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Quantification of Albendazole in Dewormer Formulations in the Kenyan market

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ABSTRACT

In this study, the amount of active ingredient, Methyl [5-(propylthio)-2-benzimidazolecarbamate] (albendazole) in dewormer formulations was quantified using High Performance Liquid Chromatography (HPLC) and Ultra–Violet/ Visible (UV/ Vis) Spectrophotometer. Dewormer samples were obtained from various drug stores in Nairobi city. The analyses results indicated that in a number of cases the concentrations of albendazole differed with that indicated on the manufacturers' labels. In two cases the concentration of albendazole grossly differed from other samples.

Key words: Albendazole, dewormer formulation, HPLC, UV/ Vis Spectrophotometer.

INTRODUCTION

Albendazole is a member of benzimidazole compounds used as a drug indicated for the treatment of a variety of worm infestations. Abendazole contains not less than 98 percent and not more than 102 percent of $C_{12}H_{15}N_3O_2S$ calculated on dried mass (USP/ NF) and is used to treat infections of tapeworms or other parasites like, whipworms, flat worms, flukes, hookworms, and roundworms. Some medicines interact with albendazole such as *cimitedine*, dexamethasone, praziquantel and theophylline. It is prepared as an oral suspension and as a tablet [Schipper *et al*.]

Albendazole was first marketed as an animal anthelmintic, in the UK in November of 1977 and was found to be considerably more active than other benzimidazoles. It was eventually approved for human use and marketing in 1987 [Horton]. It is a vermicidal and causes degenerative alterations in the tegument and intestinal cells of the worm by binding to the colchicine-sensitive

site of tubulin. It inhibits its polymerization or assembly into microtubules thus impairing uptake of glucose by the larval and adult stages of the susceptible parasites, and depletes their glycogen stores. In order for the parasite (helminth) to survive it requires adenosine triphosphate (ATP) to produce energy, which is decreased due to the action of the albendazole. Albendazole also inhibits the enzyme fumarate reductase, which is helminth-specific. This action affects the microtubules due to the decreased absorption of glucose and in the same way the parasite is immobilized and eventually dies [Horton].

Many regulatory bodies come across a number of counterfeit and substandard albendazole based dewormers. Kenya Bureau of Stanadards is blamed for laxity in dealing with counterfeits and this leads to loss of revenue by the government [Ngumbao]. The substandard albendazole based dewormers are ineffective and do not cure or control the high rate of infections [Parmar and Jadav].

The object of this study was to investigate the concentration of the albendazole in various dewormer formulations found in the Kenyan market.

MATERIALS AND METHODS

Sampling of albendazole-based dewormers

Samples of albendazole based dewormers were purchased from various drug stores in and around Nairobi city. A reference sample was purchased from Nerix Pharmaceuticals ltd, Nairobi, and was used as a working standard.

Determination of albendazole by UV-VIS

0.1ml of the different samples (zentel, valzaben, albanex (1) ,albanex (2), albanex (3), almex, albaxate and wozel) were pipetted into a 10.0 ml volumetric flask. 3.0 ml of formic acid was then added and topped to the mark using distilled water 0.10g of the albendazole working standard was weighed into a 100.0 ml volumetric flask; 30.0ml of formic acid was added and topped to volume using distilled water to make 1000 ppm. Concentrations of 10 ppm, 20 ppm, 40 ppm, 60 ppm, and 80 ppm of albendazole were prepared by serial dilution of the stock solution.

The absorbance of the working standards and the samples were measured in a double beam UV/ Vis spectrophotometer (Shimadzu) at 288 nm using 10mm quartz cuvettes. The albendazole levels in the samples were calculated from the regression equation of the best line of fit of the standards.

Quantitative analysis of albendazole using HPLC

Acidified methanol was used to dissolve dewormer and standard albendazole sample prior to analyses by HPLC, The diluent was made by dissolving 0.990 methanol (Sigma-Aldrich, UK) in 10 ml analar HCl and topped to 1000ml (BP, 2007). 0.10g of an accurately weighed quantity of USP albendazole working standard was dissolved in acidified methanol to obtain a stock solution having a known concentration of 1000 ppm. An accurately measured volume of this stock solution was serial diluted with mobile phase (11.0 g monobasic sodium phosphate in 800 ml water, diluted by 1200 ml methanol) to obtain solutions standard solutions of 10ppm, 20ppm,

40ppm, 60ppm and 80 ppm. Equal volumes of the standard albendazole and test dewormer preparations were separately injected into the HPLC system (Stationary phase – VP – ODS), the chromatograms recorded, and the responses for the albendazole peaks measured. The concentrations of albendazole were calculated, in mg/ml.

RESULTS AND DISCUSSION

Table 1: Mean Albendazole concentration (n=3) in sampled dewormer formulations

Sample Name	Bottle Label claim (mg/ml)	HPLC method	UV/ Vis method
Zentel	25a	18.44±2.83a	26.64±1.23a
Albaxate	40a	12.78±3.54b	13.26±0.75b
Wozel	40a	13.57±3.82b	11.39±0.21b
Valzaben	25a	24.77±2.76a	27.13±1.49a
Almex	40a	48.75±8.82a	39.06±1.43a
Albanex (1)	25a	22.10±2.80a	20.46±2.02a
Albanex (2)	25a	16.97±2.31b	07.25±1.05b
Albanex (3)	25a	23.91±2.54a	20.88±1.70a

Means followed by the same letter as the label claim in a row are not significantly different at p= 0.05 with the label claim (one tailed t-test).

Table 1 shows the variation of albendazole concentration in sampled dewormers. There was variance in albendazole concentrations as claimed on the manufacturers' labels in three out of eight test samples.

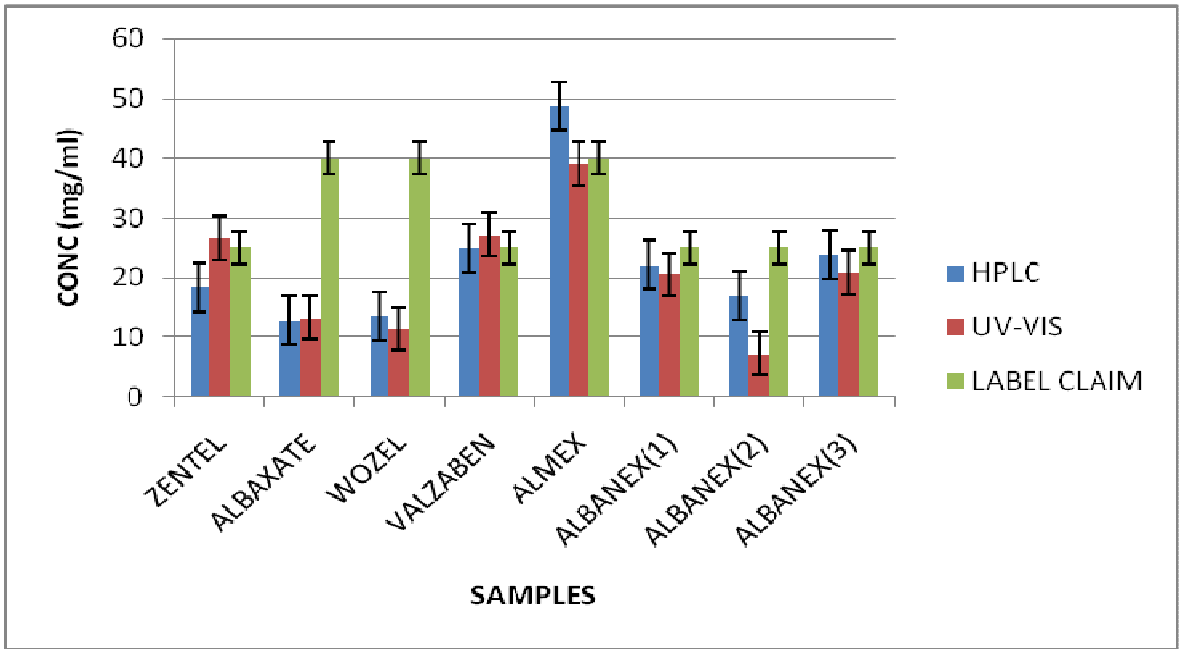
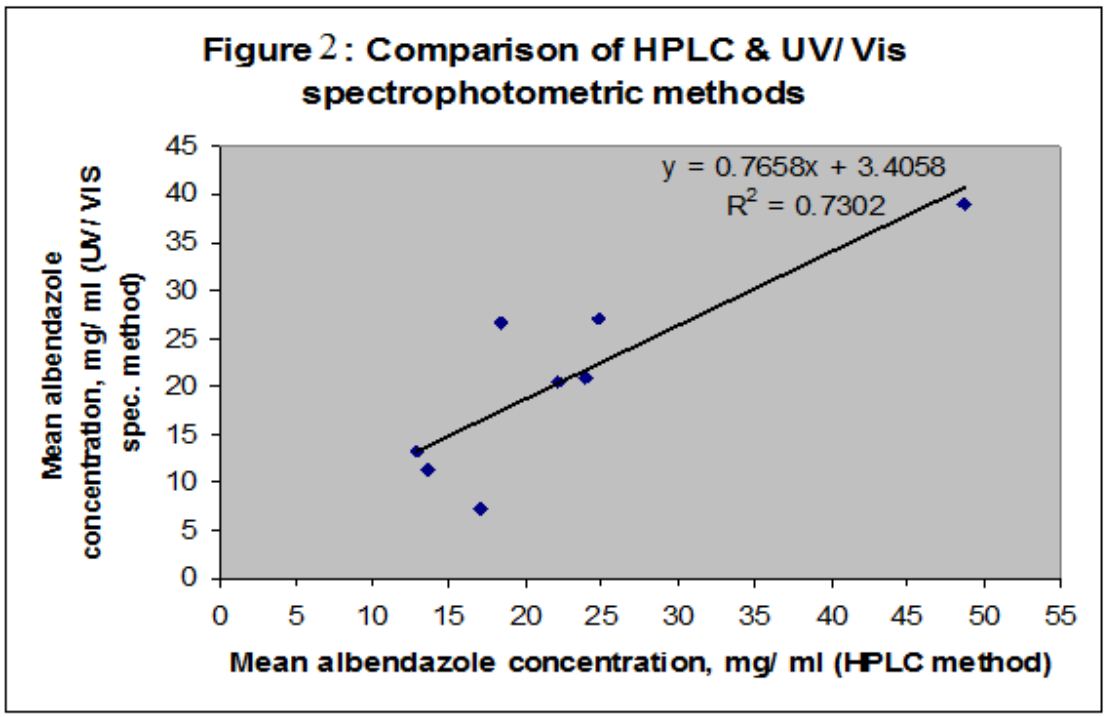


Figure 1: Comparison of mean Albendazole concentration of samples with label claims at p = 0.05.

Figure 2 showed that the two analytical methods did not give significantly different results. Three out of the eight test samples had very low concentrations of albendazole such that the concentrations indicated on the labels were misleading.



a) t critical (3.12) > t calculated on r (2.62) at p = 0.02, n = 8

A t-test on product moment correlation coefficient (r) showed that HPLC & UV/ Vis methods used to determine albendazole in dewormer formulations (Fig. 2) were not significantly different at p = 0.02. The two methods were documented for the determination of albendazole (USP/NF).

From table 1 and figure 1, the concentration of albendazole in Albaxate shows that the HPLC and UV-Vis data compared well but the values were much lower compared with the label claim. The great difference between the experimental results and the label claim may suggest that lower concentration of the active ingredient was used in formulating the product contrary to the label claim. The concentration of albendazole in Wozel also indicated a great difference between the label claim and the analytical results obtained. This showed that the concentration of the active ingredient was grossly underestimated. Albanex (2) had been stocked for four years and hence had expired. The results obtained for albendazole concentration in this sample indicated that the amount of the active ingredient used had changed. Products that have exhausted their shelf life should not be stocked since they are no longer effective.

Zentel, Valzaben, Almex, Albanex (1) and Albanex (3) showed good agreement between the experimental results and label claims (Table 1 & Figure 1). This showed that the correct concentration of the active ingredient was incorporated in their formulations by the manufactures. Only five out of the eight (62.5%) samples under consideration passed the label claim conformity test. This was proof of the great number of counterfeits and/ or expired dewormers that find their way to the hands of unsuspecting consumers. According to Parmar and

Jaday, substandard albendazole based dewormers are ineffective. Such products would lead to under-dosage administration of the drug to animals or humans and consequently drug resistance and/or toxicity.

CONCLUSION

There was a clear indication that whereas the concentration of albendazole in some dewormer products matched with the label claims, others did not. This indicated that some dewormer products not approved by the standards regulatory authority (Kenya Bureau of Standards) or other regulatory bodies found their way into the Kenyan market.

The current research finding shows a great need for the Kenyan government through the regulatory bodies to control the presence of counterfeit products in order to protect consumers from effects of under doses and exploitation by unscrupulous businessmen.

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REFERENCES

[1] British Pharmacopoeia (BP) **2007**
[2] Horton J, *Fundamental & Clinical Pharmacology*, **2003**, 17(2): 205-212
[3] Ngumbao Kithi , Standard business-3rd , August **2009,** pp 20
[4] Parmar D, Jadav S, *Indian Journal of Pharmacology*, **2005**, pp37
[5] Schipper HG, Koopmans RP, Nagy J, Butter JJ, Kager PA Van Boxtel CJ, *American journal of tropical medicine and hygiene*, **2000**, 63(5): 270-273
[6] USP/NF: United States Pharmacopoeia / National Formulary USP 30-NF25