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Preparation and Evaluation of Mouth Dissolving Tablet of Albendazole Using Different Concentrations of Super-Disintegrant

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Abstract

Anthelmintic medications are anticipated to act more quickly and have greater absorption. Mouth-dissolving albendazole tablets were created using a direct compression approach and a mixture of super disintegrants to accomplish rapid disintegration of the tablets in the oral cavity. The preparation of ten batches of mouth-dissolving tablets using different grades of Kollidon, crospovidone, sodium starch glycolate, and croscarmellose sodium as super disintegrants produced the greatest results. For a compatibility investigation, FTIR was used to characterize the drug and physical mixture. An optimization technique was used to forecast the most effective formulation out of all the prepared combinations. All the physical characteristics of the tablet are within the limit. All preformulation results indicated good flow properties. Disintegration time and drug content of the F4 batch were found to be 28 seconds and 95.69%, respectively. In vitro release of the drug was performed in a phosphorus buffer pH 6.8 for 40 min, in which F4 shows maximum drug release. Based on the stability studies, it was confirmed that the optimized formulation remained at accelerated stability conditions. It was discovered that the mouth-dissolving tablet exhibits effective drug release.

Keywords: albendazole; dissolution; direct compression; kolidon; tablet

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INTRODUCTION

Drug delivery devices (DDS) are a tactical tool for extending product life cycles, expanding markets and indications, and creating opportunities. Due to the most straightforward method of drug consumption, high levels of patient conformity, cost-effectiveness, fewer sterility restrictions, and adaptability in the creation of dosage form, oral ingestion has emerged as the most practical option among the various methods of drug delivery worldwide.[1] For oral administration, there are many different dosage forms available, including tablets and capsules, as well as liquid dosage forms such as syrups, solutions, elixirs, and tinctures. The most popular of them is the tablet dose form.[2] A variety of shapes and sizes of tablet dosage forms are available, and the medication ingredient may make up 0.1% to 90% of the tablet bulk. In comparison to other dosage forms, making tablets is a pretty simple operation. The production of

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tablets is the most cost-effective and can produce the most product per manufacturing hour, especially when using current industrial techniques like directly compressed (DC).[3] The most basic and economical method of producing tablets is direct compression. Due to the availability of better tablet excipients, particularly tablet super dissolution agents and sugar-based excipients, this technique can now be used with orally disintegrating tablets.[4] Due to their viability and convenience, oral dispersible tablets have been statistically shown to have a number of advantages over traditional tablets in terms of improving patient compliance and adoption.[4] The inability to take pills made of hard gelatin or tablets affects over 50% of people.[5] These groups of people include children and the elderly who have trouble swallowing big tablets. Orally disintegration tablets (ODT) and mouth-dissolving tablets (MDT) have been developed as substitute oral dose forms to address these issues.[6] Water is not necessary for swallowing mouth-dissolving tablets as they dissolve or disintegrate in saliva. Compared to eating tablets and capsules, they have an advantage.

An anthelmintic or anti-worm drug is albendazole. It stops freshly formed insect larvae (worms) in your body from developing or proliferating. The parasiticidal drug albendazole belongs to the benzimidazole category and interferes with the energy metabolism of parasites.[7] By attaching to colchicine-sensitive locations on the constituent cell protein - tubulin, and preventing it from assembling into microtubules, it particularly induces degenerative changes in worm cells. Its preferential attachment to the parasite - tubulin is considered being the cause of ALB's particular activity towards parasitic cells instead of mammalian cells.[8]

It is a strong antagonist of the dopamine 3 receptor and is utilized for its prokinetic and anthelmintic effects. As a result, it is mainly employed to alleviate nausea and vomiting among individuals with gastroparesis and to speed up stomach emptying.[9]

METHOD

The Mumbai Research-Lab Fine Chem Industries obtained an albendazole drug. From BASF Chemicals India Pvt. Ltd., Kollidon-CL, Kollidon-CL-F, and Kollidon-CL-SF were purchased. The following ingredients were purchased from Research-Lab Fine Chem Industries in Mumbai: Sodium Starch Glycolate, Cross Carmellose Sodium, Sucralose, Cellulose Microcrystalline, Mannitol, Magnesium Stearate, and Talc. This research article included tools like UV Spectrometer (Shimadzu 1800), FTIR Spectrometer (Shimadzu Affinity-1S), Digital Balance (Shimadzu), Hot air oven (Labline), Dissolution test apparatus (LABINDIA DS 8000), Disintegration test apparatus (DKB), Tablet Compression machine (KAMBERT), and Stability Chamber (LABLINE), Desiccator (LABLINE).

The direct compression method was used to create the fast-disintegrating albendazole tablet utilizing super disintegrants such as cross-carmellose sodium with micro-crystalline cellulose. Before mixing, all ingredients were carefully weighed, passed over 60 number sieve screens, and then transferred to a glass mortar, and then triturated until thoroughly combined. The pre-compression parameters were then assessed for the mixture. After that, a rotary tablet machine's 12 mm diameter punch was used to compress the powder combination into tablets.

Table 1. Formulation table of mouth dissolving tablet for albendazole drug

Sr. No.	INGREDIENT	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1	Albendazole (mg)	400	400	400	400	400	400	400	400	400	400
2	Croscarmellose Sodium (mg)	34	35	-	-	-	-	-	-	-	-
3	Kollidon (CL-SF) (mg)	-	-	34	35	-	-	-	-	-	-
4	Kollidon (CL-F) (mg)	-	-	-	-	34	35	-	-	-	-
5	Kollidon (CL) (mg)	-	-	-	-	-	-	-	-	34	35
6	Sodium Starch Glycolate (mg)	-	-	-	-	-	-	34	35	-	-
7	Microcrystalline Cellulose (mg)	81	81	81	81	81	81	81	81	81	81
8	Mannitol (mg)	165	165	165	165	165	165	165	165	165	165
9	Sucralose (mg)	5	5	5	5	5	5	5	5	5	5
10	Magnesium Stearate (mg)	10	10	10	10	10	10	10	10	10	10
11	Talc (mg)	5	5	5	5	5	5	5	5	5	5
	Total	700	700	700	700	700	700	700	700	700	700

The table indicates the different ratios of drugs with super disintegrants batch F1 to F10.

Evaluation of Albendazole Drug

FTIR studies:

The Shimadzu IR Affinity-IS was used to capture the Fourier transform infrared spectrum of albendazole. A range of 400 to 4000 cm-1 of the drug sample was scanned using an FTIR sample holder. By contrasting the spectrum in the infrared of albendazole, the spectrum was validated9.

Ultraviolet-visible (UV-Vis) Spectrophotometry Determination of λ-max of Albendazole

10 mg of albendazole, accurately weighed, was put into a 100 ml volumetric flask. The volume was made up of methanol, and the flask was designated as a stock solution with 1 mg/ml, or 100 parts per million (ppm). A stock solution of 10 ppm was created by diluting 1 ml of the stock solution up to 10 ml in another volumetric flask. This stock solution was then analyzed between 200 and 400 nm. 290 nm was found to be the **λ** max. In the same way, **λ** max was also identified in a buffer with phosphate pH-6.8 with methanol10.

Estimation of calibration Curve in water, Phosphate Buffer 6.8, and methanol:

Dilutions of 2, 4, 6, and 10 ppm were made from the 100-ppm stock solution mentioned above, and at max, absorbance was measured using a UV spectrophotometer.

Determination of solubility

Albendazole's solubility in water, methanol, and phosphate buffer (pH-6.7) was assessed10.

Physical mixture

In order to create a uniform physical mixture, the medication and excipient were blended in a crusher for ten minutes. The obtained mixture was put into a desiccator for additional testing after being sieved through a 60-mesh sieve and then kept in an airtight container.

Pre-Compression Evaluation of Powder[11]

Bulk density

The powder was precisely weighed and then poured onto a graduated cylinder to calculate the bulk density. The total volume (Vb) and powder weight (M) were calculated. The equation was used to calculate the bulk density (it shows equation number 1).

$$bulk\ density = \frac{weight\ of\ powder\ (M)}{bulk\ volume\ (Vb)}$$ .....equation no.1

Tapped density

By using a digital tapping density apparatus, a preset number of taps were made on the measurement cylinder. The final volume, or tapped volume (Tb), was recorded, and the equation was used to compute the tapped density (It was given equation number 2).

$$Tapped\ density\ (TD) = \frac{weight\ of\ powder(M)}{volume\ (Vt)tapped}$$ .....equation no.2

Carr's Compressibility Index

It is a measurement of how easily an object can be made to flow, and it is computed using the formula below (equation number 3).

$$carrs\ index\ (I) = \frac{Tapped\ density\ (TD) - Bulk\ density\ (BD)}{tapped\ density\ (TD)} * 100$$.....equation no 3

Hausner's ratio

The Hausner's ratio measures how easily powder flows. Good flow is indicated by the Hausner's ratio being less than 1.25. The formula used to compute it is as follows: equation number 4.

$$Hausners\ ratio = \frac{Tapped\ Density\ (TD)}{bulk\ Density\ (BD)}$$ .....equation no.4

Angle of repose

A fixed funnel approach was used to calculate the angle of repose. A funnel that can be elevated vertically to achieve a maximum conical height (h) was used to pour the mixture through. The heap's radius (r) was determined, and the formula below equation no.5 was used to obtain the angle of repose:

5) Angle of repose (θ) = tan-1 $\frac{h}{r}$

.....equation no.5

Where r is its radius at the base pile,
h is the height of the pile and is the angle of repose.

Evaluation of Fast Disintegrating Tablet

Weight variation

20 tablets of each formulation were weighed in total, and their mean was calculated. The weights of the various tablets were precisely ascertained, and then the weight variance was determined.[12]

Hardness

It measures the amount of force needed to shatter the tablet when it is put to the test. For uncoated tablets, a hardness of 0.1-3 kg/cm2 is sufficient. Force is expressed in kg. Using a Monsanto hardness tester, the hardness of 10 tablets of each formulation was determined.[13]

Friability test

Programmable Digital Friability: The use of apparatus allowed the friability of these tablets to be determined. Each formulation's 20 tablets were weighed before being put into an apparatus that rotated for four minutes at a speed of 25 rpm. The tablets were cleaned and then weighed once more. It was determined what percentage of weight was lost.[14]

Disintegration time

The one tablet contained in each of the six glass tubes of the disintegration apparatus was placed in a 1-liter beaker of distilled water so that the tablets would rise above the liquid's surface but not come nearer than 2.5 cm to the bottom. The time it took for the tablet to begin to dissolve was recorded.[15]

***In-vitro* dissolution study**

The USP Type II dissolution evaluation device (Labindia) was used for the dissolving test. The dissolution medium was 500 ml of phosphate solution pH 6.8 at 50 rpm and 37.7 °C ± 0.5 °C. At regular intervals, five milliliter-sized aliquots were removed, then the collected volume was substituted with an equivalent volume of brand-new dissolving media. At 290 nm, the samples underwent spectrophotometric analysis, and the % drug release was estimated.[16]

Wetting Time

In a tiny Petri dish with an interior diameter of 6.5 cm and 10 ml of synthetic saliva with a phosphate buffer pH of 6.8, an area of tissue paper that had been folded twice was put. On the paper, a tablet was placed, and the amount of time needed to completely wet it was recorded. Each batch underwent three trials, and the average wetting duration and standard deviation were determined.

Drug Content

In a glass mortar, ten tablets were measured and ground into powder. Weighted powder containing 19 mg of albendazole has been dispersed in 50 ml of methanol to make up 100 ml. The resultant solution was then subjected to UV light at 290 nm and filtered using Whatman filter paper.[18]

Stability studies

According to ICH requirements, stability investigations of the developed tablet were completed. The finished product's physical and chemical characteristics were examined during the stability testing19. By ICH recommendations, the produced tablets were put in a stability test chamber and then submitted to stability studies in accelerated testing settings (40 2°C/75 5% RH) for 3 months. During the stability research, the following evaluation criteria for F3 tablets were examined: appearance, hardness, weight fluctuation, drug content, disintegration time, and in vitro dissolution investigations at intervals of one month.[20]

RESULTS AND DISCUSSION

UV Spectroscopy

Max. The 295 nm with 290 nm wavelength curves of calibration for albendazole diluted methanol with PBS pH 6.8 were discovered at 10 ppm dosage. A graph of absorbance vs. concentration was drawn, with y representing absorbance and x representing concentration. The obtained R2 values of 0.996 and 0.998 indicated linearity with albendazole purity. Figure 1 depicts the UV spectrum of albendazole as diluted methanol and PBS at pH 6.8.

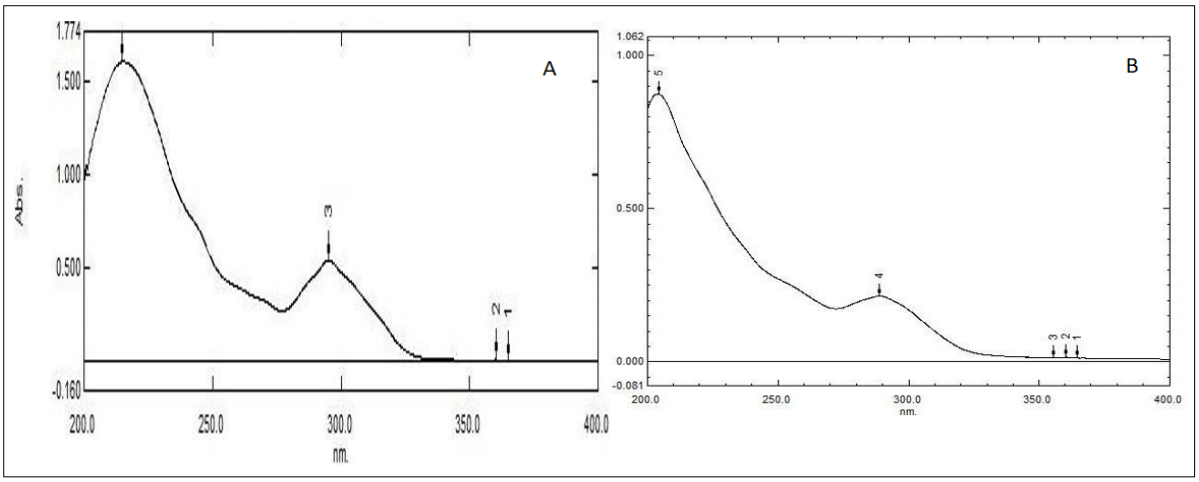

Figure 1. (A). Absorption Spectrum of Albendazole in methanol. (B). Absorption Spectrum of PBS pH 6.8

FTIR Spectroscopy

Analysing Albendazole's IR spectra allowed for the identification of the medication. The Albendazole-detected peaks were discovered to be within the range, confirming that the drug acquired was not deteriorated and was appropriate for use in experiments for the development of formulations. Albendazole's FTIR spectra are displayed in Figure 2. The distinctive bands of medication are given below.

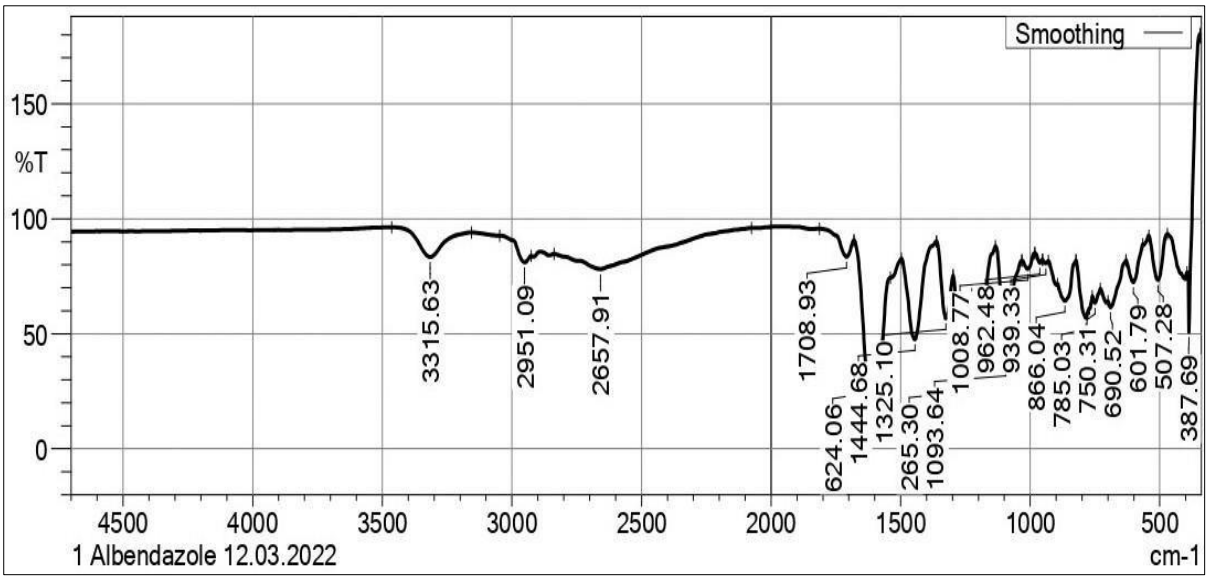

Figure 2. FTIR Spectra of Albendazole

That study can show the spectrum of albendazole drug using excipients FT-IR spectroscopy peak points to give no interaction of drug and drug with excipients (mouth-dissolving tablet) formulation. It gives compatibility with the optimized batch prepared using this peak of 1708.93cm^{-1}, 1624.06cm^{-1}, 1325.10 cm^{-1}, 1444.68 cm^{-1}, 2951.09 cm^{-1} due to the presence of C=O, -C=C-, N=O, C-N Stretch, C-H stretch. Thus, bonds were present in the FT-IR spectroscopy.

Pre-Compression Evaluation Result

Bulk density

The bulk density values, which ranged from 0.3 to 0.5 g/cc, revealed that the powder mixes had satisfactory flow characteristics. Results are shown in table 2.

Tapped density

The tapped density values have been determined to be in the 0.3–0.5 g/cc range, indicating that the powder mixes had satisfactory flow characteristics, indicated in Table 2.

Carr's Index

The powder's compressibility is represented by the compressibility index, which indicates the friction between particles. By utilizing Carr's index, it was discovered that the powder's flowability ranged from 11.66% to 17.15%, which is shown in Table 2.

Table 2. Pre-Compression parameters evaluation result

Sr. No	Formulation Code	Bulk Density	Tapped Density	Carr's Index	Hausner's Ratio	Angle of Repose
1	F1	0.399	0.410	17.15	1.10	29.16
2	F2	0.374	0.394	11.66	1.13	30.17
3	F3	0.402	0.425	13.75	1.17	28.18
4	F4	0.419	0.439	14.97	1.16	26.19
5	F5	0.398	0.430	14.81	1.15	27.92
6	F6	0.385	0.410	15.11	1.17	26.63
7	F7	0.359	0.380	11.89	1.14	25.98
8	F8	0.366	0.389	10.27	1.09	29.78
9	F9	0.376	0.411	13.08	1.17	27.01
10	F10	0.391	0.457	17.51	1.18	29.19

The table indicates the precompression parameters such as bulk density, tapped density, carr's index, Hausner's ratio, Angle of repose of batch F1 to F10.

Hausner's Ratio

The flowability of a powder and granular substance is connected with a value called the Hausner ratio. It was discovered that Hausner's ratio was less than 1.25, indicating unrestricted flow, as shown in Table 2.

Angle of Repose

The angle of repose is related to inter-particle friction or resistance to particle movement. When the blend's angle of repose was measured, it was discovered to be between 26.18 and 31.16 degrees, indicating good to exceptional flow given in Table 2.

Post-Compression Evaluation Results

The manufactured tablet batches underwent post-compression evaluations for characteristics including appearance, durability, flexibility, weight variation, disintegration time, and in-vitro dissolution tests. It was discovered that all tablet batches' post-compression parameters were within allowable bounds.

Hardness

A Monsanto Hardness Tester was used to determine the hardness. The hardness suggested excellent handling qualities.

Friability

By using Roche friability, all pills underwent the friability test. The reported friability was determined to be less than 1%, ensuring that the tablets' surface

hardness remained constant while maintaining mechanical stability.

Wetting Time

These parameters showed that the optimized batch F4 wetting time was 33 seconds, as shown in Table 3.

Weight Variation

Manufactured tablet batches completed the test for weight variation and proved to be uniform in weight. It illustrated optimum powder blend mixing and high flowability at dies and punched for compressing tablets. Table 3 indicates the results of hardness, friability, wetting time, and average tablet weight.

Table 3. Post-compression evaluation results

Sr. no	Formula code	Hardness (kg/c m^2)	Friability (%)	Wetting time (min)	Average tablet weight (mg)
1	F1	2.58	0.31	40	700
2	F2	2.55	0.53	51	700
3	F3	2.80	0.81	34	698
4	F4	2.15	0.69	33	700
5	F5	2.89	0.71	49	700
6	F6	2.15	0.44	44	699
7	F7	2.77	0.91	56	700
8	F8	2.91	0.25	49	700
9	F9	2.55	0.96	38	695
10	F10	2.45	0.34	45	700

Table 3 indicates the post-compression parameters such as hardness, friability, wetting time, average tablet weight of batch F1 to F10.

Disintegration time and drug content

All formulation disintegration times indicated that drugs would dissolve more quickly in a dissolving medium. All formulations were disintegrated within 60 seconds. 28 seconds was the shortest disintegration time for the F4 formulation. All of the formulations' medication content was found to be between 95% and 98%. F4 demonstrated the greatest drug concentration of 97.86% when compared to other formulations, as shown in Table 4.

Table no. 4 Disintegration time and drug content

Sr. No	Formulation Code	Disintegration time (sec)	Drug Content (%)
1	F1	60	96.65
2	F2	58	96.78
3	F3	30	97.86
4	F4	28	95.69
5	F5	41	96.35
6	F6	35	96.98
7	F7	58	94.16
8	F8	51	96.76
9	F9	44	98.20
10	F10	39	96.99

Table 4 shows the result of disintegration time and drug content of tablet formulation.

***In-vitro* dissolution studies**

All tablet formulations' dissolving analyses showed that the tablets with shorter disintegration times and greater solubilities exhibited the quickest rates of dissolution. Batch F4 demonstrated quicker dissolving relative to all other formulations, with a maximum release of drugs of 96.55% after 40 minutes, as shown in Table 5 and Figure 3.

Table 5. *In-Vitro* Drug Release of all Formulation of Albendazole tablet (F1-F2)

Sr.no	Time	Formulation									
		F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1	0	25.67	13.72	21.19	16.16	26.90	19.70	17.39	19.11	14.57	12.63
2	5	44.71	20.65	27.11	32.90	30.02	25.87	25.71	29.81	22.83	22.54
3	10	52.46	31.45	30.64	44.78	36.16	28.30	31.49	38.09	35.15	34.19
4	15	59.10	40.48	38.20	53.62	41.55	37.22	39.03	44.98	44.38	41.92
5	20	68.43	43.63	49.31	68.77	46.68	41.54	42.78	56.16	58.41	53.16
5	25	72.39	54.07	68.66	70.63	52.36	50.91	58.03	60.08	69.90	60.99
7	30	78.09	59.27	70.59	81.39	68.36	68.57	66.26	66.75	73.99	71.89
8	35	82.99	66.29	82.21	88.98	71.70	77.40	75.01	75.68	82.16	78.11
9	40	87.29	86.41	90.49	96.55	89.55	86.76	82.58	83.18	90.48	88.87

This table shows the drug release study of tablet formulation.

***In-Vitro* Drug Release Study:**

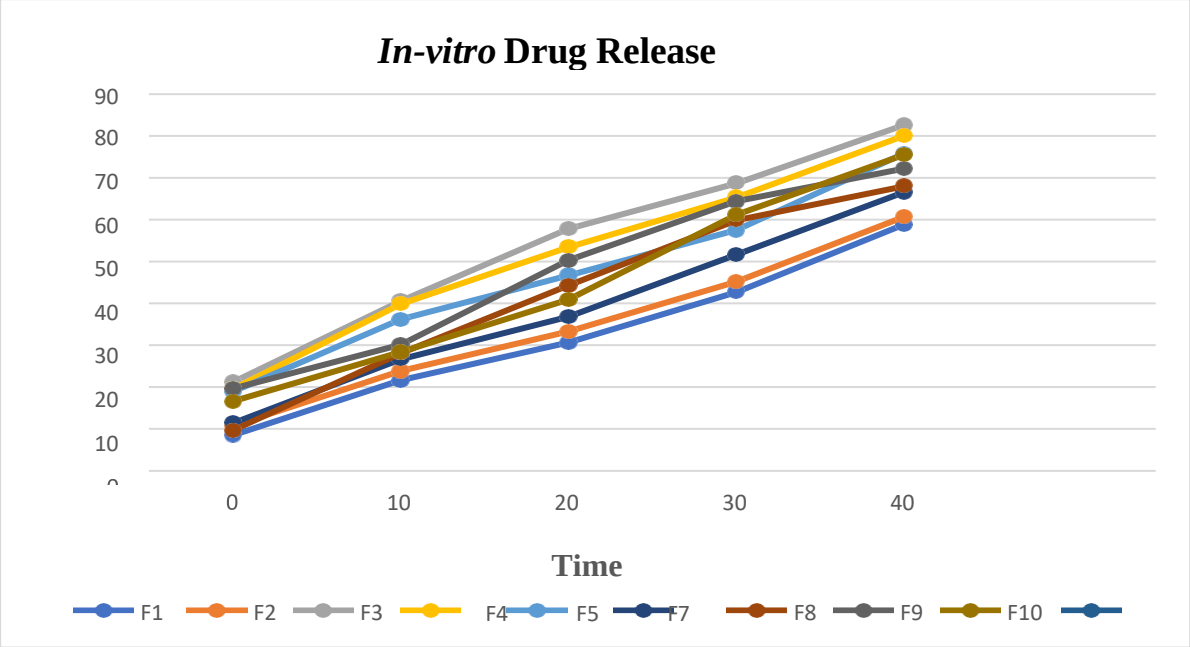

Figure 3. Drug release study of formulation batches

According to ICH recommendations, stability experiments of the F4 tablet were conducted to determine how aging affected the tablet's physicochemical characteristics and rate of dissolution. At one-month intervals, the appearance, hardness, typical tablet weight, friability, duration of disintegration, drug content, and dissolving rates were assessed. The findings indicated that the evaluation criteria for the original and stored pills did not differ significantly. The F4 pills remained stable at 40 2 °C and 75 5% RH. The findings of the stability study are given in Table 6.

Table 6. Stability Study for F4 formulation batch

Sr.no	Parameters	Time Span			
		Initial	1 Month	2 Months	3 Months
1	Appearance	White colour	White colour	White colour	White colour
2	Hardness (kg/cm²)	2.95	2.88	2.67	2.45
3	Average Weight of tablet (mg)	700	700	700	700
4	Drug content (%)	97.86	97.74	97.65	96.98
5	Disintegration Time (sec)	28	28	28	30
6	% Drug Release at 40 mins	96.55	95.86	95.63	94.92

CONCLUSION

Based on the results of the study, it can be concluded that direct compression techniques could be used to create fast-dissolving albendazole tablets successfully employing a variety of super disintegrants. Drug-carrier compatibility was found in the FTIR research. The produced tablets were found to have a hardness between

2.5 and 3.0 kg/cm2. All tablets had a friability of under 1%. The F4 formulation achieved maximum drug release within 40 minutes, as indicated by in vitro dissolution profiles. The dissolving rates of other formulations also significantly increased. Furthermore, after a three-month investigation, the stability analysis revealed no appreciable alterations in the tablets. Based on the findings, it can be said that the fast-disintegrating tablets that were created employing super disintegrants may display every characteristic of a fast-disintegrating tablet required by law. As a result, they were acting therapeutically more quickly and with greater bioavailability. These methods can be applied to improve the dissolution and solubility of other weakly soluble medicines.

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