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Research Article

Comparative Quality Evaluation of Different Brands of Albendazole Tablets Marketed in India

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Abstract: Anthelmintic drugs are primarily used to treat parasitic infections. More than 1.5 billion individuals, or 24% of the world's population, were estimated to be infected by soil-transmitted helminths. Pharmaceuticals are essential for preserving human health and fostering happiness. However, it is vital to determine the drug's safety, efficacy, and quality to provide the intended pharmacological effect. The drugs must have the necessary physical properties and the correct quantity of active pharmaceutical ingredient (API) to be effective. The quality of various brands of albendazole tablets sold in India was assessed qualitatively and quantitatively in this study. The current study aims to investigate the physicochemical comparability of three different brands of albendazole containing tablets obtained from several retail pharmacies in Agra, Uttar Pradesh, India. The Indian Pharmacopeia standards were used as a control to evaluate the identity and content of the API in the tablets. The tablet's uniformity of weight, friability, hardness, thickness, rate of dissolution, and content analysis were assessed using an assay. Ultraviolet-Visible Spectroscopy (UVS) was used to identify and evaluate Indian Pharmacopoeial standards. All *in vitro* evaluation tests showed that all three tablet brands complied with the Indian Pharmacopoeial standards. The quantity of albendazole released from the various brands did not differ noticeably. These findings showed that the tablets of albendazole sold in retail stores in Agra are produced and marketed by Indian firms that have received WHO-GMP certification. On the bioequivalence of these tablets, more research is suggested.

Keywords: Albendazole Tablet, Indian Pharmacopoeia, WHO-GMP, Physicochemical Equivalence, In-Vitro Evaluation

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1. INTRODUCTION

A sizeable fraction of the world's population is impacted by Helminthes infections, the most common human infection. The drugs known as anthelmintics are used without discrimination to treat parasite illnesses. These drugs kill or render comatose parasitic worms, which eliminates them. Flatworms like flukes (trematodes), tapeworms (cestodes), and roundworms (nematodes) are examples of parasitic worms[1]. More than 1.5 billion individuals, or 24% of the world's population, were estimated to be infected by soil-transmitted helminths. While these illnesses are present in tropical and subtropical regions, most are in sub-Saharan Africa, the Americas, China, and East Asia[2]. Many anthelmintics have been created thus far to combat this, but albendazole is among the most significant benzimidazole derivatives with various anthelmintic activities. Albendazole has a good track record of efficacy in treating the most prevalent forms of intestinal helminths found in people. It acts against *A. lumbricoides* and *E. vermicularis* in a single dose, just as other anthelmintics, but it also works against both species of hookworms. No severe or life-threatening cases of intestinal helminth infections were documented, and all known cases appear to be moderate and self-limiting[3]. It has the chemical formula $C_{12}H_{15}N_3O_2S$, which stands for methyl 5-(propylthio)-2-benzimidazolecarbamate (Figure 1). It functions by preventing the parasites from absorbing glucose. As a result, glycogen stores are used up, which results in a drop in adenosine triphosphate levels. After losing its ability to float, the parasite dies. When taken orally, it is quickly absorbed and transformed into sulfoxide and sulfone, which may cause the anthelmintic effect[4-6]. They eventually have tumoricidal effects on hosts and ovicidal, larvicidal, and vermicidal impacts on parasites. The most typical intestinal nematode infections treated with albendazole are ascariasis, hookworm infections, trichuriasis, strongyloidiasis, and enterobiasis. Infections with intestinal tapeworms can also be treated with it (taeniases and hymenolepiasis). However, it also has considerable therapeutic benefits in treating infections brought on by tissue nematodes and cestodes (visceral, neural, ocular, and cutaneous larva migrans, trichinosis, anisakiasis, hepatic and intestinal capillariasis, dracunculiasis, gongylonemiasis, angiostrongyliasis, gnathostomiasis, thelaziasis, cerebral and subcutaneous cysticercosis, and echinococcosis). To treat filarial diseases, ivermectin or diethylcarbamazine may also be used with albendazole. Albendazole is used to treat illnesses caused by trematodes and protozoa. Interestingly, albendazole has been used in a new way to treat cancer. These drugs successfully treat liver, lung, ovary, prostate, colorectal, breast, head and neck, and melanoma malignancies. Although the drug is often safe and rarely causes side effects if taken for longer than 14 to 28 days or even only once, liver damage and other adverse effects may appear[7-10]. The oral route is the most common and simple way to administer drugs. For youngsters who haven't mastered taking tablets, it could be challenging. As a result, chewable albendazole tablets are useful for improving children's compliance. Chewable tablets must be broken and consumed in between the teeth before ingestion. These tablets are provided to those who find swallowing unpleasant and children who have trouble swallowing. The advantages of chewable tablets include being pleasant, stable, exact in dosage, portable, and easy to use. As a result, chewable tablets provide a secure, well-tolerated alternative to traditional paediatric drug formulations for children two years of age and older[11-15].

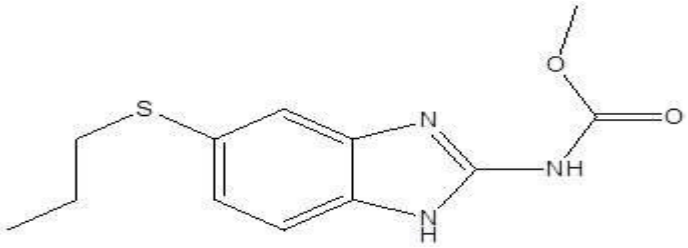

Fig 1: Albendazole chemical structure

2. MATERIALS AND METHODS

2.1 Design of the study

The current study aims to determine whether three brands of tablets containing albendazole marketed in India are physicochemically equivalent. The tablet's uniformity of weight, friability test, hardness, thickness, rate of dissolution, and assay-based content analysis was all assessed.

2.2 Sample collection and identification

Three commercial brands of 400 mg albendazole tablets were easily obtained from Agra, India, pharmacies. All of the tablets were chewable, uncoated tablets. Before the investigation, all of the collected tablets were stored in accordance with the manufacturers' recommendations. From 10 November to 20 December 2013, study samples were collected from the retail pharmacies in Agra, Uttar Pradesh, India (Table 1).

2.3 Materials

2.3.1 **Table***Chemicals*

0.1M Methanolic hydrochloric acid solution, 0.1 M Sodium hydroxide solution, Distilled Water.

2.3.2 Instruments

Pfizer Hardness tester, Friability test apparatus I.P., Dissolution test apparatus I.P., Electronic balance, U.V Spectrophotometer (Shimadzu 1800).

2.3.3 Glasswares

Volumetric flask, beaker, pipette, measuring cylinder, conical flask, Test tube, test tube stand etc.

Table 1: Details of Albendazole uncoated chewable tablets used for comparative study

S. No.	Brand Name	Manufacturer	Batch No.	Mfd. Date	Expiry Date	MRP (in Rs.) per tablet
1	Olworm	Biochem Pharmaceuticals Ltd. New metro theatre, Mumbai- 400002, India.	BD-11568	12/11	11/14	14.58/-
2	Troyzole	Troikaa Pharmaceuticals, ltd. Thol-382-728 Gujarat, India.	MTTZ-1301	05/13	04/16	17.00/-
3	Ridkil-400	Ridley Life Science Private Ltd. An ISO-9001-2000 Certified copy D-1615, D-SIDC, Industrial complex, Narela, Delhi-110040	TRDK-1302	07/13	06/16	9.94/-

Table 1 illustrates brand name and manufacturer details with batch number, manufacturer date, expiry date, and price rate of Albendazole uncoated chewable tablets used for the comparative study.

2.4 Methods

2.4.1 Quality evaluation processes

In the current investigation, various analytical quality control procedures were used to evaluate the brands of albendazole tablets. Some of these tests were

2.5 Weight Variation

Each of the twenty tablets was weighed separately and collectively. From the combined weight of all tablets, the average weight was determined. The average weight was contrasted with the individual weights. The following formula was used to determine the per cent deviation

[(Individual weight - Average weight) / Average weight] 100 is the formula for percentage variation.

Five per cent deviation is the required acceptance threshold for uncoated chewable tablets containing 250 mg or more as per I.P.[16-17]

2.6 Hardness Test

Pfizer's hardness tester was used to measure the tablets of albendazole's hardness. The same idea behind how a set of pliers works also applies to this tester. The tablet can only be broken with kilos of force. It was calculated and stated that the typical tablet hardness was [16].

2.7 Friability Test

Ten whole tablets were sampled, and they were meticulously dedusted. First, ten tablets were carefully weighed and turned 100 times in the drum. The tablets were taken out, cleaned of loose dust, and precisely weighed. Three times the test was administered, and the mean of the three results was calculated. For most tablets, a maximum weight loss of not more than 1.0 per cent (from a single test or the average of the three tests) is allowed[16].

2.8 Dissolution test

Utilizing the I.P. dissolution apparatus, a dissolution test was conducted. The dissolution media, which included 900 ml of 0.1M hydrochloric acid, was rotated at 50 rpm while remaining at a constant temperature of 37± 0.5 ^{0}C. At intervals of 10 minutes, 20 minutes, and 30 minutes, aliquots were drowned and replaced by adding an equal volume of new dissolution medium. The samples were properly diluted, and a UV spectrophotometer was used to measure the solution's absorbance at its maximum wavelength, around 309 nm[16].

2.9 Assay

2.9.1 Preparation of calibration curve

100mg of Albendazole was weighed and dissolved into 100 ml methanol to form the primary standard (1mg/mL). Next, 10 mL of the primary standard was diluted with methanol: HCl solution (70:30 ratio) to prepare the secondary standard (100 mL, 100 µg/mL). 0.5 mL, 1 mL, 1.5 mL, 2 mL, 2.5 mL and 3 mL of secondary solution were diluted with methanol: HCl solution (70:30 ratio) up to 10 mL to give 5 µg/mL, 10 µg/mL, 15 µg/mL, 20 µg/mL, 25 µg/mL and 30 µg/mL standard solution. The UV-spectrophotometric absorbance of these solutions was measured at 309 nm (λmax).

2.9.2 Sample preparation

Weighed and powdered 20 tablets of albendazole. Accurately weighed powder containing around 0.1 g of albendazole was added along with 150 ml of 0.1M methanolic 0.1M hydrochloric acid (70:30), which was then agitated for 15 minutes before being diluted to 250.0 ml. Filtered through the Whatman filter paper (#41) and blended it. 5.0 ml of the filtrate was diluted with 0.1M sodium hydroxide to make 250.0 ml. Using a UV Spectrophotometer, the absorbance of the standard and the resultant solution was determined at its maximum wavelength, around 309 nm. Utilizing a calibration curve that had been constructed, calculated the Albendazole content[17].

3. STATISTICAL ANALYSIS

To examine the weight uniformity, hardness, friability, disintegration and dissolution times of albendazole tablets from each brand, the mean and standard deviation (SD) for each parameter were calculated using Microsoft Excel 2007.

4. RESULTS & DISCUSSION

The physical characteristics of three distinct brands of chewable albendazole without a coating were examined, including their hardness, friability, uniformity of weight, dissolution, and assay. The common appearance of all brands was sunset yellow. Each brand has a circular, biconvex form that is slightly bent. For all of the tablets, the hardness was between 3.2 and 9.6 kg/cm^2, indicating good mechanical strength (Table 6). All tablets had a percentage of friability between 0.30 and 0.40 per cent; a number below 1% indicates a tablet with strong mechanical resistance (Table 5). The

average weight of the three branded tablets, Ridkil-400, Olworm, and Troyzole, was 0.789 g, 0.979 g, and 0.986 g, respectively. The allowable deviation was 5% (Table 2, 3, 4). It was found that the weight of every tablet, regardless of brand, was uniform and within the allowable range. A calibration curve was plotted between drug concentration (x-axis) and absorbance (y-axis). The regression equation and regression coefficient value were determined from the curve (Figure 2). Olworm, Troyzole, and Ridkil-400, respectively, all three products' *in-vitro* release of albendazole were determined to be 95.09%, 97.08%, and 100% at 30 minutes (Table 7 & 8) (Figure 3). As a result, each tablet brand's albendazole content complies with I.P. Similar results were observed by Othman[18] (2017) and Gebrezgabiher[19] *et al.* (2015) in their study.

Table 2: Weight Variation of *Olworm* Brand Albendazole Tablets.

Weight of Individual Tablet (gm)	Percentage Deviation (%)	Average Weight of 20 Tablets (gm±SD)
0.98	0.00	0.980±0.007
0.988	0.82	
0.991	1.12	
0.973	-0.71	
0.976	-0.41	
0.977	-0.31	
0.988	0.82	
0.977	-0.31	
0.966	-1.43	
0.98	0.00	
0.972	-0.82	
0.983	0.31	
0.989	0.92	
0.987	0.71	
0.973	-0.71	
0.98	0.00	
0.986	0.61	
0.983	0.31	
0.982	0.20	
0.967	-1.33	

Table 2 illustrates the weight of individual tablets, the average weight of 20 tablets and the percentage deviation with a standard deviation of Olworm brand Albendazole tablets. The average weight of all the tablets was found to be 0.980±0.007 g. The allowable deviation was 5%. It was found that the weight of every tablet, regardless of brand, was uniform and within the allowable range.

Table 3: Weight Variation of *Troyzole* Brand Albendazole Tablets.

Weight of Individual Tablet (gm)	Percentage Deviation (%)	Average Weight of 20 Tablets (gm±SD)
0.992	0.51	0.987±0.026
1.005	1.82	
0.97	-1.72	
0.981	-0.61	
1.005	1.82	
0.98	-0.71	
1.025	3.85	
0.978	-0.91	
0.997	1.01	
1.043	5.67	
0.979	-0.81	
0.954	-3.34	
0.993	0.61	
0.992	0.51	
0.993	0.61	
0.993	0.61	
0.98	-0.71	
0.917	-7.09	
0.996	0.91	
0.958	-2.94	

Table 3 illustrates the weight of individual tablets, the average weight of 20 tablets and the percentage deviation with a standard deviation of Troyzole brand Albendazole tablets. The average weight of all the tablets was found to be 0.987±0.026g. The allowable deviation was 5%. It was found that the weight of every tablet, regardless of brand, was uniform and within the allowable range.

Table 4: Weight Variation of *Ridkil-400* Brand Albendazole Tablets.		
Weight of Individual Tablet (gm)	**Percentage Deviation (%)**	**Average Weight of 20 Tablets(gm±SD)**
0.808	2.28	0.790±0.025
0.806	2.03	
0.802	1.52	
0.797	0.89	
0.805	1.90	
0.803	1.65	
0.807	2.15	
0.801	1.39	
0.804	1.77	
0.802	1.52	
0.805	1.90	
0.799	1.14	
0.795	0.63	
0.803	1.65	
0.707	-10.51	
0.769	-2.66	
0.777	-1.65	
0.782	-1.01	
0.76	-3.80	
0.759	-3.92	

Table 4 illustrates the weight of individual tablets, the average weight of 20 tablets and the percentage deviation with a standard deviation of Ridkil-400 brand Albendazole tablets. The average weight of all the tablets was found to be 0.790±0.025g. The allowable deviation was 5%. It was found that the weight of every tablet, regardless of brand, was uniform and within the allowable range.

Table 5: Friability test for branded tablets.						
S. No.	**Name of Brand**	**Initial weight of 10 tablets (g)**	**Final weight of 10 tablets (g)**	**Average weight**		**Friability (%)**
				Initial (g) ±SD	**Final** (g) ±SD	
1	Olworm	9.98	9.96	9.96 ±0.02	9.92 ±0.04	0.40
		9.96	9.92			
		9.95	9.90			
2	Troyzole	9.98	9.95	9.98 ±0.01	9.94 ±0.02	0.40
		9.99	9.96			
		9.97	9.93			
3	Ridkil-400	9.96	9.92	9.95±0.04	9.92 ±0.04	0.30
		9.99	9.95			
		9.92	9.89			

Table 5 illustrates the average weight of 10 tablets and the percentage friability with a standard deviation of Olworm, Troyzole, and Ridkil-400 Albendazole tablets. All tablets had a percentage of friability between 0.30 and 0.40 per cent; a number below 1% indicates a tablet with strong mechanical resistance.

Table 6: Hardness test for branded tablets			
S. No.	**Olworm (kg/cm^2±SD)**	**Ridkil-400 (kg/cm^2±SD)**	**Troyzole (kg/cm^2±SD)**
1	7.5±0.3	5.4±0.2	3.2±0.3
2	8.4±0.1	6.2±0.3	4.5±0.3
3	7.3±0.2	5.5±0.1	4.5±0.1
4	9.6±0.2	5.2±0.1	3.4±0.2
5	8.2±0.1	4.6±0.2	3.6±0.2
6	7.3±0.3	7.2±0.2	4.3±0.2

Table 6 illustrates hardness in kg/cm^2 with a standard deviation of Olworm, Troyzole, and Ridkil-400 Albendazole tablets. For all of the tablets, the hardness was between 3.2 and 9.6 kg/cm^2, indicating good mechanical strength.

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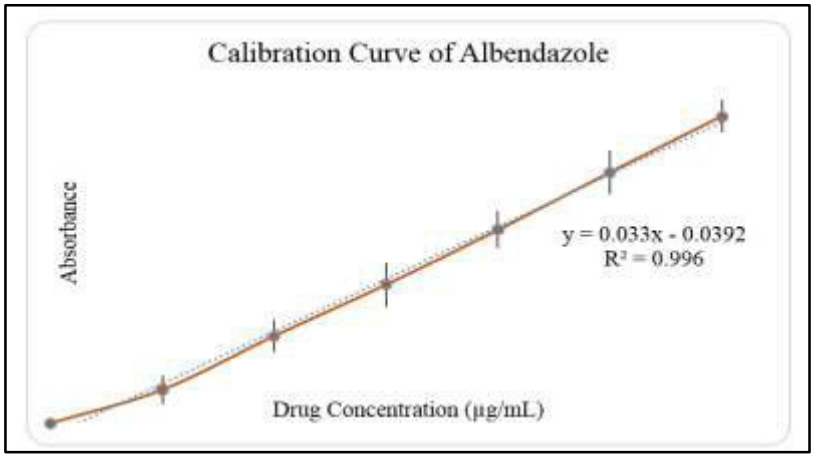
Table 7: Dissolution test for Branded tablets					
S. No.	Name of Brand	Time (minutes)	Absorbance (nm)	Drug release (mg)	Drug content (%±SD)
1	Olworm	10	0.453	61.280	15.32±5.42
		20	2.127	318.049	79.51±4.61
		30	2.680	380.786	95.19±5.15
2	Troyzole	10	0.563	77.29	19.32±4.05
		20	2.100	301.01	75.25±6.34
		30	2.780	388.35	97.08±4.15
3	Ridkil-400	10	0.632	87.33	21.83±7.23
		20	2.120	303.93	75.98±3.24
		30	2.802	400	100±6.34

Table 7 illustrates details of the dissolution test along with absorbance, drug release, and drug content with a standard deviation of Olworm, Troyzole, and Ridkil-400 Albendazole tablets. For all three brand tablets, the in-vitro release of albendazole was determined to be 15.32±5.42%, 19.32±4.05%, and 21.83±7.23% at 10 minutes, 79.51±4.61%, 75.25±6.34%, and 75.98±3.24% at 20 minutes, 95.19±5.15%, 97.08±4.15%, and 100±6.34% at 30 minutes respectively.

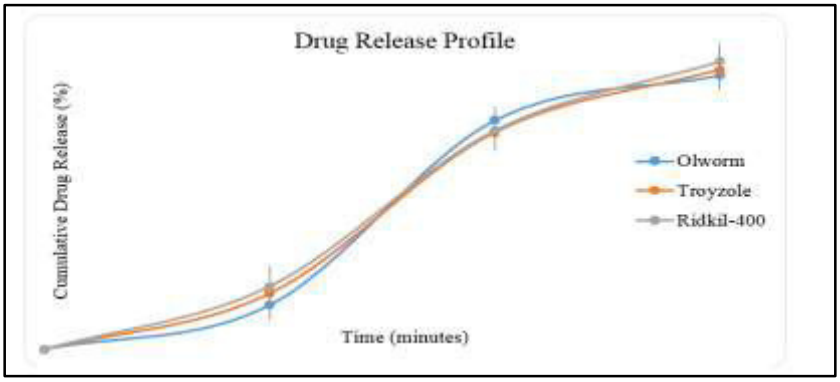
Table 8: Drug content analysis (Assay) for Branded tablets			
S. No.	Brands	Absorbance (nm)	Drug Content (%±SD)
1	Olworm	0.228	99.06±3.25
2	Troyzole	0.226	98.05±2.25
3	Ridkil-400	0.227	98.55±3.15

Table 8 illustrates Drug content analysis (Assay) along with absorbance and drug content with the standard deviation of Olworm, Troyzole, and Ridkil-400 Albendazole tablets. For all three brands, Olworm, Troyzole, and Ridkil-400 tablets in-vitro release of albendazole was determined to be 99.06±3.25%, 98.05±2.25%, and 98.55±3.15%, respectively.



After scanning the over UV range, maximum absorbance was recorded at 309 nm (λmax). The calibration curve was plotted between drug concentration (x-axis) and absorbance (y-axis). The regression equation and regression coefficient values were determined from the curve.

Fig 2: Calibration (standard) curve of Albendazole in methnolic HCl (70:30).



In-vitro release of albendazole form tablets of Olworm, Troyzole, and Ridkil-400 brands were determined to be 95.09%, 97.08%, and 100% at 30 minutes

Fig 3: *In Vitro* Dissolution Profiles of Three Brands of Albendazole tablets.

5. CONCLUSION

All three brands passed all of the official I.P. tests. However, the observed dissolution profiles can differ from one manufacturer to the next due to formulation additives in the tablet, the physical form of the drug in the tablet, and manufacturing processes.

6. AUTHORS CONTRIBUTIONS

Mukesh Kumar Kumawat - The sample collection conceived the study, verified the methodologies, carried out the laboratory analysis and data analysis and authored the final version of the manuscript.Gufran Ajmal - The laboratory analysis and participated in the data analysis, Drafting and revision of the manuscript.Heena Jindal - Carried out the laboratory work, Drafting and revising the manuscript. The finished manuscript has been read and approved by all authors.

7. CONFLICT OF INTEREST

Conflict of interest declared none.

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