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Research Article

**PREPARING AND EVALUATING SUSTAINED-RELEASE (SR)
MATRIX TABLETS OF ALBENDAZOLE USING DIFFERENT
POLYMERS**

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India**Abstract:**

In the present investigation an attempt has been made to study the formulation and evaluation of sustained release tablets of Albendazole using okra gum and starch. The matrix tablets were formulated using different polymer concentrations of okra gum. The developed formulations of tablets were evaluated for pre-compression and post-compression parameters. The results of pre-compression parameters like bulk density, tapped density, Carr's index and Hausner's ratio were found to be within the limits indicating good flow properties of the granules. In-vitro drug release for F13 formulation was found to be 98.3% at the end of 12 hrs. With increase in gum concentration the drug release from the matrix tablets got retarded. In-vitro drug release data obtained were fitted to various release models access the possible mechanism of drug release. All the formulations showed matrix (exponential model) as a best fit model and the release mechanism was found to be anomalous (non Fickian) transport mechanism. Matrix tablets of albendazole using okra gum and starch and water as a release retardant could be employed for retardant drug release.

Keywords: Okra gum, Albendazole, Sustained release tablet.

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INTRODUCTION:

A solid dosage form is drug delivery system that includes tablets, capsules, sachets and pills as well as a bulk or unit-dose powders and granules. Among the various dosage forms oral solid dosage forms have greater importance and occupy a prime role in the pharmaceutical market [1,2]. Oral route of drug administration is widely acceptable and drugs administered orally as solid dosage form represents the preferred class of products. Over 90% of drugs formulated to produce systemic effects are produced as solid dosage forms. Because of these reason whenever New chemical entity (NCE) has discovered, which shows a sufficient pharmacological action, first the pharmaceutical company asks whether the drug is successfully administered by oral route or not. The currently employed CR technologies for oral drug delivery are diffusion-controlled systems, solvent activated systems, and chemically controlled systems [3,4,5]. Diffusion-controlled systems include monolithic and reservoir devices in which diffusion of the drug is the rate-limiting step, respectively, through a polymer matrix or a polymeric membrane [6-9].

Solvent-activated systems may be either osmotically controlled or controlled by polymer swelling. Chemically controlled systems release drugs via polymeric degradation (surface or bulk matrix erosion) or cleavage of drug from a polymer chain. It is worth mentioning here that the so-called programmed-release (“tailored-release”) profile of a final CR product is rarely the outcome of a single pharmaceutical principle. Depending on the specific physicochemical properties of the drug in question and desired therapeutic objectives, different formulation and CR principles may be proportionally combined within the same dosage form. This task appears to be simpler when realized in terms of appropriate selection of polymers and excipients that incorporate desired principles [10].

Sustained release dosage forms are formulated in such manner as to make the contained drug available

Formulation Development**Table 1: Composition of Sustained Release Tablets by using PVA + IPA**

Ingredients	F1	F2	F3	F4	F5	F6	F7
ALBENDAZOLE	200	200	200	200	200	200	200
Okra gum	20	30	40	50	100	150	250
Lactose	255	245	235	225	175	125	25
Mg.stearate	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5
PVA+IPA	15	15	15	15	15	15	15
Total weight	500	500	500	500	500	500	500

over an extended period following administration. A typical controlled release system is designed to provide constant or nearly constant drug levels in plasma with reduced fluctuations via slow release over an extended period of time. In practical terms, an oral controlled release should allow a reduction in dosing frequency as compared to when the same drug is presented as a conventional dosageform. A *matrix device* consists of drug dispersed homogeneously throughout a polymer matrix.

Albendazole is a broad-spectrum anthelmintic. The principal mode of action for albendazole is by its inhibitory effect on tubulin polymerization which results in the loss of cytoplasmic microtubules.

The present work is aimed at preparing and evaluating sustained-release (SR) matrix tablets of Albendazole using different polymers to study the effect of nature of the different natural polymers and percentage of the polymer on the rate of drug release. Preparation of sustained release tablets of Albendazole. To study the evaluation parameters of prepared tablets.

MATERIALS AND METHOD:

Albendazole Provided by Chandra labs, Okra gum Extraction done in Chandra labs, Lactose and Mg.stearate from Standard reagents Hyderabad.

Method:**Preparation of Calibration Curve of Albendazole in 0.1N HCl**

Procedure: 100 mg of Albendazole was accurately weighed and dissolved in 20ml of glacial acetic acid into a 100ml volumetric flask and finally the volume was adjusted to 100ml with glacial acetic acid (1000 µg/ml).

The standard solution of Albendazole was subsequently diluted with 0.1N HCl and 6.8pH Phosphate buffer separately to obtain a series of dilutions containing 4, 6, 8, 10, 12, 14 and 16µg/ml. The absorbance of the above dilutions was measured on a spectrophotometer at 254nm, using 0.1N HCl,6.8 pH Phosphate buffer as the blank.

Table 2: Composition of Sustained Release Tablets By Using Starch and Water

Ingredients	F8	F9	F10	F11	F12	F13	F14
ALBENDAZOLE	200	200	200	200	200	200	200
Okra gum	20	30	40	50	100	150	250
Lactose	255	245	235	225	175	125	25
Mg.stearate	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5
Starch	15	15	15	15	15	15	15
Water	q.s						
Total weight	500	500	500	500	500	500	500

Formulation Planning:

The sustained release tablets containing 200mg Albendazole were prepared with a total tablet weight of 500mg.

Lactose, half amount of the disintegrates, sodium lauryl Sulphate were weighed and sifted through 40 mesh. To the above blend Albendazole was added and sifted through 18 mesh. The sifted material was placed in cantabin blender and mixed for 8, 10, 12 min. Dry mix samples were taken at respective time points for content uniformity. Pvp k-30 was dissolved in IPA (F1-F7) and starch + water from formulations F7-F14 was granulated. The wet mass passed through 12 mesh and dried in tray dryer at 60°C. The dried granules were passed through 18 mesh. Magnesium Stearate were weighed and sifted through 40 mesh, dried granules lubricated blend was added and placed in cantabin blender, the lubricated blend was mixed for 1, 2, 3 min. samples were taken at respective time points for content uniformity. The lubricated blend was compressed using 16X8mm round punches.

Pre- Compression Parameters:**Bulk Density:**

Bulk density was determined by pouring gently 20 gm of sample (Albendazole) through a glass funnel into 50 ml graduated cylinder. The volumes occupied by the samples were recorded. Bulk density was calculated as:

$$\text{Bulk density} = \frac{\text{weight of sample in gram}}{\text{volume occupied by the sample}}$$

Tapped density was determined by using Electro lab density tester, which consists of a graduated cylinder mounted on a mechanical tapping device. An accurately weighed sample of powder was carefully added to the cylinder with the aid of a funnel. Typically, the initial volume was noted, and the sample is then tapped (500, 750 or 1250 tapping) until no further reduction in volume is noted or the percentage of difference is not more than 2%. A sufficient number of taps should be employed to

assure reproducibility for the material in question. Volume was noted and tapped density is calculated using following formula.

$$\text{Tapped density} = \frac{\text{Wt. of sample in gm}}{\text{Tapped volume}}$$

Compressibility Index and Hausner ratio:-

In recent years the compressibility index and the closely related Hausner's ratio have become the simple, fast, and popular methods of predicting powder flow characteristics. Both the Compressibility index and the Hausner's ratio were determined by using bulk density and the tapped density of a powder.

Relation of flow property with HR & CI

$$\text{Carr's index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

Angle of Repose: -

The angle of repose has been used to characterize the flow properties of solids. Angle of repose is a characteristic related to inter particulate friction or resistance to movement between particles. This is the maximum angle possible between surface of pile of powder or granules and the horizontal plane.

$$\tan \theta = h / r$$

$$\theta = \tan^{-1} h / r$$

Where

θ = angle of repose,

h = height,

r = radius.

A funnel was fixed at a height approximately of 2-4 cm over the platform. The loose powder was slowly passed along the wall of funnel, till the cone of the powder formed. Determine the angle of repose by measuring the height of the cone of powder and radius of the heap of powder.

Evaluation of Tablets:

To design tablets and later monitor tablet production quality, quantitative evaluation and assessment of tablet chemical, physical and bioavailability properties must be made. The important parameters in the evaluation of tablets can be divided into physical and chemical parameters.

Physical Appearance:

The general appearance of tablets, its visual identity and overall elegance is essential for consumer acceptance. The control of general appearance of tablet involves measurement of number of attributes such as tablet size, shape, colour, presence or absence of odour, taste, surface texture and consistency of any identification marks.

Hardness Test:

This is the force required to break a tablet in a diametric compression. Hardness of the tablet is determined by Stock's Monsanto hardness tester which consists of a barrel with a compressible spring. The pointer moves along the gauze in the barrel fracture.

Tablet Size and Thickness:

Control of physical dimensions of the tablets such as size and thickness is essential for consumer acceptance and tablet-tablet uniformity. The diameter size and punch size of tablets depends on the die and punches selected for making the tablets. The thickness of tablet is measured by Vernier Callipers scale. The thickness of the tablet related to the tablet hardness and can be used an initial control parameter. Tablet thickness should be controlled within a $\pm 5\%$. In addition thickness must be controlled to facilitate packaging.

Friability:

This test is performed to evaluate the ability of tablets to withstand abrasion in packing, handling and transporting. Initial weight of 20 tablets is taken and these are placed in the friabilator, rotating at 25rpm for 4min. The difference in the weight is noted and expressed as percentage. It should be preferably between 0.5 to 1.0%.

$$\% \text{Friability} = (W_1 - W_2) / W_1 \times 100$$

Where, W_1 = weight of tablets before test

W_2 = weight of tablets after test

Weight variation of Tablets:

It is desirable that all the tablets of a particular batch should be uniform in weight. If any weight variation is there, that should fall within the prescribed limits:

Twenty tablets were taken randomly and weighed accurately. The average weight was calculated by,

$$\text{Average weight} = \frac{\text{weight of 20 tablets}}{20}$$

Dissolution Test:

Dissolution: It is the amount of the solid substance that goes into the solution per unit time under standard conditions of the temperature and pressure

Method: dissolution media was taken as 0.1N HCL, 500ml was placed in the vessel and the USP apparatus -I (Basket Method) was assembled. The medium was allowed to equilibrate to temp of $37 \pm 0.5^\circ\text{C}$. Tablet was placed in the basket and placed in the vessel, the apparatus was operated for 15min at 50 rpm. At definite time intervals, 5 ml of the fluid was withdrawn; filtered and again 5ml of the fluid was replaced. Suitable dilutions were done with the dissolution fluid and the samples were analyzed using UV.

Preparation of Dissolution Media (0.1N HCL): pipette out 8.5ml of concentrated HCL into 1000ml volumetric flask and make up with water to 1000ml.

Assay

The Assay for Albendazole sustained release was estimated by UV spectrophotometer

Kinetic Data Analysis:

The analysis of drug release mechanism from a pharmaceutical dosage form is an important but complicated process and is practically evident in the case of matrix systems. As a model-dependent approach, the dissolution data was fitted to five popular release models such as zero, first-order, diffusion and exponential equations. The order of drug release from matrix systems was described by using zero order kinetics or first orders kinetics.

Kinetic Studies**Zero Order Release Equation**

- The equation for zero order release is

$$Q_t = Q_0 + K_0 t$$

Where

Q_0 = initial amount of drug

Q_t = cumulative amount of drug release at time

"t"

K_0 = zero order release constant

t = time in hours

- It describes the systems where the drug release rate is independent of its concentration of the dissolved substance.

- A graph is plotted between the time taken on x-axis and the cumulative percentage of drug release on y-axis and it gives a straight line.

First Order Release Equation

- The first order release equation is

$$\text{Log } Q_t = \text{Log } Q_0 + Kt / 2.303$$

Where

Q_0 = initial amount of drug

Q_t = cumulative amount of drug release at time

K = first order release constant

t = time in hours

- Here, the drug release rate depends on its concentration
- A graph is plotted between the time taken on x-axis and the log cumulative percentage of drug remaining to be released on y-axis and it gives a straight line.

Higuchi's Model

Drug release from the matrix devices by diffusion has been described by following Higuchi's classical diffusion equation.

$$Q = [D\varepsilon / \tau (2A - \varepsilon Cs) Cst]^{1/2}$$

Where, Q = Amount of drug released at time 't'.

D = Diffusion coefficient of the drug in the matrix.

A = Total amount of drug in unit volume of matrix.

Cs = the solubility of the drug in the matrix.

ε = Porosity of the matrix.

τ = Tortuosity.

t = Time (hrs) at which 'q' amount of drug is released.

Above equation may be simplified if one assumes that 'D', 'Cs', and 'A', are constant. Then equation becomes:

$$Q = Kt^{1/2}$$

When the data is plotted according to equation i.e. cumulative drug release versus square root of time yields a straight line, indicating that the drug was released by diffusion mechanism. The slope is equal to 'K' (Higuchi's 1963).

Korsmeyer Equation / Peppas's Model

To study the mechanism of drug release from the sustained release matrix tablets

Of Ciprofloxacin, the release data were also fitted to the well-known exponential equation (Korsmeyer equation / Peppas's law equation), which is often used to describe the drug release behavior from polymeric systems.

$$M_t / M_\infty = Kt^n$$

Where, M_t / M_∞ = the fraction of drug released at time 't'.

K = Constant incorporating the structural and geometrical characteristics of the drug / polymer system.

n = Diffusion exponent related to the mechanism of the release.

Above equation can be simplified by applying log on both sides, and we get:

$$\log M_t / M_\infty = \log K + n \log t$$

When the data is plotted as log of drug released versus log time, yields a straight line with a slope equal to 'n' and the 'K' can be obtained from y-intercept. For Fickian release 'n' = 0.5 while for anomalous (non - Fickian) transport 'n' ranges between 0.5 and 1.0.

Stability Studies:

The optimized matrix tablets were subjected to stability studies (as per ICH guide lines) at 25°C ± 2°C / 60% ± 5% RH and 40°C ± 2°C / 75% ± 5% RH. The products were evaluated for their physical characteristics, drug content, and In-vitro drug release profiles over a period of 3 months.

RESULTS AND DISCUSSION:

Table 3: A Standard curve of Albendazole in 0.1N HCL

Sr. No.	Conc.($\mu\text{g/ml}$)	Absorbance
1	0	0
2	4	0.182
3	6	0.302
4	8	0.401
5	10	0.515
6	12	0.633
7	14	0.751
8	16	0.882

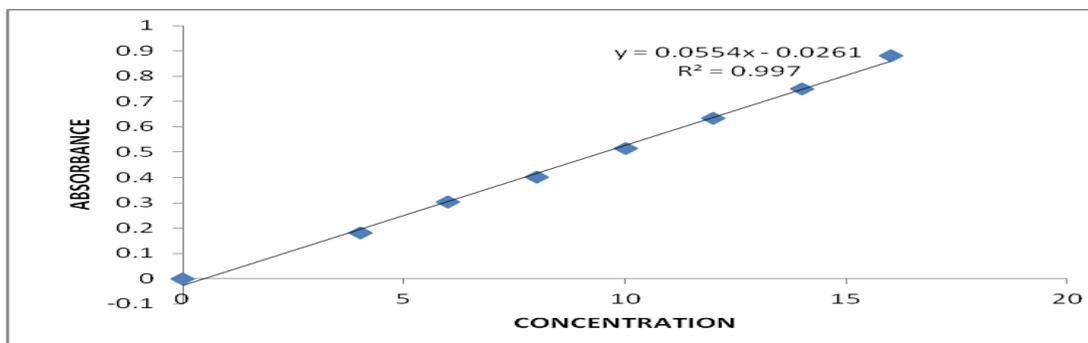


Fig1: Standard curve of Albendazole in 0.1N HCL

Table 4: Standard Calibration Curve of Albendazole in 6.8 pH Phosphate Buffer

Sr. No.	Conc.(µg/ml)	Absorbance
1	0	0
2	4	0.140
3	6	0.216
4	8	0.288
5	10	0.360
6	12	0.432
7	14	0.504
8	16	0.559

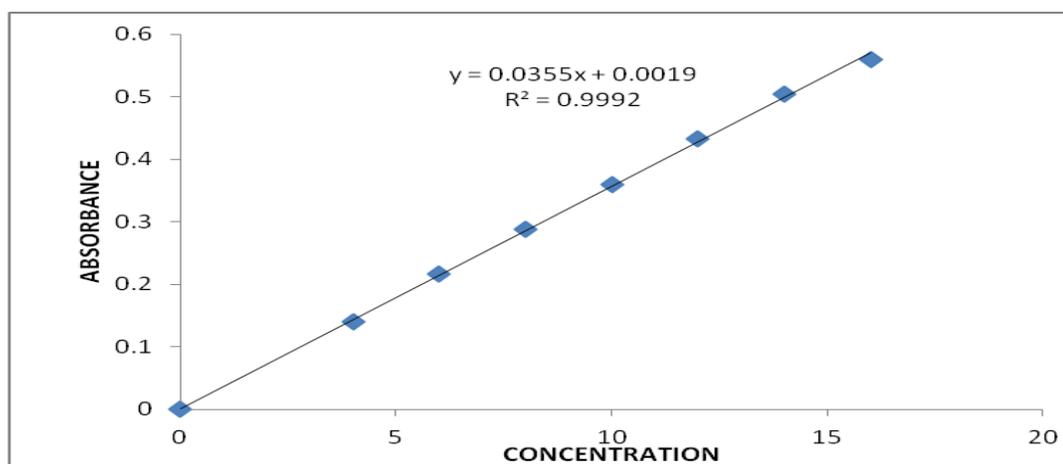


Fig2: Standard curve of Albendazole in 6.8 pH Phosphate Buffer

Table 5: Evaluations of Granules

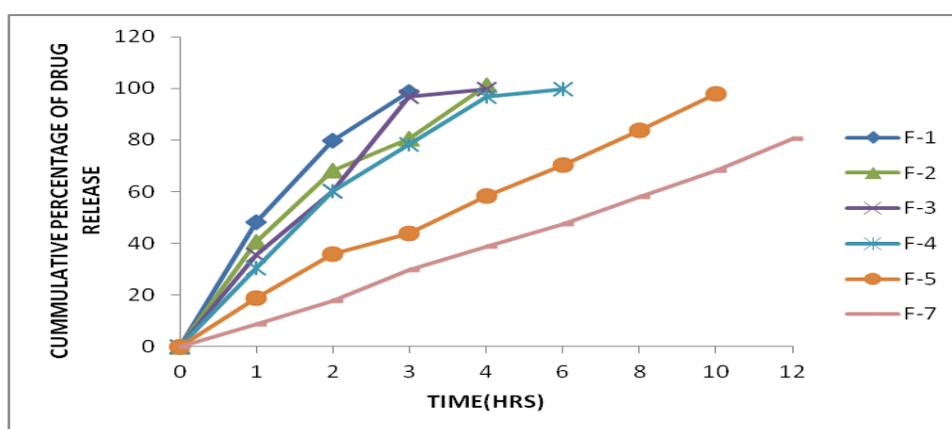
S.No	Formulations	Bulk Density (g/ml)	Tapped Density (g/ml)	Compressibility Index (%)	Hausner's Ratio	Angle Of Repose
1	F-1	0.419	0.432	13.09	1.13	Good
2	F-2	0.436	0.500	12.8	1.14	Good
3	F-3	0.428	0.496	13.7	1.15	Good
4	F-4	0.445	0.505	11.8	1.13	Good
5	F-5	0.400	0.470	14.8	1.17	Good
6	F-6	0.417	0.482	13.4	1.15	Good
7	F-7	0.393	0.460	14.5	1.17	Good
8	F-8	0.428	0.490	12.6	1.14	Good
9	F-9	0.415	0.476	12.8	1.14	Good
10	F-10	0.416	0.485	14.2	1.16	Good
11	F-11	0.445	0.505	11.8	1.13	Good
12	F-12	0.428	0.490	12.6	1.14	Good
13	F-13	0.415	0.476	12.8	1.14	Good
14	F-14	0.393	0.460	14.5	1.17	Good

Table 6: Evaluations of Tablets

S.No	Formulations	Weight variation	Thickness (mm)	Hardness (kg/cm ²)	Friability (%)	Assay (%)
1	F-1	500± 0.05	3.69± 0.065	7.12± 0.05	0.12	98.3
2	F-2	502± 0.011	3.62 ± 0.016	7.15 ± 0.03	0.06	98.3
3	F-3	498± 0.015	3.86 ± 0.035	7.19 ± 0.22	0.09	98.1
4	F-4	501± 0.011	3.45± 0.024	7.14 ± 0.51	0.15	98.9
5	F-5	502± 0.025	3.82 ± 0.029	7.14 ± 0.49	0.18	98.4
6	F-6	500± 0.009	3.57 ± 0.053	7.16 ± 0.32	0.09	96.3
7	F-7	500± 0.015	3.67 ± 0.052	7.18 ± 0.59	0.08	98.4
8	F-8	503± 0.007	3.42 ± 0.022	7.16 ± 0.47	0.16	98.7
9	F-9	499± 0.024	3.64± 0.019	7.14± 0.35	0.14	98.5
10	F-10	500± 0.014	3.90 ± 0.016	7.12 ± 0.27	0.13	100.2
11	F-11	500± 0.019	3.59± 0.019	7.09± 0.23	0.12	99.12
12	F-12	499± 0.011	3.84 ± 0.016	7.16 ± 0.21	0.15	99.54
13	F-13	501± 0.31	3.68 ± 0.021	7.08 ± 0.011	0.17	98.13
14	F-14	500± 0.011	3.62 ± 0.021	7.12 ± 0.013	0.09	99.3

Table 7: Percentage of Drug Release using PVA+IPA (Albendazole)

Time	F-1	F-2	F-3	F-4	F-5	F-6	F-7
0.1N Hcl							
1	48	40.4	35.4	30.3	18.6	14.1	8.5
2	79.6	68.3	60.2	60.2	35.7	27.2	17.6
6.8pH Phosphate buffer							
3	98.8	80.6	96.8	78.3	43.8	34.5	29.8
4	-	101.2	99.7	96.8	58.3	45.4	38.6
6	-	-	-	99.7-	70.4	61.1	47.4
8	-	-	-	-	83.8	75.1	57.9
10	-	-	-	-	97.8	85.2	68.3
12	-	-	-	-	-	98.67	80.3

**Fig 3: Dissolution graph for F1-F7****Table 8: Percentage of Drug Release using Starch and Water (Albendazole)**

Time	F-8	F-9	F-10	F-11	F-12	F-13	F-14
0.1N Hcl							
1	46.8	38.6	33.2	28.9	17.3	14.5	8.9
2	73.2	63.7	57.6	50.6	32.5	27.8	18.3
6.8pH Phosphate buffer							
3	96.5	77.5	70.6	68.5	40.6	35.8	30.3
4	101.3	98.3	89.2	83.9	55.9	46.9	37.6
6	-	-	98.9	92.5	70.2	60.1	50.7
8	-	-	-	99.7	82.3	76.3	59.4
10	-	-	-	-	98.8	84.6	70.2
12	-	-	-	-	-	98.3	81.5

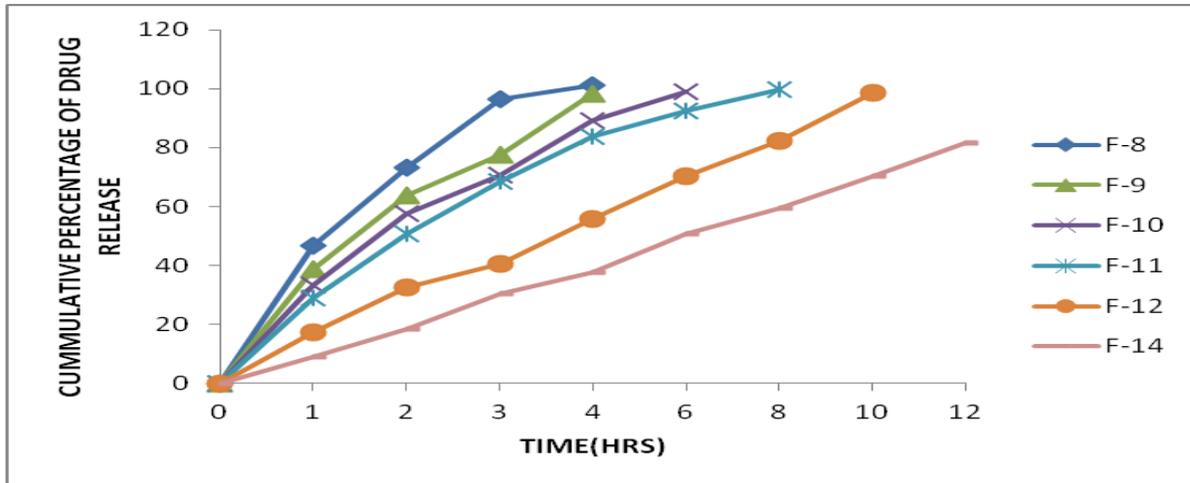


Fig 4: Dissolution Graph for F8-F14

Table 9: Kinetic Profiles

RELEASE KINETICS				
	ZERO	HIGUCHI	PEPPAS	FIRST
Slope	0.1309	4.3639	0.7539	-0.0167
Intercept	9.2240	-20.7320	-0.1484	2.3947
R 2	0.9753	0.9969	0.9949	0.8372

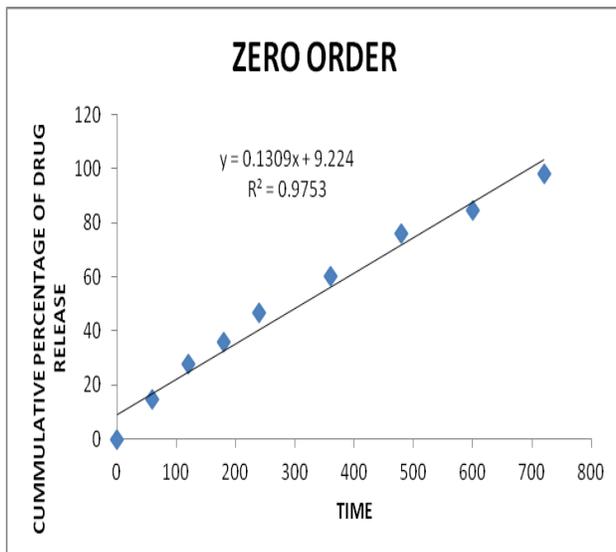


Fig 5: Zero Order Kinetics Graphs

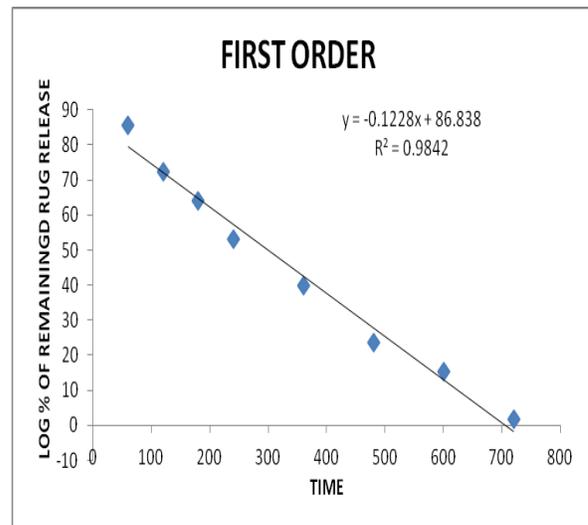


Fig 6: First Order Kinetics Graph

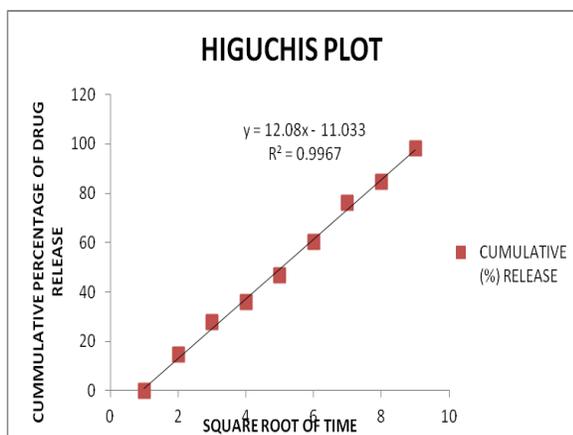


Fig 7: Higuchis Plot Kinetics Graph

From the standard curve of Albendazole, it was observed that the drug obeys beer's law in concentration range of 4-16 $\mu\text{g/ml}$ in 0.1N HCL. The linear regression equation generated was used for the calculation of amount of drug.

Evaluation of Powder Flow Properties:

a. Bulk Density and Tapped Density

Bulk density and tapped density of powder blend was evaluated. The results were shown in the Table 5

b. Angle of Repose

The angle of repose for the entire formulations blend was evaluated. The results were shown in the Table 5. Range from 21-28.

c. Compressibility Index

Compressibility index for the entire formulations blend was evaluated. The results were shown in the Table 5, range from 11.8-14.5.

d. Hausner's Ratio

The Hausner's ratio for the entire formulations blend was evaluated. The results were shown in the Table 5, range from 1.13-1.17. All these are within the limit.

Evaluation Of Tablets

Hardness

The prepared tablets in all the formulations possessed good mechanical strength with sufficient hardness in the range of 5.0 to 5.9 kg/sq cm. Shown in table no6.

Friability

Friability values below 1% were an indication of good mechanical resistance of the tablets.

Weight Variation

All the tablets from each formulation passed weight variation test, as the % weight variation was within the pharmacopoeial limits of $\pm 5\%$ of the weight. The weight variation in all the eight formulations was found to pharmacopoeial limits of $\pm 7.5\%$ of the average weight. Shown in table 6.

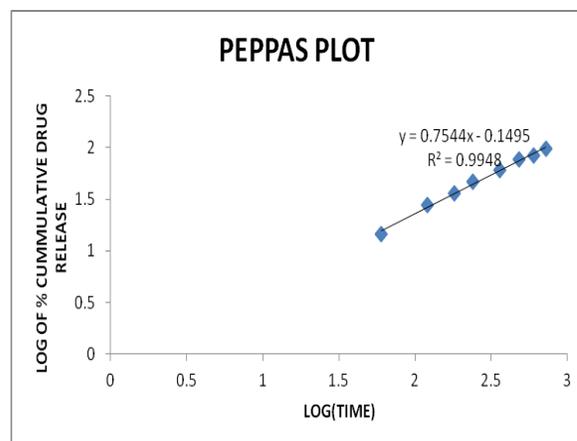


Fig 8: Peppas Plot Kinetics Graph

In-Vitro Dissolution Study:

Based on dissolution data the formulation F-6 and F-13 both are selected for optimization and it clearly showed an evident that there does not exist any influence of binder on formulations. As it is a natural polymer the concentration of polymer was started with least percentage to highest percentage. The drug release of different concentration was as follows

F1 - 98.8% of drug release in 3rd hr with 4% of polymer. F2 - 101.2% of drug release in 4th hr with 6% of polymer. F3 - 99.7% of drug release in 6th hr with 8% of polymer. F4 - 98.8% of drug release in 6th hr with 10% of polymer. F5 - 97.8% of drug release in 10th hr with 20% of polymer. F6 - 98.67% of drug release in 12th hr with 30% of polymer.

F7 - 80.3% of drug release in 12th hr with 50% of polymer. F8 - 101.3% of drug release in 4th hr with 4% of polymer. F9 - 98.3% of drug release in 4th hr with 6% of polymer. F10 - 98.9% of drug release in 6th hr with 8% of polymer. F11 - 99.7% of drug release in 8th hr with 10% of polymer. F12 - 98.8% of drug release in 10th hr with 20% of polymer. F13 - 98.3% of drug release in 12th hr with 30% of polymer. F14 - 81.5% of drug release in 12th hr with 50% of polymer.

Drug Release Kinetics:

The cumulative amount of Albendazole released from the formulated matrix tablets at different time intervals were fitted in to several kinetic models such as Zero order kinetics, first order kinetics, Higuchi model and Korsmeyer-peppas model to characterize mechanism of drug release.

The Release Kinetics Follows Zero Order with an R^2 value of 0.9753 which is independent of concentration And Higuchis model which is followed by Peppas Model with an R^2 of 0.9969 and 0.9949 respectively.

CONCLUSION:

The Sustained released tablets containing Albendazole SR were successfully prepared by wet granulation method.

The physiochemical evaluation results for the granules of all trials pass the official limits in angle of repose, compressibility index. The physiochemical evaluation results for the dry blend of all trials pass the official limits in angle of repose, compressibility index.

The prepared granules were also maintained the physiochemical properties of tablets such as thickness, hardness, weight variation, friability. The optimized formulation contains the thickness of 3.68 ± 0.021 , hardness of 7.08 ± 0.011 , average weight of 501 ± 0.31 , friability of 0.17 and drug content in between 98.13%.

In the F13 trial, the optimized formulation was F13 trial which releases the Albendazole in sustained manner in 1st hour it releases 14.5 % but the remaining drug release was sustained up to 12 hours.

Hence it may be summarized that the trial F13 tablets prepared by wet granulation method by using starch as binder for sustained release might be a perfect and effective formulation to treat the Anthelmintic.

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