in Table 5 when the proposed method was compared with non - aqueous method for the estimation of Albendazole pure drug compared favourably with non - aqueous method. The non - aqueous method is generally adopted for the analysis of nitrogen - containing heterocyclic compounds when used as the basis for comparison. No difference was obtained in the spectrum of prepared standard solution of Albendazole and the standard stock solution stored at different condition of ±4° C and ambient temperature for one month (Thangabalan et al., 2009)

CONCLUSION

A method for the estimation of Albendazole in pure drug, solid and suspension dosage forms has been developed. From the spectrum of Albendazole as shown in Figure 2, it was found that the maximum absorbance was 235 nm in methanolic glacial acetic acid. A good linear relationship (0.998) was observed in the concentration range of 2.5 - 20 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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