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EFFECT OF DRUG RELEASE ON ALBENDAZOLE CHEWABLE TABLETS BY USING DIFFERENT FORMULATION TECHNIQUES

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ABSTRACT: In this research study, the effect of drug release of albendazole chewable tablets has been determined. The drug release is calculated by using the disintegration process, which is directly related to the hardness of tablets. The tablets are prepared by using three types of granulating methods are non-aqueous granulation, aqueous granulation, and direct compression. The tablets are evaluated by calculating different parameters such as hardness, friability, disintegration, assay, and *in-vitro* dissolution studies**.** The % drug release was determined by using U V spectrophotometry. In the three techniques and the non-aqueous granulation was the better technique for the formulation of tablets, dissolution rate, and % drug release other than aqueous granulation and direct compression method. So by this, we can say the non- aqueous technique gives immediate drug release by which the drug can be used at the time of emergency and gives relief to the patient, and the chewable tablets can use for the children easily. The present study was to prepare the chewable albendazole tablets by granulating techniques, *i.e.*, non aqueous granulation, aqueous granulation, and direct compression methods and to compare the drug release profiles of the tablets with the marketed product.

INTRODUCTION: Albendazole is a benzimidazole drug used for the treatment of a variety of parasitic worm infestations. It has low water solubility, limiting its oral absorption and resulting in a lower bioavailability [1]. So we prepared the chewable albendazole tablets [2-7]. Mainly, the chewable tablets are designed especially for children and such persons who may have difficulty in swallowing the tablets.

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These are intended to be chewed in the mouth before swallowing and are not intended to be swallowed intact and facilitate more rapid release and hence more rapid absorption of active ingredients and provide quick onset of action. Hence, we formulated the albendazole chewable tablets to improve the compliance in children and rapid action in the dissolution of the drug. The formulation of the drug product can have a significant effect on the rate of disintegration and dissolution

This includes the physiochemical properties of the active ingredients and excipients, as well as the procedures used in the production process. Two preparations that contain the same active ingredient in identical amounts do not always exert an

identical therapeutic effect. An identical effect would occur only if the released quantity of the active ingredient were identical within an equivalent period. Tablet disintegration is one part of the complex process of the release of the active ingredient from the dosage form.

MATERIALS AND METHODS

Materials: Albendazole, Sodium starch glycolate, lactose, starch, Mannitol, and all other ingredients were obtained from S D fine Chem. Ltd.

Types of equipment used were Compression machine of Create company Pvt Ltd, veriner callipers of Edison, Roche friabilator, Disintegration apparatus and Dissolution apparatus of DBK instruments, Electronic balance of Citizen scales and UV spectrophotometer of ELICO SL 244.

Methods: We employed three methods for the preparation of granules, and the amounts of all ingredients required for the tablets are shown in **Table 1.**

Nonaqueous Granulation: All the ingredients were separately weighed and sifted using mesh no. 40. Albendazole, Lactose monohydrate, Starch, and Sodium Starch Glycolate was mixed in a polybag for ten minutes. For the preparation of binder dispersion, isopropyl alcohol was taken in a beaker, stirred with a glass rod to disperse starch until no lumps were observed. Then the above dry mixture was granulated with binder solution and dried in the tray drier at the temperature of 40-50 ºC until the moisture reduces down to NMT-2%.

The dried granules were passed through mesh no. 30, Mannitol (Perlitol200) through mesh no. 30. Sodium Saccharine, Carmofine color, and pineapple flavor were passed through mesh no. 100. All these were finally added to the dried granules and blended for ten minutes. The above blend was lubricated with Magnesium stearate, Talc, Aerosil for two minutes.

Aqueous Granulation: All the ingredients were separately weighed and sifted using mesh no. 40. Albendazole, Lactose monohydrate, Starch, and Sodium starch glycolate were mixed in a polybag for ten minutes. For the Preparation of binder dispersion, purified water was taken in a beaker, stirred with a glass rod to disperse starch until no lumps were observed. Then the above dry mixture was granulated with binder solution and dried in the tray drier at the temperature of 40-500 ºC until the moisture reduces down to NMT-2%. The dried granules were passed through mesh no. 30. Then Mannitol (pearlitol200) was passed through mesh no. 30, Sodium saccharine, Carmofine, and pineapple flavor were passed through mesh no. 100. All these were then added to the dried granules and blended for ten minutes. Finally, the above blend was lubricated with Magnesium stearate, Talc, Aerosil for two minutes.

Direct Compression: All the ingredients were separately weighed and sifted using mesh no. 40. Albendazole, Lactose monohydrate, Starch, and Sodium starch glycolate Mannitol (pearlitol200) were passed through mesh no. 30. Sodium saccharine, Carmofine color, and pineapple flavor were passed through 100 mesh, and required quantities were blended for ten minutes in poly bag. Finally, the above blend was lubricated with Magnesium Stearate, Talc, and Aerosil for two minutes.

Finally, the preparation of tablets using the above three methods with the suitable ingredients by weighing of each tablet of 785mg and the powder blend was evaluated for flow properties such as bulk density, tapped density, compressibility index, Hausner's ratio, angle of repose and results are presented in **Table 2.**

Evaluation of Granules: [8-9]

Bulk Density: [10] An accurately weighed quantity of powder, which was previously passed through sieve # 40 [USP] was carefully poured into the graduated cylinder. Then after pouring the powder into the graduated cylinder, the powder bed was made uniform without disturbing. Then the volume was measured directly from the graduation marks on the cylinder as ml. The volume measured was called as the bulk volume, and the bulk density is calculated by the following formula;

Bulk density = Weight of powder / Bulk volume

Tapped Density: [10] The same measuring cylinder which was used for the bulk volume was set into tap density apparatus. The tap density apparatus was set to 300 taps drop per min and operated for

500 taps. Volume was noted as (V_a) and again tapped for 750 times, and volume was noted as (V_b). If the difference between V_a and V_b not greater than 2% then V_b is considered as final tapped volume. The tapped density is calculated by the following formula.

Tapped density = Weight of powder / Tapped volume

TABLE 1: COMPOSITION OF ALBENDAZOLE TABLETS FORMULATION

S. no.	Ingredients	NAQ	AQ	DC
1	Albendazole	410 mg	410 mg	410 mg
2	Lactose	120 mg	120 mg	120 mg
3	Starch	60 mg	43 mg	86 mg
4	Sodium starch glycolate	49 mg	49 mg	49 mg
5	Starch	25 mg	41.2 mg	-
6	Isopropyl alcohol	q.s	-	-
7	Mannitol	100 mg	100 mg	100 mg
8	Sodium saccharide	10 mg	10 mg	10 mg
9	Magnesium stearate	6 mg	6 mg	6 mg
10	Talc	6 mg	6 mg	6 mg
11	Purified Water	-	q.s	-
	Total	785 mg	785 mg	785 mg

AQ = Aqueous granulation; NAQ = non aqueous granulation; DC = direct compression

Carr's Index and Hausner's Ratio: [10] The volume of a known quantity of the granules from each batch was obtained before and after tapping. The volume before tapping was used to determine the bulk density while the volume after tapping was employed to determine the tap density mathematically. Furthermore, Hausner's quotient and Carr's compressibility index used to determine the flow and compressibility properties of granules were obtained from the equations:

Carr's index = (Tapped density – Bulk density / Tapped density) × 100

Hausner's Ratio = Tapped density / Bulk density

Angle of Repose: [11-12] The angle of repose of powder was determined by the funnel method. The accurately weighed powder was taken in a funnel. The height of funnel (h) was adjusted in such a way that the tip of the funnel just touches the apex of the heap of the powder. The powder was allowed to flow through the funnel freely on to the surface.

Evaluation of Tablets: The mechanical strength of the formulated and prepared tablets of albendazole were evaluated the parameters such as hardness, weight variation, thickness, friability, and disintegration time.

Tablet Hardness: [13] Hardness is the crushing strength of tablet, which determines the ease of handling and rigors of the transportation. For each formulation, 3 tablets were used for the study. The hardness of the tablet was determined and expressed in kg/cm^2.

Thickness: [14] The thickness of the tablets was measured using manual Vernier Calliper and expressed in mm.

Friability: [15] It is a measure of the mechanical strength of tablets. The friability of the tablet was determined using Roche Friabilator. It is expressed in percentage (%). 10 tablets were initially weighed (W_0) and transferred into the friabilator.

The friabilator was operated at 25 rpm for four mins. The tablets were weighed again (W). The percentage friability was then calculated by

$$\% F = \{(W - W_0)/W_0\} \times 100$$

Disintegration: [15] The *in-vitro* disintegration time was determined using the disintegration test apparatus. A tablet was placed in each of the six tubes of the apparatus, and one disc was added to each tube. The time in seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured in seconds. The *in-vitro* disintegration of the tablets was found to be within 15 mins**.**

Dissolution: [16] Dissolution of core tablets of albendazole formulation was studied using USP II dissolution rate test apparatus employing paddle stirrer. 900 ml of 0.1N HCL was used as dissolution medium. A 410mg tablet was used for

the test. The stirrer was adjusted to rotate at 50 rpm, and a temperature of 37 ± 0.5 ºC was maintained throughout the experiment. 10 ml of samples were withdrawn at various time intervals and analyzed by measuring the absorbance at 309.0 nm. The volume withdrawn at various intervals was immediately replaced with a fresh quantity of dissolution medium. The above results are given in **Fig. 1**.

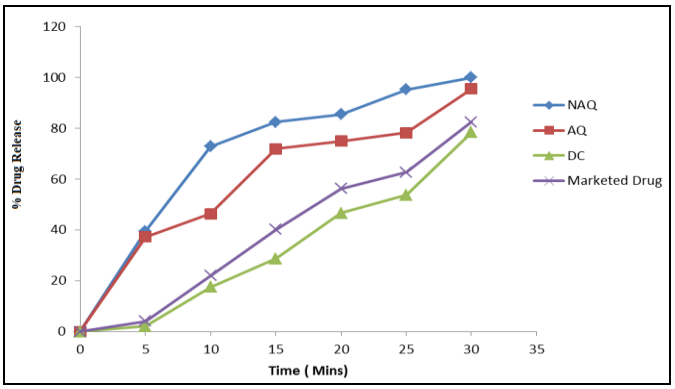

FIG. 1: DISSOLUTION PROFILE OF ALBENDAZOLE TABLETS WITH DIFFERENT METHODS

RESULTS AND DISCUSSION: Albendazole chewable tablets are prepared by using the three methods, which are non-aqueous granulation, aqueous granulation, and direct compression. The physical properties of formulated granules show the parameters in their limits, which are Hausner's ratio are in the range of 1.10 - 1.15, so the value indicates the fair flow.

The physical properties of tablets are in the prescribed limits only the breaking strength of all experimental tablets ranged from 4-5 kg/cm^2, the other properties of tablets results are shown in **Table 3**.

TABLE 2: PHYSICAL PROPERTIES OF ALBENDAZOLE GRANULES OF DIFFERENT TECHNIQUES

Test	NAQ	AQ	DC
Bulk density	0.35 g/ml	0.34 g/ml	0.33 g/ml
Tapped density	0.40 g/ml	0.40 g/ml	0.38 g/ml
Carr's index (%)	12	15	13
Hausner's ratio	1.108	1.1	1.15
Angle of Repose	21.80	20.0	21.0

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Angle of Repose	21.80	20.0	21.0

CONCLUSION: The present research study concludes that the non-aqueous granulation method shows the better dissolution rate compared to aqueous granulation method, direct compression method and also to the marketed drug. The *in-vitro* drug release of the albendazole chewable tablets are immediately prepared by the non-aqueous granulation method, the granules and tablets were found satisfactory in terms of physical parameters, dissolution time as well as the drug release profiles from the tablets prepared from different granulation techniques.

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CONFLICT OF INTEREST: Nil

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