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EVALUATION OF VARIOUS BRANDS OF ALBENDAZOLE IP FOR ITS QUALITY CONTROL TEST

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ABSTRACT

Albendazole is a Anthelmintic drug used to Broad spectrum Anthelmintic agents, it is the drug of choice for treatment of Hydatid disease and Cysticercosis. It is also used in the treatment of Pin worm, Hook warm, Round warm whip warm and thread warm. Albendazole (ABZ) is a benzimidazole derivative that has been widely used in the treatment of worm infestations in both humans and animals.The drug absorption varies in different patients from the gut. Selected brands of Albendazole IP 400mg were procured from the market with the same label claim amount of drug for quality control test. Various quality control tests such as weight variation, friability, disintegration, dissolution were performed as per Indian Pharmacopeia. The quality control tests were done for five different brands of Telmisartan IP marketed Products. The result proved that the Albendazole IP Tablets 400mg, varies with disintegration, dissolution, uniformity content tests but within the limit. Further studies are needed to support the variation in the quality control test with human volunteers.

KEYWORDS: Albendazole, broad spectrum Anthelmintic agents, Drug absorption, Quality control tests.

1. INTRODUCTION

Albendazole is a Anthelmintic drug used to Broad spectrum Anthelmintic agents, it is the drug of choice for treatment of Hydatid disease and Cysticercosis. It is also used in the treatment of Pin worm, Hook warm, Round warm whip warm and thread warm. The drug absorption varies in different patients from the gut.[1] Selected brands of Albendazole IP 400mg were procured from the market with the same label claim amount of drug for quality control test. Various quality control tests such as weight variation, friability, disintegration, dissolution were performed as per Indian Pharmacopeia. The quality control tests were done for five different brands of Albendazole IP Tablets 400mg marketed Products. The result proved that the Albendazole IP 400mg, varies with disintegration, dissolution, uniformity content tests but within the limit. Further studies are needed to support the variation in the quality control test with human volunteers.[2]

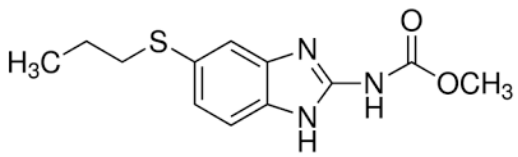

Fig No 1: Chemical Structure of Albendazole.

A. WEIGHT VARIATION TESTER

The weight of the tablet is usually determined by the quantity of powder fill in the die of a tablet press. The volume of fill is adjusted with the first few tablets to yield the desired weight and content.[3] If there is any improper flow of powder to the die, it forms the uneven tablets which contain the low dose or high dose of the drug. The percentage of deviation allowed as per IP is 10% for 80mg or less, 7.5 % for 80mg to 250mg, 5% for more than 250mg. For Albendazole IP Tablets 400mg it is 10%.[4]

B. FRIABILITY

Friability is a tablet's durability or the ability of the tablets to withstand the mechanical shocks during manufacturing, packing, handling, and shipping. It is intended to determine the physical strength of the tablet. It is one of the in-process quality control tests for tablets.[5] The maximum loss of percentage allowed as per IP is 1%. For Albendazole IP Tablets 400mg of various brands, the average is found to be 0.8%.

Friability = (W1-W2/W1) *100

Where as W1= weight of the tablets before test

W2= weight of the tablet after test

C. DISINTEGRATION

Disintegration is the mechanical break up of a compressed tablet into small granules upon ingestion and therefore it is characterized by the breakdown of the inter particulate bonds, which were forged during the compaction of the tablet. It is the state in which no residue of the unit under the test remains on the screen of the disintegrating Apparatus. For uncoated tablets, the

time needs to disintegrate is 15 minutes as per IP. For Albendazole IP Tablets 400mg tablets it varies in the brand but they are within the limit.

D. HARDNESS

Hardness is a force required to break a tablet across the diameter. The hardness of a tablet is an indication of its strength. The hardness was measured using Monsanto Hardness tester. The values were expressed in Kg/cm2.[6]

E. DISSOLUTION

Dissolution is the amount of drug that goes into the solution per unit time. It demonstrates that the drug will be readily available for absorption after oral administration during dissolution, the drug molecules in the surface layer dissolve, which leads to a saturated solution around the particles. dissolved drug molecules then pass through out the dissolving fluid to contact absorbing mucosa and are absorbed. **Figure No: 2** explains the dissolution process in detail. It is usually performed to maintain the batch to batch consistency of tablets in the pharmaceutical industry.

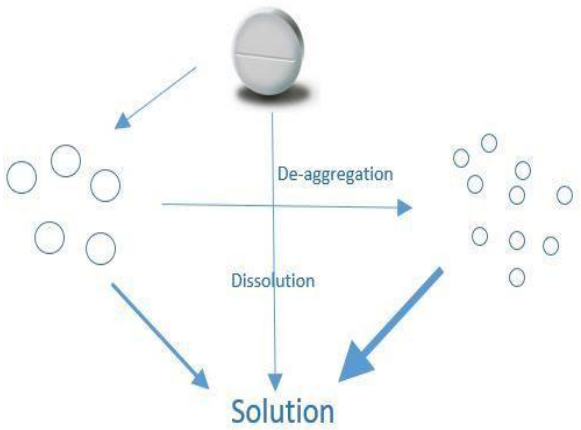

Fig No 2: Dissolution Studies.

2. MATERIALS AND METHODS

Various marketed brand of Albendazole tablets were chosen for the experiment.

1. Bandy 400mg
2. Bendex 400mg
3. Dispel 400mg
4. Zentel 400mg
5. Zeebee 400mg

A. WEIGHT VARIATION

Weigh individually 20 units of selected Albendazole tablets at random, and calculate its average weight. Not more than two of the individual weights deviate from the average weight by more than the percentage which stated in the IP and none deviates by more than twice that percentage.[5]

Instrument Used: Digital Weighing Balances.

B. FRIABILITY

Take the Albendazole tablets and dedust the tablets carefully, weigh them accurately to 10 Tablets, Then the weighed tablets are placed in the drum and rotate the drum in 100 times rotation or set the RPM to 25 for 4 minutes. At the end of operation remove all the tablets and ensures that the tablets are free from the dust and weigh them accurately, determine the percentage loss.

Instrument Used: Roche's Friability.

DISINTEGRATION TEST

Disintegration test was carried out by using Disintegration test apparatus. One tablet is placed in each tube, and the basket rack was positioned in a 1liter beaker of water, at 37°C ± 2°C. A standard motor driven is used to move the basket assembly containing the tablets up and down through a distance of 5 to 6 cm at a frequency of 28 to 32 cycles per minutes. The time taken for the tablet to disintegrate completely was noted.

Instrument Used: Disintegration Tester.

V. DISSOLUTION

Table No: 1 Dissolution media preparation.

Apparatus No:	2 (IP Basket apparatus)
Medium	900 mL. 0.1 N hydrochloric acid
Speed and time :	50 rpm
Time Point	30 min
Temperature	37 ^{0}C (for both medium and water bath)

DISSOLUTION MEDIA PREPARATION

Acidified methanol: To prepare 50ml of methanol in a 100ml volumetric flask add 2 ml of HCL, dilute with methanol to volume mix.

Standard solution: Transfer about 90 mg of accurately weighed, to a 250ml volumetric flask, add 10 mL of Acidified methanol, and shake to dissolve. Dilute with 0.1 N Hcl to volume, and mix. Transfer 5.0ml of this solution to a 200-ml volumetric flask, dilute with 0.1 N sodium hydroxide to volume mix.

Procedure: Transfer 10ml of a filtered portion of the solution under test to a 250-ml volumetric flask, dilute with 0.1 N NaOH to volume, and mix. Concomitantly determine the absorbances of this solution and the Standard solution at the wavelengths of maximum

and minimum absorbance at about 249 nm, using 0.1 N sodium hydroxide as the blank.

Instrument Used: Dissolution Apparatus.

4. RESULT AND DISSCUSSION

A. WEIGHT VARIATION TEST: The weight variation of various brands of Albendazole are shown below in **Table No : 2.**

Table No 2: Weight variation studies of marketed Albendazole products.

S.No	Brand	Label Claim	Average weight of 10 tablets	Percentage of difference	Conclusion
1	Bandy 400mg	400mg	697.1	0.414	Passes
2	Bendex 400mg	400mg	654.2	0.630	Passes
3	Dispel 400mg	400mg	691.7	0.243	Passes
4	Zentel 400mg	400mg	714.5	0.633	Passes
5	Zeebee 400mg	400mg	697.5	0.375	Passes

B. FRIABILITY TESTER : The Friability tester of various brands of Albendazole are shown below in **Table No : 3.**

Table No 3: Weight variation studies of marketed Albendazole products.

S.No	BRANDS	Friability (%)
1	Bandy 400mg	0.25
2	Bendex 400mg	0.40
3	Dispel 400mg	0.11
4	Zentel 400mg	0.23
5	Zeebee 400mg	0.00

C. DISINTEGRATION: The disintegration of various brands of Albendazole is shown below in **Table No : 4**

Table No 4: Disintegration data of studies of marketed Albendazole products.

S.No	BRANDS	Disintergration Time (mins)
1	Bandy 400mg	6.30
2	Bendex 400mg	4.50
3	Dispel 400mg	6.10
4	Zentel 400mg	5.30
5	Zeebee 400mg	5.45

D. HARDNESS

Hardness of various marketed brands of Albendazole are shown below in **Table No: 5.**

Table No 5: Hardness studies of marketed Albendazole products.

S.NO	BRANDS	HARDNESS(kg/cm^2)
1	Bandy 400mg	8.6
2	Bendex 400mg	9.0
3	Dispel 400mg	7.3
4	Zentel 400mg	8.3
5	Zeebee 400mg	6.5

E. DISSOLUTION

The dissolution profile of marketed tablets like BENDEX 400mg BANDY 400mg DISPEL 400mg ZENTEL 400mg ZEEBEE 400mg are listed in the following **Table No: 6.**

Table No: 6 Drug release profile of BENDEX 400mg Tablets:

S.No	Time (min)	Abs at 249nm	Conc (mg/ml)	Dilution factor	Conc (mg/ml)	Amount In 5ml (mg)	Amount in 900ml (mg)	Cumulative amount	% Drug release
2	2	0.097	1.905	100	190	950	171.0	171.94	26.45
4	4	0.172	3.48	100	348	1740	313.2	318.09	48.93
6	6	0.292	6.002	100	600	3000	540.0	550.09	84.62
8	9	0.331	6.906	100	690.8	3454	621.7	644.13	98.42

Table No: 7 Drug release profile of BANDY 400mg mg Tablet

S.No	Time (min)	Abs at 249nm	Conc (mg/ml)	Dilution factor	Conc (mg/ml)	Amount In 5ml (mg)	Amount in 900ml (mg)	Cumulative amount	% Drug release
2	2	0.165	3.334	100	333.4	1667	300.06	300.06	46.25
4	4	0.281	5.771	100	577	2885	519.3	524.14	80.65
6	5	0.317	6.527	100	652.7	3263.5	587.43	599.15	95.17

Table No: 8 Drug release profile of DISPEL 400mg Tablets

S.No	Time (min)	Abs at 249nm	Conc (mg/ml)	Dilution factor	Conc (mg/ml)	Amount In 5 ml (mg)	Amount In 900ml (mg)	Cumulative amount	% Drug Release
2	2	0.146	2.934	100	293.4	1469.5	264.0	264.4	40.61
4	4	0.204	4.153	100	415.3	2078	373.7	375.5	57.78
6	6	0.301	6.191	100	619.1	3095.5	557.1	566.1	87.09
8	7	0.365	7.535	100	753.5	3767.5	678.1	696.4	96.54

Table No: 9 Drug release profile of ZENTEL 400mg Tablet.

S.No	Time (min)	Abs at 249nm	Conc (mg/ml)	Dilution factor	Conc (mg/ml)	Amount In 5 ml (mg)	Amount In 900ml (mg)	Cumulative amount	% Drug Release
2	2	0.240	4.972	100	497.2	2486	447.48	447.67	68.85
4	4	0.286	5.951	100	595.1	2975.5	535.59	540.9	83.19
6	6	0.336	701.48	100	701.4	3507.4	631.2	642.33	96.79

Table No: 10 Drug release profile of Zeebee 400mg Tablet.

S.No	Time (min)	Abs at 249nm	Conc (mg/ml)	Dilution factor	Conc (mg/ml)	Amount In 5 ml (mg)	Amount In 900ml (mg)	Cumulative amount	% Drug Release
2	2	0.286	5.876	100	587.6	2938	528.84	531.15	76.41
4	4	0.381	7.871	100	787.1	3935	708.39	712.25	98.86

Table No 11: Comparative drug release profiles of Albendazole Tablets.

S.No	Time	Bandy 400mg	Bendex 400mg	Dispel 400mg	Zentel 400mg	Zeebee 400mg
1	2	26.45	46.25	40.61	68.85	76.41
2	4	48.93	80.65	57.78	83.19	98.86
3	6	84.62	95.17	87.09	96.79	
4	8	98.42		96.54		

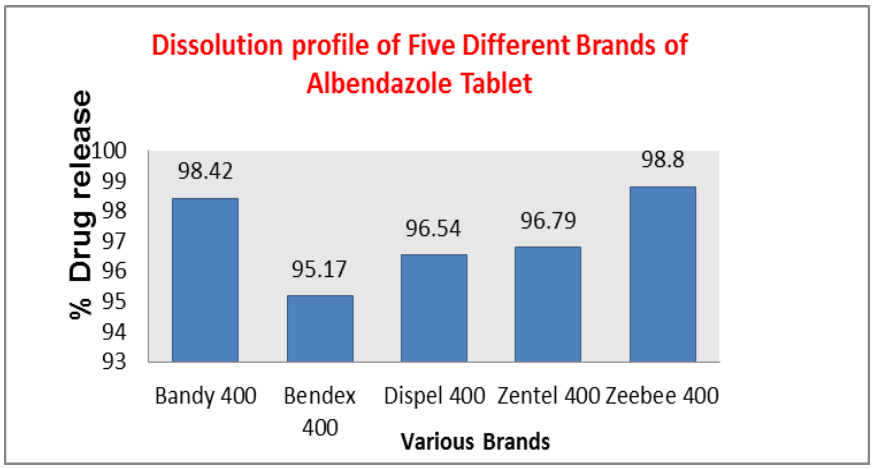

Fig No 3: Dissolution profile of Five Different Brands of Albendazole Tablets.

S.No	Brand name	Label claim	Weight variation test	Friability	Disintegration	Assay	Dissolution
1	Bandy	400mg	✓	✓	✓	✓	✓
2	Bendex	400mg	✓	✓	✓	✓	✓
3	Dispel	400mg	✓	✓	✓	✓	✓
4	Zentel	400mg	✓	✓	✓	✓	✓
5	Zeebee	400mg	✓	✓	✓	✓	✓

✓ - Pass the IP Limit
× - Fails the IP Limit

5. CONCLUSION

As a result of the evaluation study of different marketed brands of Albendazole tablets 400 mg, we have concluded that all the five brands which we have taken comply with the Indian Pharmacopeial standards. As quality control parameters are important for the desired pharmacological action of the drug, a high-quality tablet should meet all the standard quality control parameters for getting its desired therapeutic response. Here for Albendazole tablets 400 mg drugs there might be quantitative variation often exists among drugs of different brands. However, despite the variation, most of the brands are within the official limit (i.e. IP).The prescribing patterns of Albendazole should be changed depending upon the socio-economic status of the patients. In conclusion, these formulations of different brands of Albendazole tablets 400 mg were passing the Indian Pharmacopeial limit and it will produce the desired pharmacological action to the patient.

6. ACKNOWLEDGEMENT

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