International Journal of Pharmacy and Analytical Research (IJPAR)

ISSN: 2320-2831

IJPAR |Vol.11 | Issue 3 | July - Sept -2022
www.ijpar.com

Research article ***Analytical research***

Formulation and Evaluation of Sustained Release Albendazole Tablet

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ABSTRACT

The present focus is on the development of sustained release formulations due to its inherent boons. There are several advantages of sustained release drug delivery over conventional dosage forms like improved patient compliance, reduction in fluctuation of drug level in the blood and increased safety margin of potent drug. The present study was aimed to prepare a sustained drug delivery system of Albendazole. The sustained release matrix tablets of Albendazole were prepared by direct compression method and evaluated for different parameters such as weight variation, drug content, thickness, hardness, friability and *In vitro drug* release studies. The *in vitro* dissolution study was carried out for 12 hours using USP (Type- II) paddle apparatus in hydrochloride (0.1N) as dissolution media for first 2 hours and phosphate buffer (pH 6.8) for next 10 hours. Based on the *in vitro* dissolution data, formulation F7 was selected as the best formulation from Albendazole formulations (F1 – F9) as the drug release was retarded up to 12 hours and followed zero order release kinetics & drug release mechanism was diffusion.

Keywords: Albendazole, Tragacanth, Guar gum, Acacia and Sustained release system.

INTRODUCTION

A drug delivery system (DDS) is defined as a formulation or a device that enables the introduction of a therapeutic substance in the body and improves its efficacy and safety by controlling the rate, time, and place of release of drugs in the body[1]. This process includes the administration of the therapeutic product, the release of the active ingredients by the product, and the subsequent transport of the active ingredients across the biological membranes to the site of action[2, 3]. The term therapeutic substance also applies to an agent such as gene therapy that will induce in vivo production of the active therapeutic agent. Sustained release tablets are commonly taken only once or twice daily, compared with counterpart conventional forms that may have to take three or four times daily to achieve the same therapeutic effect[4]. The advantage of administering a single dose of a drug that is released over an extended period of time to maintain a near-constant or uniform blood level of a drug often translates into better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use[5, 6]. The first sustained release tablets were made by Howard Press in New Jersy in the early 1950's. The first tablets released under his process patent were called 'Nitroglyn' and made under license by Key Corp. in Florida. Sustained release, prolonged release, modified release, extended release or depot formulations are terms used to identify drug delivery systems that are designed to achieve or extend therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. The goal in designing sustained or sustained delivery systems is to reduce the frequency of the dosing or to increase effectiveness of the drug by localization at the site of action, reducing the dose required or providing uniform drug delivery. So, sustained release dosage form is a dosage form that release one or

more drugs continuously in predetermined pattern for a fixed period of time, either systemically or to a specified target organ[7, 8]. Sustained release dosage forms provide a better control of plasma drug levels, less dosage frequency, less side effect, increased efficacy and constant delivery. There are certain considerations for the preparation of extended release formulations:

- ✓ If the active compound has a long half-life, it is sustained on its own,
- ✓ If the pharmacological activity of the active is not directly related to its blood levels,
- ✓ If the absorption of the drug involves an active transport and
- ✓ If the active compound has very short half-life then it would require a large amount of drug to maintain a prolonged effective dose.

The above factors need serious review prior to design.

Introduction of matrix tablet as sustained release (SR) has given a new breakthrough for novel drug delivery system in the field of Pharmaceutical technology. It excludes complex production procedures such as coating and Pelletization during manufacturing and drug release rate from the dosage form is controlled mainly by the type and proportion of polymer used in the preparations. Hydrophilic polymer matrix is widely used for formulating an SR dosage form. Because of increased complication and expense involved in marketing of new drug entities, has focused greater attention on development of sustained release or controlled release drug delivery systems. Matrix systems are widely used for the purpose of sustained release. It is the release system which prolongs and controls the release of the drug that is dissolved or dispersed[9].

In fact, a matrix is defined as a well-mixed composite of one or more drugs with gelling agent i.e. hydrophilic polymers. By the sustained release method therapeutically effective concentration can be achieved in the systemic circulation over an extended period of time, thus achieving better compliance of patients. Numerous SR oral dosage forms such as membrane controlled system, matrices with water soluble/insoluble polymers or waxes and osmotic systems have been developed, intense research has recently focused on the designation of SR systems for poorly water soluble drugs.

MATERIALS AND EQUIPMENTS

List of Materials Used

Name of the material	Source
Albendazole	Provided by **SURA LABS,** Dilsukhnagar, Hyderabad.
Tragacanth	Merck Specialities Pvt Ltd, Mumbai, India
Guar gum	Merck Specialities Pvt Ltd, Mumbai, India
Acacia	Merck Specialities Pvt Ltd, Mumbai, India
MCC PH 102	Merck Specialities Pvt Ltd, Mumbai, India
Sodium Stearyl Fumarate	Merck Specialities Pvt Ltd, Mumbai, India

List of Equipments used

Name of the Equipment	Manufacturer
Weighing Balance	Sartourius
Tablet Compression Machine (Multistation)	Lab Press Limited, India.
Hardness tester	Monsanto, Mumbai, India.
Vernier callipers	Mitutoyo, Japan.
Roche Friabilator	Labindia, Mumbai, India
DissolutionApparatus	Labindia, Mumbai, India
UV-Visible Spectrophotometer	Labindia, Mumbai, India
pH meter	Labindia, Mumbai, India
FT-IR Spectrophotometer	Bruker, Alpha

METHODOLOGY

Analytical method development

a) Determination of absorption maxima

100mg of Albendazole pure drug was dissolved in 15ml of Methanol and make up to 100ml with 0.1N HCL (stock solution-1). 10ml of above solution was taken and make up with100ml by using 0.1 N HCL (stock solution-2 i.e 100µg/ml). From this 10ml was taken and make up with 100 ml of 0.1 N HCL (10µg/ml). Scan the 10µg/ml using Double beam UV/VIS spectrophotometer in the range of 200 – 400 nm.

b) Preparation calibration curve

100mg of Albendazole pure drug was dissolved in 15ml of Methanol and volume make up to 100ml with 0.1N HCL (stock solution-1). 10ml of above solution was taken and make up with100ml by using 0.1 N HCl (stock solution-2 i.e 100µg/ml). From this take 0.2, 0.4, 0.6, 0.8, and 1ml of solution and make up to 10ml with 0.1N HCl to obtain 2, 4, 6, 8 and 10 µg/ml of Albendazole solution. The absorbance of the above dilutions was measured at 228nm by using UV-Spectrophotometer taking 0.1N HCl as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight line Linearity of standard curve was assessed from the square of correlation coefficient (R^2) which determined by least-square linear regression analysis. The above procedure was repeated by using pH 6.8 phosphate buffer solutions.

Drug – Excipient compatibility studies

Fourier Transform Infrared (FTIR) spectroscopy

Drug excipient interaction studies are significant for the successful formulation of every dosage form. Fourier Transform Infrared (FTIR) Spectroscopy studies were used for the assessment of physicochemical compatibility and interactions, which helps in the prediction of interaction between drug and other excipients. In the current study 1:1 ratio was used for preparation of physical mixtures used for analyzing of compatibility studies. FT-IR studies were carried out with a Bruker, ATR FTIR facility using direct sample technique.

Formulation development of Sustained release Tablets

All the formulations were prepared by direct compression method. The compositions of different formulations are given in Table. The tablets were prepared as per the procedure given below and aim is to prolong the release of Albendazole.

Procedure

In the present work the Albendazole tablets were prepared by direct compression method. The drug and the excipients were passed through 72# size mesh prior to the preparation of dosage form. The entire ingredients were weighed separately and mixed thoroughly for 10 minutes in double cone blender to ensure uniform mixing in geometric ratio. The tablets were prepared by direct compression technique using 8mm punch.

Table 1: Formulation of Albendazole release tablets

Ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Albendazole	200	200	200	200	200	200	200	200	200
Tragacanth	30	60	90	-	-	-	-	-	-
Guar gum	-	-	-	30	60	90	-	-	-
Acacia	-	-	-	-	-	-	30	60	90
MCC PH 102	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Sodium Stearyl Fumarate	4	4	4	4	4	4	4	4	4
Talc	3	3	3	3	3	3	3	3	3
Total Wt	350	350	350	350	350	350	350	350	350

Flow property

Table 2: The flow property of powder blend

Flow property	Angle of repose	Compressibility index (%)	Hausner's ratio
Excellent	25-30	<10	1.00-1.11
Good	31-35	11-15	1.12-1.18
Fair	36-40	16-20	1.19-1.25
Passable	41-45	21-25	1.26-1.34
Poor	46-55	26-31	1.35-1.45
Very poor	56-65	32-37	1.46-1.59
Very very poor	>66	>38	>1.60

Post Compression parameters

Weight variation test

Twenty tablets were randomly selected and weighed, to estimate the average weight and that were compared with individual tablet weight. The percentage weight variation was calculated as per Indian Pharmacopoeial Specification. Tablets with an average weight 250 mg so the % deviation was ±5 %.

Table 3: IP standards of uniformity of weight

S. No.	Average weight of tablet	% of deviation
1	≤ 80 mg	10
2	> 80 mg to <250 mg	7.5
3	≥ 250 mg	5

Friability test

Twenty tablets were weighed and subjected to drum of friability test apparatus. The drum rotated at a speed of 25 rpm. The friabilator was operated for 4 minutes and reweighed the tablets. % loss (F) was calculated by the following formula.

F =100 (W0-W)/W0

Where W0 = Initial weight,

W = Final weight

Hardness test

The hardness of tablets was measured by using Monsanto hardness tester. The results were complies with IP specification.

Thickness test

The rule of physical dimension of the tablets such as sizes and thickness is necessary for consumer acceptance and maintain tablet uniformity. The dimensional specifications were measured by using screw gauge. The thickness of the tablet is mostly related to the tablet hardness can be used as initial control parameter.

Drug content

The amount of drug in tablet was important for to monitor from tablet to tablet, and batch to batch is to evaluate for efficacy of tablets. For this test, take ten tablets from each batch were weighed and powdered. Weighed equivalent to the average weight of the tablet powder and transferred into a 100 ml volumetric flask and dissolved in a suitable quantity of media. The solution was made up to the mark and mixed well. Then filter the solution. A portion of the filtrate sample was analyzed by UV spectrophotometer.

In vitro drug release studies

Apparatus -- USP-II, Paddle Method
Dissolution Medium -- pH 6.8 Phosphate buffer
RPM -- 50
Sampling intervals (hrs) -- 1, 2, 3, 4, 5, 6, 7, 8, 10, & 12.
Temperature -- 37°C ± 0.5°C

Procedure

900ml 0f 0.1 HCl was placed in vessel and the USP apparatus –II (Paddle Method) was assembled. The media was allowed to equilibrate to temp of 37°C ± 0.5°C. Tablet was placed in the vessel and apparatus was operated for 2 hours. Then 0.1 N HCl was replaced with pH 6.8 phosphate buffer and process was continued up to 12 hrs at 50 rpm. At specific time intervals, withdrawn 5 ml of sample and again 5ml media was added to maintain the sink condition. Withdrawn samples were analyzed at 228nm wavelength of drug using UV-spectrophotometer.

RESULTS AND DISCUSSION

The present work was designed to developing Sustained tablets of Albendazole using various polymers. All the formulations were evaluated for physicochemical properties and *in vitro* drug release studies.

Analytical Method

1. Standard graph of Albendazole in 0.1N HCl:

The scanning of the 10µg/ml solution of Albendazole in the ultraviolet range (200-400nm) against 0.1 N HCl the maximum peak observed at λ_{max} as 228 nm. The standard concentrations of Albendazole (2-10 µg/ml) was prepared in 0.1N HCl showed good linearity with R^2 value of 0.998, which suggests that it obeys the Beer-Lamberts law.

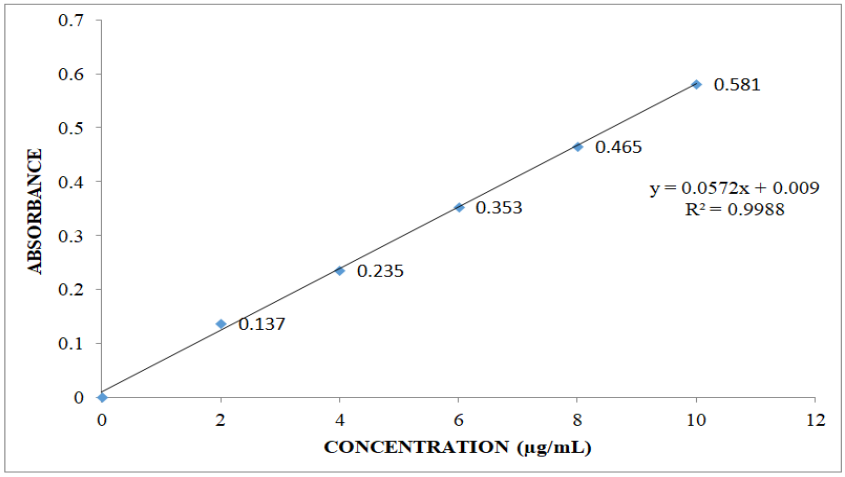

Fig .1: Calibration curve of Albendazole in 0.1 N HCl at 228nm

2. Standard Curve of Albendazole in Phosphate buffer pH 6.8

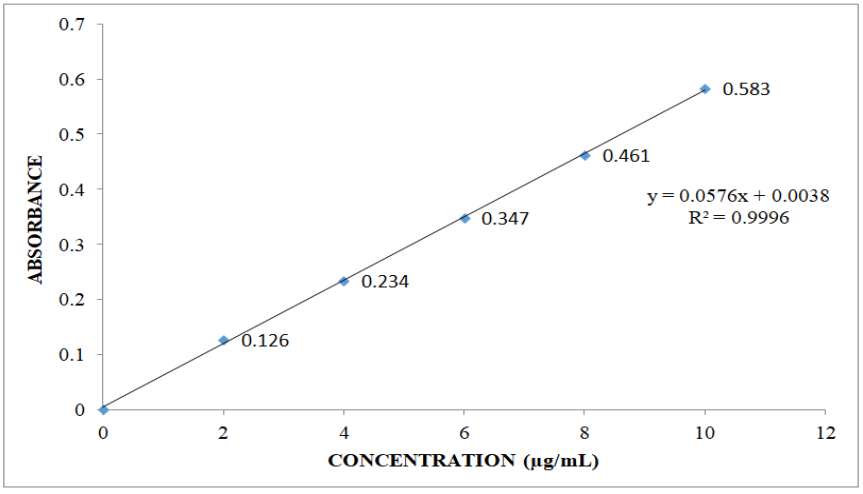

Fig 2: Calibration of Albendazole in Phosphate buffer pH 6.8

Drug and Excipient Compatibility Studies

1. FTIR study

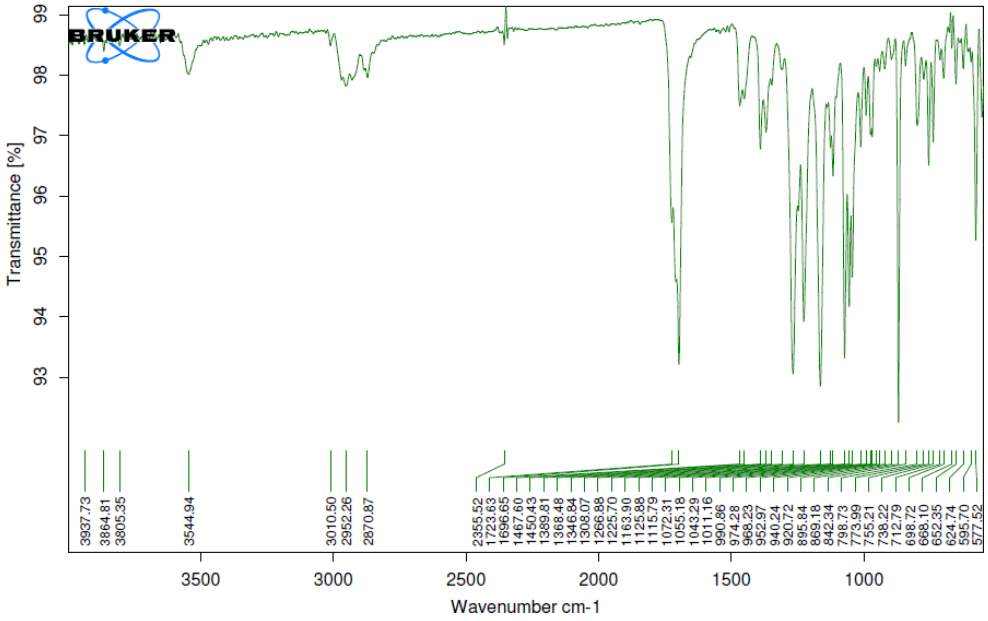

Fig 3: FTIR GRAPH OF PURE DRUG

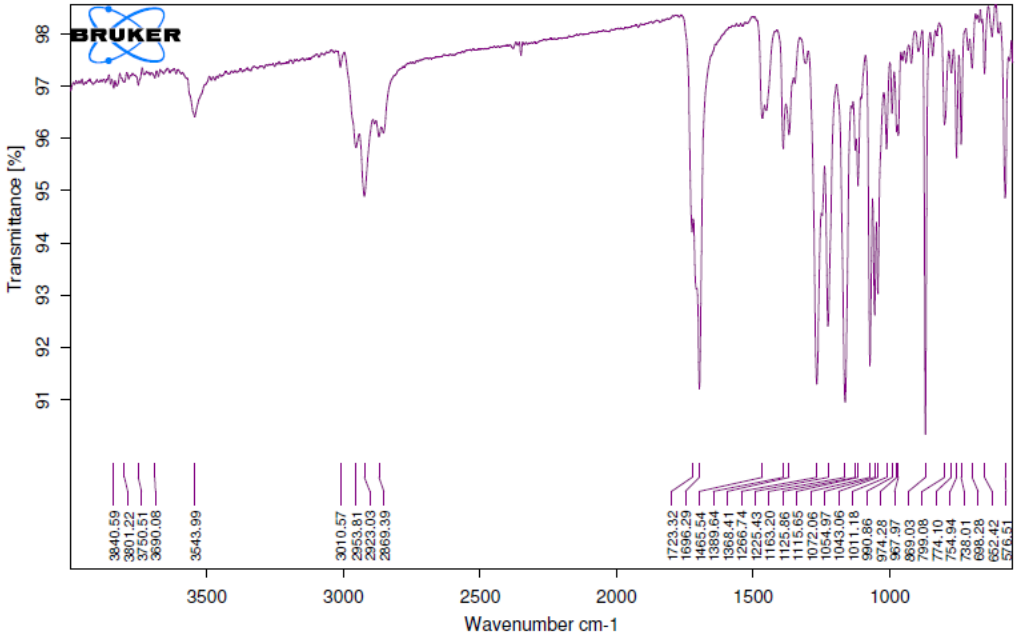

Fig 4: FTIR GRAPH OF OPTIMISED FORMULATION

From the FTIR data it was evident that the drug and excipients does not have any interactions. Hence they were compatible.

3. EVALUATION PARAMETERS

Pre-compression parameters

Table 4: Pre-compression parameters of powder blend

Formulation Code	Angle of Repose	Bulk density (gm/ml)	Tapped densit (gm/ml)	Carr's index (%)	Hausner's Ratio
F1	29.35	0.538	0.649	17.10	1.20
F2	30.30	0.546	0.665	17.89	1.21
F3	31.65	0.576	0.672	14.28	1.16
F4	29.98	0.524	0.657	20.24	1.25
F5	29.66	0.564	0.677	16.69	1.20

F6	29.98	0.536	0.635	15.59	1.18
F7	30.32	0.576	0.650	11.38	1.12
F8	27.33	0.547	0.657	16.74	1.20
F9	30.62	0.567	0.678	16.37	1.19

Tablet powder blend was subjected to various pre-formulation parameters. The angle of repose values indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.524 to 0.576 (gm/ml) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.635 to 0.678 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 20.24 which show that the powder has good flow properties. All the formulations has shown the hausners ratio ranging between 1.12 to 1.25 indicating the powder has good flow properties.

Post Compression Parameters For tablets

Table 5: Post Compression Parameters of Tablets

Formulation codes	Weight variation (mg)	Hardness (kg/cm2)	Friability (% loss)	Thickness (mm)	Drug content (%)
F1	349.25	4.3	0.36	3.97	97.62
F2	347.64	5.0	0.42	3.46	98.14
F3	350.05	4.9	0.41	3.27	100.05
F4	348.47	**5.1**	0.53	3.59	99.62
F5	350.92	4.7	0.34	3.17	98.76
F6	345.69	4.3	0.29	3.77	96.14
F7	349.22	5.1	0.43	3.94	98.24
F8	350.12	4.7	0.31	3.36	99.67
F9	349.79	5.9	0.27	3.81	98.79

Weight variation and thickness

All the formulations were evaluated for uniformity of weight using electronic weighing balance and the results are shown in table 9.5. The weight variation of the tablet of all the formulations was found to be between 347.6 to 350.12**.** The maximum allowed percentage weight variation for tablets weighing >350 mg is 5% and no formulations are not exceeding this limit. Thus all the formulations were found to comply with the standards given in I.P. And thickness of all the formulations was also complying with the standards that were found to be between 3.17 to 3.97.

Hardness and friability

All the formulations were evaluated for their hardness, using Monsanto hardness tester and the results are shown in table 9.5. The average hardness for all the formulations was found to be between **(**4.3 **to** 5.9) Kg/cm^2 which was found to be acceptable. Friability was determined to estimate the ability of the tablets to withstand the abrasion during packing, handling and transporting. All the formulations were evaluated for their percentage friability using Roche friabilator and the results were shown in table 9.5. The average percentage friability for all the formulations was between 0.27 and 0.53, which was found to be within the limit.

Drug content

All the formulations were evaluated for drug content according to the procedure described in methodology section and the results were shown in table 9.5. The drug content values for all the formulations were found to be in the range of **(**96.14- 100.05**).** According to IP standards the tablets must contain not less than 95% and not more than 105% of the stated amount of the drug. Thus, all the tablets formulations comply with the standards given in IP.

In Vitro Drug Release Studies

The formulations prepared with different polymers by direct compression method. The tablets dissolution study was carried out in paddle dissolution apparatus using 0.1N HCl for 2 hours and 6.8 pH phosphate buffers for remaining hours as a dissolution medium.

Table 6: Dissolution Data of Albendazole Tablets

TIME (HR)	CUMULATIVE PERCENTAGE OF DRUG RELEASE								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	28.92	15.58	13.29	20.99	15.82	11.34	16.50	10.29	06.91
2	36.34	28.25	18.13	26.63	20.90	18.26	21.32	15.72	10.30
3	40.68	38.71	23.96	38.24	28.35	22.54	28.11	22.90	18.61
4	58.15	43.90	28.14	42.81	37.45	28.87	35.08	28.38	23.52
5	67.76	50.65	35.20	56.60	45.76	36.93	40.96	35.27	28.81
6	76.50	59.12	42.87	64.32	50.81	45.27	48.60	40.12	37.32
7	90.31	65.08	49.73	70.41	57.96	50.71	56.14	46.90	45.60
8	96.83	78.70	56.51	87.88	66.75	59.56	61.73	54.63	51.97

9		89.36	68.09	96.59	71.31	66.81	75.69	61.28	58.82
10		97.18	76.80		85.85	73.04	83.82	67.12	64.35
11			88.66		98.91	77.10	91.09	76.30	70.82
12			93.37			90.17	99.59	89.27	78.99

Application of Release Rate Kinetics to Dissolution Data

Data of *in vitro* release studies of formulations which were showing better drug release were fit into different equations to explain the release kinetics of Albendazole release from Sustained tablets. The data was fitted into various kinetic models such as zero, first order kinetics; higuchi and korsmeyer peppas mechanisms and the results were shown in below table it follows the zero order kinetics.

Table 7: Release kinetics data for optimized formulation (F7)

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG (%) RELEASE	LOG (T)	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE % RELEASE/ t)	1/CUM % RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3 -Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
16.5	1	1.000	1.217	0.000	1.922	16.500	0.0606	-0.783	83.5	4.642	4.371	0.271
21.32	2	1.414	1.329	0.301	1.896	10.660	0.0469	-0.671	78.68	4.642	4.285	0.357
28.11	3	1.732	1.449	0.477	1.857	9.370	0.0356	-0.551	71.89	4.642	4.158	0.484
35.08	4	2.000	1.545	0.602	1.812	8.770	0.0285	-0.455	64.92	4.642	4.019	0.623
40.96	5	2.236	1.612	0.699	1.771	8.192	0.0244	-0.388	59.04	4.642	3.894	0.748
48.6	6	2.449	1.687	0.778	1.711	8.100	0.0206	-0.313	51.4	4.642	3.718	0.923
56.14	7	2.646	1.749	0.845	1.642	8.020	0.0178	-0.251	43.86	4.642	3.527	1.115
61.73	8	2.828	1.790	0.903	1.583	7.716	0.0162	-0.210	38.27	4.642	3.370	1.272
75.69	9	3.000	1.879	0.954	1.386	8.410	0.0132	-0.121	24.31	4.642	2.897	1.745
83.82	10	3.162	1.923	1.000	1.209	8.382	0.0119	-0.077	16.18	4.642	2.529	2.112
91.09	11	3.317	1.959	1.041	0.950	8.281	0.0110	-0.041	8.91	4.642	2.073	2.568
99.59	12	3.464	1.998	1.079	-0.387	8.299	0.0100	-0.002	0.41	4.642	0.743	3.899

CONCLUSION

The ultimate aim of the present study was to prepare sustained release matrix tablet of Albendazole using natural polymers like Tragacanth, Guar gum and Acacia by direct compression technique. The conc. of Albendazole was kept constant. Lactose was used as filler. Following conclusions were made.

The FT-IR study indicates that there is no interaction of the drug with polymer used for the study.

Precompression parameter indicated that granules prepared with dry binders were free flowing.

The prepared granules for the compression of sustained release tablets were evaluated for various precompression parameters like bulk density, tapped density, Carr's index, hausner ratio and angle of repose which indicate that the prepared blend exhibited good flow properties.

Post compression parameter (Hardness, friability, thickness and drug content) was within the acceptable limit.

In vitro drug release of Albendazole tablets showed controlled release pattern, which may be attributed to the using various concentration of Tragacanth, Guar gum and Acacia.

On the basis of *in vitro* release studies, the equal concentration of polymers like Acacia showed better release of retarding than other combinations.

The study concluded that as the amount of polymer in the tablet formulation increases, the drug release rate decreases.

The drug release of nine formulations was compared with each other and the formulation F7 is considered to be the best formulation, as the drug release was retarded up to 12 hrs with 99.59% drug release.

This can help to reduce the dose and frequency. Based on kinetic data it was concluded that optimized formula showed zero order release and drug release mechanism was diffusion.

Matrix tablet of Albendazole that contained a blend of Acacia successfully sustained the release of Albendazole for a period of 12 hrs.

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