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FORMULATION AND EVALUATION OF AN ORAL FLOATING TABLET OF ALFUZOSIN HYDROCHLORIDE

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Abstract:

The present study focuses on the formulation and evaluation of an oral floating drug delivery system of Alfuzosin Hydrochloride designed to enhance gastric residence time and improve bioavailability. Alfuzosin Hydrochloride, used in the management of benign prostatic hyperplasia, exhibits better absorption in the upper gastrointestinal tract, making it a suitable candidate for gastro-retentive delivery. Floating tablets were prepared using the direct compression method employing hydrophilic polymers such as HPMC and gas-generating agents like sodium bicarbonate to achieve buoyancy. The formulated tablets were evaluated for pre-compression parameters including bulk density, tapped density, angle of repose, Carr's index, and Hausner ratio to ensure good flow properties. Post-compression evaluation included hardness, friability, thickness, weight variation, drug content uniformity, floating lag time, total floating duration, and in-vitro dissolution studies. The optimized formulation demonstrated acceptable physical characteristics, rapid floating lag time, prolonged buoyancy exceeding 12 hours, and controlled drug release behavior following near zero-order kinetics. Stability studies indicated that the formulation remained stable under accelerated conditions. The results suggest that the developed oral floating tablet system is a promising approach for sustained delivery of Alfuzosin Hydrochloride with enhanced therapeutic effectiveness.

Keywords: *Alfuzosin Hydrochloride, Oral Floating Tablet, Gastro-retentive Drug Delivery System, Floating Lag Time, HPMC, Sustained Release.*

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1. INTRODUCTION:

Oral delivery of drugs is the most preferable route of drug delivery. Oral route is considered most natural, uncomplicated, convenient and safe due to its ease of administration, patient compliance and flexibility in formulation and cost-effective manufacturing process[1]. Many of the drug delivery systems, available in the market are oral drug delivery type systems pharmaceutical products designed for oral delivery are mainly immediate release type or conventional drug delivery systems, which are designed for immediate release of drug for rapid absorption.

Out of the many routes of administration available, the oral route remains the most popular dosage form among patients as it is easy to administer, carry around, formulation design flexibility, cost-effectiveness, causes minimal discomfort for many patients, and least sterility restrictions during manufacturing. Most of the newly discovered drugs are lipophilic in nature and have poor aqueous solubility, thereby posing problems in their formulation into delivery systems[2].

These immediate release dosage forms have some limitations such as:

1. Drugs with short half-life require frequent administration, which increases chances of missing dose of drug leading to poor patient compliance.
2. A typical peak-valley plasma concentration-time profile is obtained which makes attainment of steady state condition difficult.
3. The unavoidable fluctuations in the drug concentration may lead to under medication or overmedication as the C_s values fall or rise beyond the therapeutic range.
4. The fluctuating drug levels may lead to precipitation of adverse effects especially of a drug with small therapeutic index, whenever overmedication occurs.

In order to overcome the drawbacks of conventional drug delivery systems, several technical advancements have led to the development of controlled drug delivery system that could revolutionize method of medication and provide a number of therapeutic benefits.[3]

1.1 Controlled Drug Delivery Systems:

Controlled drug delivery systems have been developed which are capable of controlling the rate of drug delivery, sustaining the duration of therapeutic activity and/or targeting the delivery of drug to a tissue.[4]

Controlled drug delivery or modified drug delivery systems are divided into four categories.

1. Delayed release
2. Sustained release
3. Site-specific targeting
4. Receptor targeting

More precisely, controlled delivery can be defined as:-

1. Sustained drug action at a predetermined rate by maintaining a relatively constant, effective drug level in the body with concomitant minimization of undesirable side effects.
2. Localized drug action by spatial placement of a controlled release system adjacent to or in the diseased tissue.
3. Targeted drug action by using carriers or chemical derivatives to deliver drug to a particular target cell type.
4. Provide physiologically/therapeutically based drug release system. In other words, the amount and the rate of drug release are determined by the physiological/ therapeutic needs of the body.[5]

A controlled drug delivery system is usually designed to deliver the drug at particular rate. Safe and effective blood levels are maintained for a period as long as the system continues to deliver the drug (Figure 1).[6] Controlled drug deliveries usually results in substantially constant blood levels of the active ingredient as compared to the uncontrolled fluctuations observed when multiple doses of quick releasing conventional dosage forms are administered to a patient.[7-10]

METHODOLOGY:

7.2. Drug – Excipient compatibility studies

Fourier Transform Infrared (FTIR) spectroscopy:

The compatibility between the pure drug and excipients was detected by FTIR spectra obtained on Bruker FTIR Germany (Alpha T). The solid powder sample directly place on yellow crystal which was made up of ZnSe. The spectra were recorded over the wave number of 4000 cm^{-1} to 550 cm^{-1}.

7.3. Preformulation parameters

Angle of repose:

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

$\tan \theta$ = Angle of repose

h = Height of the cone ,

r = Radius of the cone base

Table 7.1: Angle of Repose values (as per USP)

Angle of Repose	Nature of Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Bulk density:

The bulk density was calculated using the formula:

$$\text{Bulk Density} = M / V_o$$

Where, M = weight of sample

V_o = apparent volume of powder

Tapped density:

$$\text{Tap} = M / V$$

Where, Tap= Tapped Density

M = Weight of sample

V= Tapped volume of powder

Measures of powder compressibility:

$$\text{Carr's Index} = [(\text{tap} - b) / \text{tap}] \times 100$$

Where, b = Bulk Density

Tap = Tapped Density

Table 7.2: Carr's index value (as per USP)

Carr's index	Properties
5 – 15	Excellent
12 – 16	Good
18 – 21	Fair to Passable
2 – 35	Poor
33 – 38	Very Poor
>40	Very Very Poor

7.3. Formulation development of floating Tablets:

For optimization of sodium bicarbonate concentration, granules were prepared by direct compression method.

Procedure for direct compression method:

1) Drug and all other ingredients were individually passed through sieve no ≠ 60.
2) All the ingredients were mixed thoroughly by triturating up to 15 min.
3) The powder mixture was lubricated with talc.
4) The tablets were prepared by using direct compression method by using 7 mm punch.

FORMULATION OF TABLETS:

Table 7.4: Formulation composition for Floating tablets

Formulation Code	F1	F2	F3	F4	F5	F6	F7	F8	F9
Alfuzosin	10	10	10	10	10	10	10	10	10
Xanthan Gum	5	10	15	-	-	-	-	-	-
Guar Gum	-	-	-	5	10	15	-	-	-
Karaya Gum	-	-	-	-	-	-	5	10	15
PVP K30	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
$NaHCO_3$	15	15	15	15	15	15	15	15	15
Citric Acid	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5

Mg. Stearate	3	3	3	3	3	3	3	3	3
Talc	3	3	3	3	3	3	3	3	3
MCC PH 102	69	64	59	69	64	59	69	64	59
Total weight	120	120	120	120	120	120	120	120	120

All the quantities were in mg

7.4. Evaluation of post compression parameters for prepared Tablets

The designed compression tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability and drug content.

Weight variation test:

Table 7.5: Pharmacopoeial specifications for tablet weight variation

Average weight of tablet (mg) (I.P)	Average weight of tablet (mg) (U.S.P)	Maximum percentage difference allowed
Less than 80	Less than 130	10
80-250	130-324	7.5
More than	More than 324	5

***I*n vitro drug release studies**

Dissolution parameters:

Apparatus -- USP-II, Paddle Method
Dissolution Medium -- 0.1 N HCL
RPM -- 50
Sampling intervals (hrs) -- 0.5,1,2,3,4,5,6,7,8,10,11,12
Temperature -- 37°c ± 0.5°c

As the preparation was for floating drug release given through oral route of administration, different receptors fluids are used for evaluation the dissolution profile.

Procedure:

900ml 0f 0.1 HCL was placed in vessel and the USP apparatus –II (Paddle Method) was assembled. The medium was allowed to equilibrate to temp of 37°c ± 0.5°c. Tablet was placed in the vessel and the vessel was covered the apparatus was operated for 12 hours and then the medium 0.1 N HCL was taken and process was continued from 0 to 12 hrs at 50 rpm. At definite time intervals of 5 ml of the receptors fluid was withdrawn, filtered and again 5ml receptor fluid was replaced. Suitable dilutions were done with media and analyzed by spectrophotometrically at 243 nm using UV-spectrophotometer.

RESULTS AND DISCUSSION:

8.2. Drug – Excipient compatability studies

Fourier Transform-Infrared Spectroscopy:

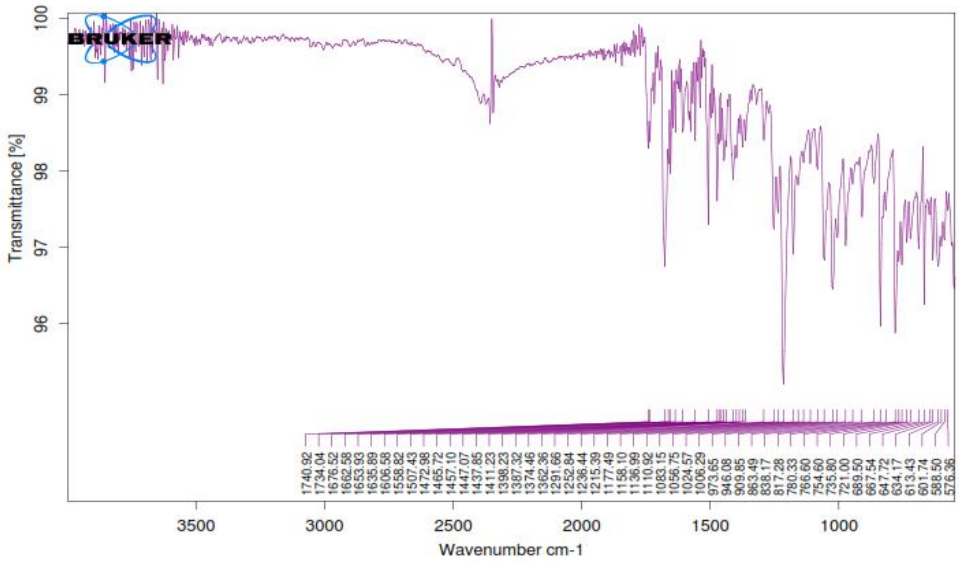

Figure 8.2: FTIR Spectrum of pure drug

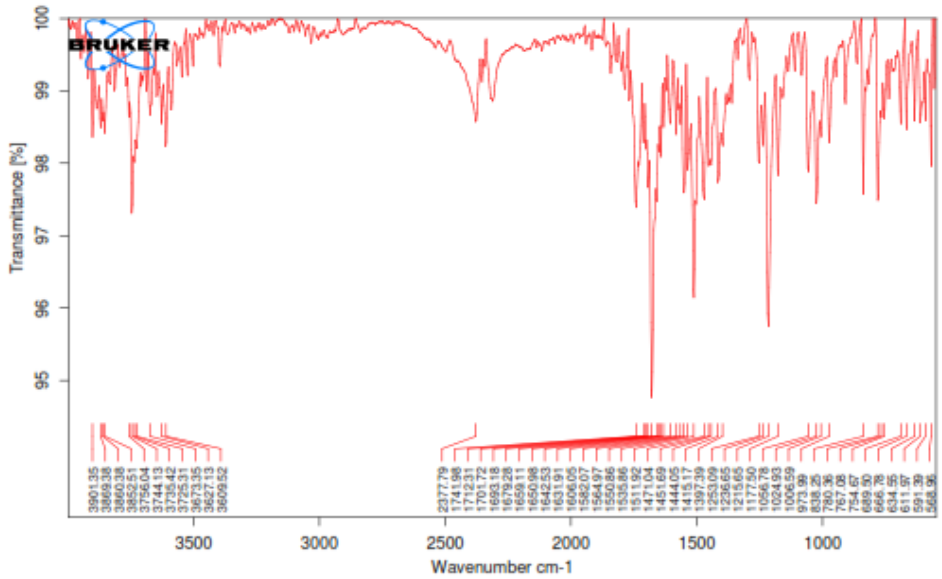

Fig 8.3 FTIR Spectrum of optimised formulation

Alfuzosin are also present in the physical mixture, which indicates that there is no interaction between drug and the polymers, which confirms the stability of the drug.

8.3. Preformulation parameters of powder blend:

Table8.2: Pre-formulation parameters of blend

Formulation Code	Angle of Repose	Bulk density (gm/mL)	Tapped density (gm/mL)	Carr's index (%)	Hausner's Ratio
F1	25.12	0.59	0.66	11.86	1.11
F2	26.8	0.48	0.54	12.5	1.12
F3	23.74	0.56	0.66	17.85	1.17
F4	26.33	0.44	0.55	18.18	1.18
F5	25.21	0.48	0.57	16.66	1.16

F6	27.18	0.51	0.59	15.68	1.15
F7	24.29	0.46	0.56	17.85	1.21
F8	26.01	0.50	0.59	15.25	1.18
F9	26.12	0.52	0.63	17.46	1.21

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 0.48 to 0.59 (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 0.54 to 0.66 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 18 which shows that the powder has good flow properties. All the formulations has shown the hausners ratio ranging between 0 to 1.2 indicating the powder has good flow properties.

8.4. Optimization of sodium bicarbonate concentration:

Three formulations were prepared with varying concentrations of sodium bicarbonate by direct compression method and three more formulations were prepared by wet granulation method to compare the floating buoyancy in between direct and wet granulation methods. The formulation containing sodium bicarbonate in 15mg concentration showed less floating lag time in wet granulation method and the tablet was in floating condition for more than 12 hours.

8.5. Quality Control Parameters For tablets:

Tablet quality control tests such as weight variation, hardness, and friability, thickness, Drug content and drug release studies were performed for floating tablets.

8.3. *In vitro* quality control parameters

Formulation codes	Average Weight (mg)	Hardness(kg/cm2)	Friability (%loss)	Thickness (mm)	Drug content (%)	Floating lag time (min)	Total Floating Time(Hrs)
F1	300.4	5.1	0.61	3.3	98.42	5.5	4
F2	301.2	5.2	0.58	3.2	99.65	4.2	6
F3	299.3	5.5	0.45	3.4	99.12	5.0	12
F4	299.8	5.1	0.61	3.3	98.42	5.1	6
F5	298.6	5.3	0.59	3.5	99.65	4.0	8
F6	300.4	5.5	0.65	3.4	99.12	3.2	12
F7	301.6	5.3	0.62	3.6	98.16	4.5	5
F8	298.2	5.2	0.59	3.4	98.11	3.6	12
F9	297.5	5.4	0.60	3.3	98.25	4.7	12

All the parameters for tablets such as weight variation, friability, hardness, thickness, drug content were found to be within limits.

***8.6. In Vitro* Drug Release Studies**

Table no 8.4: Dissolution data of Floating Tablets

Time (hr)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
0.5	35.32	30.04	24.63	19.17	14.90	10.49	23.56	16.76	10.15
1	54.53	47.56	30.63	24.12	20.45	17.63	46.45	21.89	15.41
2	69.90	54.35	42.52	38.64	32.02	26.55	51.23	28.24	20.98
3	74.96	63.52	50.31	50.20	39.31	32.84	70.54	33.32	25.09

4	86.14	74.75	58.25	69.56	47.82	39.39	79.73	37.75	29.54
5	92.85	82.54	65.78	75.43	53.47	44.71	86.46	42.09	33.36
6		89.26	70.17	83.01	59.74	53.05	98.12	49.16	39.67
7		95.95	75.79	95.57	64.05	60.87		53.36	44.36
8			82.27		79.93	67.02		59.12	50.77
9			89.64		84.26	74.15		63.78	56.42
10			94.87		95.45	79.24		67.79	60.02
11						87.54		76.31	64.46
12						96.32		84.45	69.39

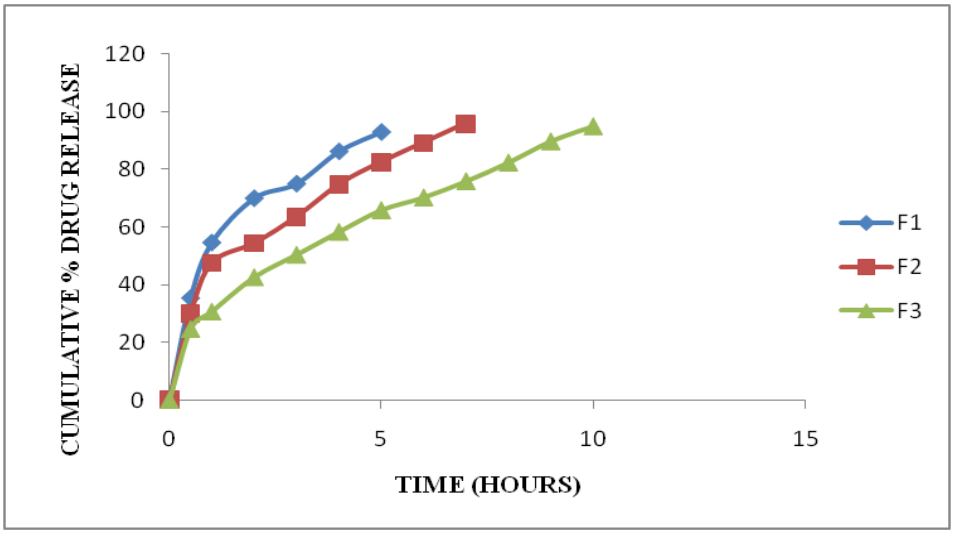

Fig 8.4: Dissolution data of Alfuzosin Floating tablets containing Xanthan Gum

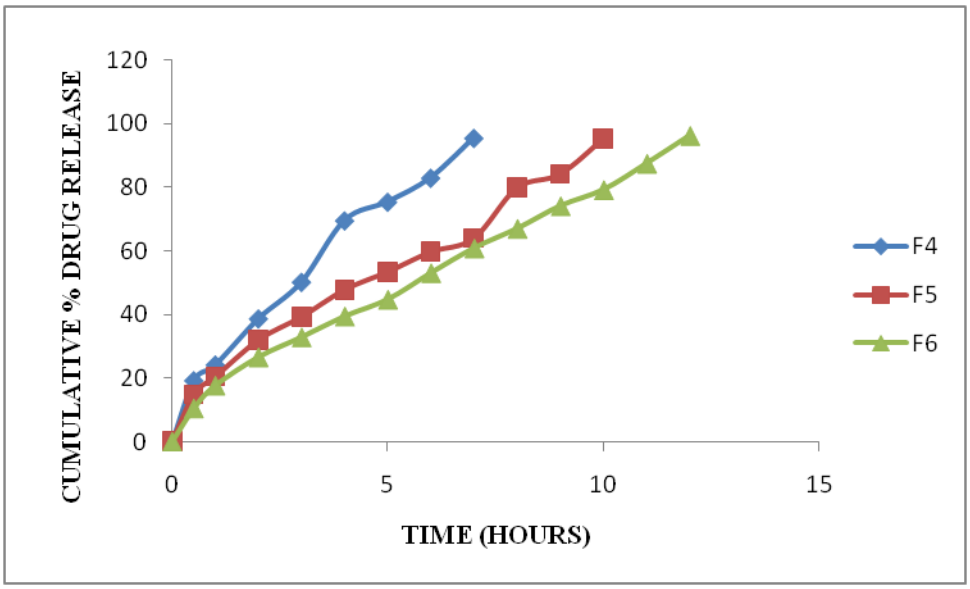

Fig:8.5Dissolution data of Alfuzosin Floating tablets containing Guar Gum

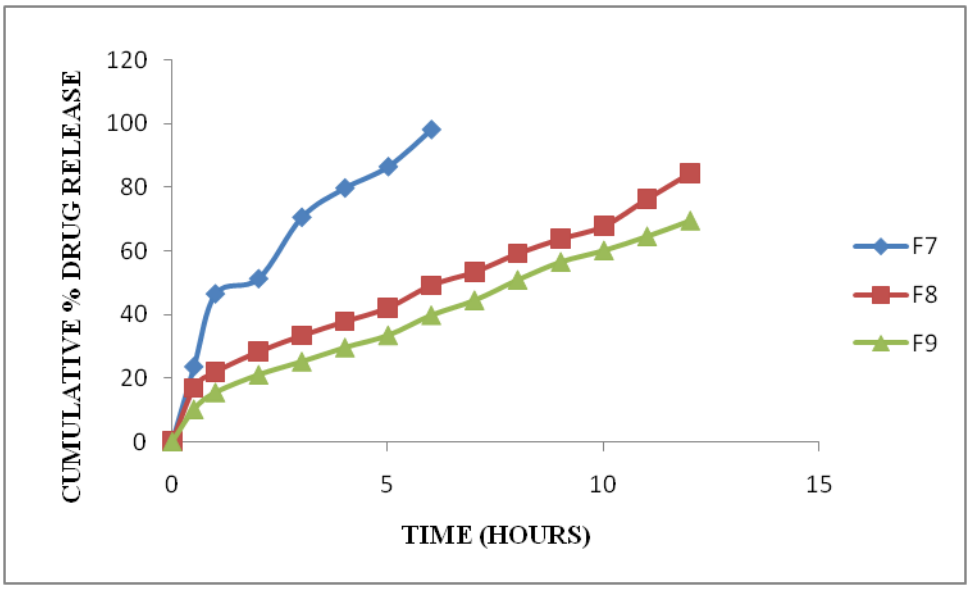

Fig: 8.6 Dissolution data of Alfuzosin Floating tablets containing Karaya Gum

From the dissolution data it was evident that the formulations prepared with Karaya Gum as polymer were retarded the drug release more than 12 hours.

Whereas the formulations prepared with higher concentration of guar gum retarded the drug release up to 12 hours in the concentration 150 mg. In lower concentrations the polymer was unable to retard the drug release.

The formulations prepared with xanthan gum showed very less retardation capacity hence they were not considered.

Hence from the above dissolution data it was concluded that F6 formulation was considered as optimised formulation because good drug release (96.32%) in 12 hours.

Application of Release Rate Kinetics to Dissolution Data for optimised formulation:

Table no 8.5 Application kinetics for optimised formulation

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
10.49	**0.5**	0.707	1.021	-0.301	1.952	20.980	0.0953	-0.979	89.51	4.642	4.473	0.168
17.63	**1**	1.000	1.246	0.000	1.916	17.630	0.0567	-0.754	82.37	4.642	4.351	0.291
26.55	**2**	1.414	1.424	0.301	1.866	13.275	0.0377	-0.576	73.45	4.642	4.188	0.454
32.84	**3**	1.732	1.516	0.477	1.827	10.947	0.0305	-0.484	67.16	4.642	4.065	0.577
39.39	**4**	2.000	1.595	0.602	1.783	9.848	0.0254	-0.405	60.61	4.642	3.928	0.713
44.71	**5**	2.236	1.650	0.699	1.743	8.942	0.0224	-0.350	55.29	4.642	3.810	0.832
53.05	**6**	2.449	1.725	0.778	1.672	8.842	0.0189	-0.275	46.95	4.642	3.608	1.034
60.87	**7**	2.646	1.784	0.845	1.593	8.696	0.0164	-0.216	39.13	4.642	3.395	1.247
67.02	**8**	2.828	1.826	0.903	1.518	8.378	0.0149	-0.174	32.98	4.642	3.207	1.435
74.15	**9**	3.000	1.870	0.954	1.412	8.239	0.0135	-0.130	25.85	4.642	2.957	1.685
79.24	**10**	3.162	1.899	1.000	1.317	7.924	0.0126	-0.101	20.76	4.642	2.748	1.893

87.54	**11**	3.317	1.942	1.041	1.096	7.958	0.0114	-0.058	12.46	4.642	2.318	2.323
96.32	**12**	3.464	1.984	1.000	0.566	8.027	0.0104	-0.016	3.68	4.642	1.544	3.098

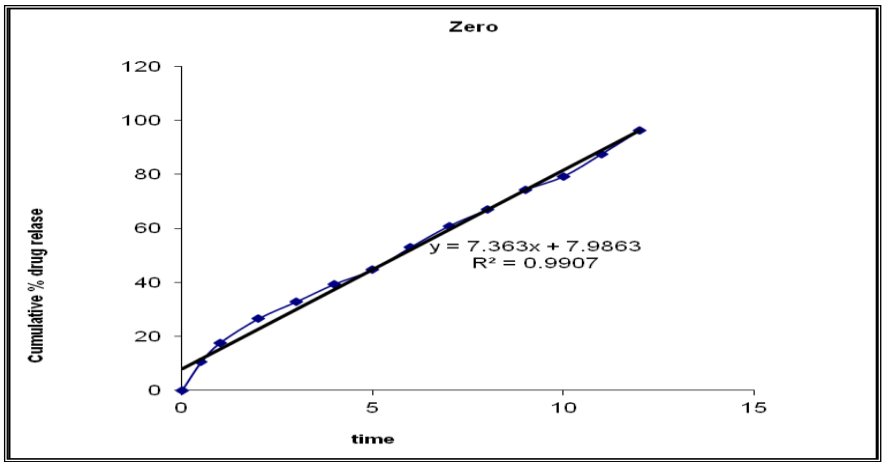

Fig no 8.7: Zero order release kinetics

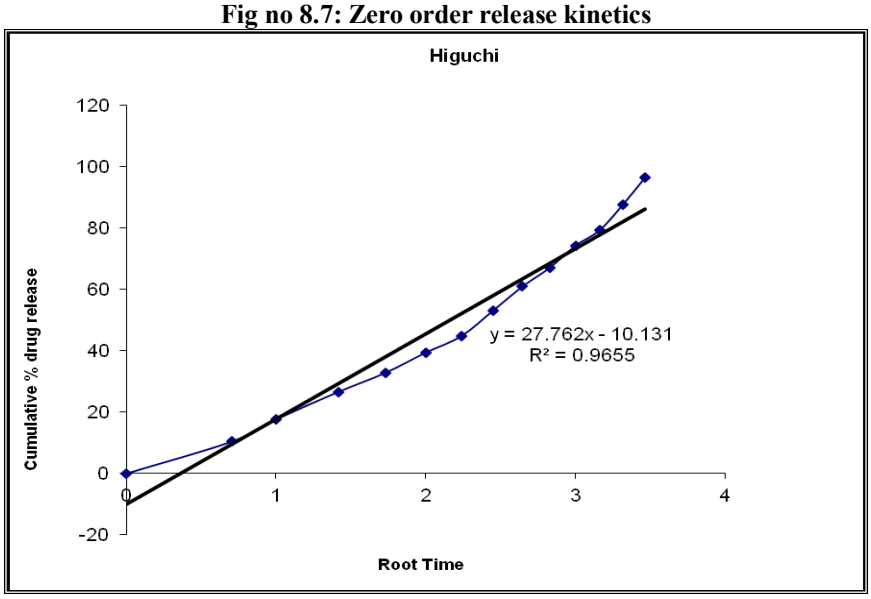

Fig no 8.8: Higuchi release kinetics

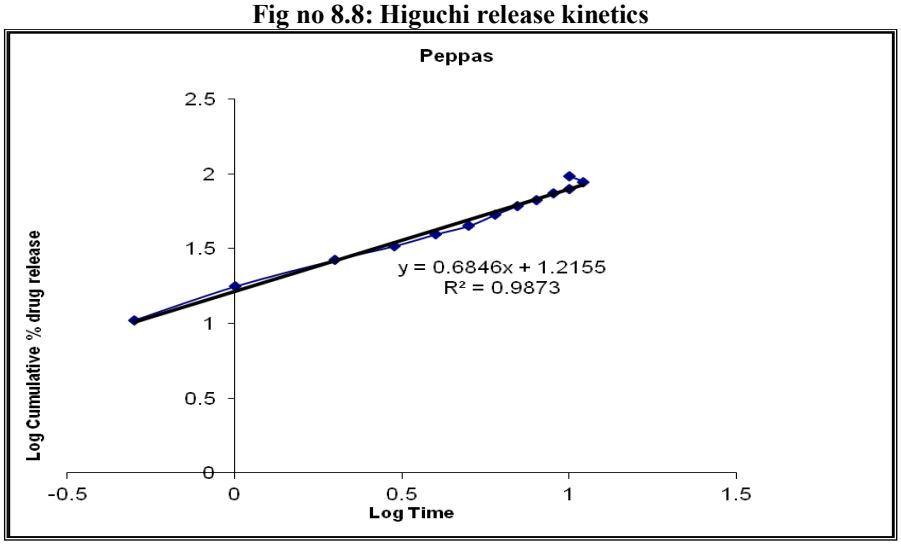

Fig8.9 : Kors mayer peppas release kinetics

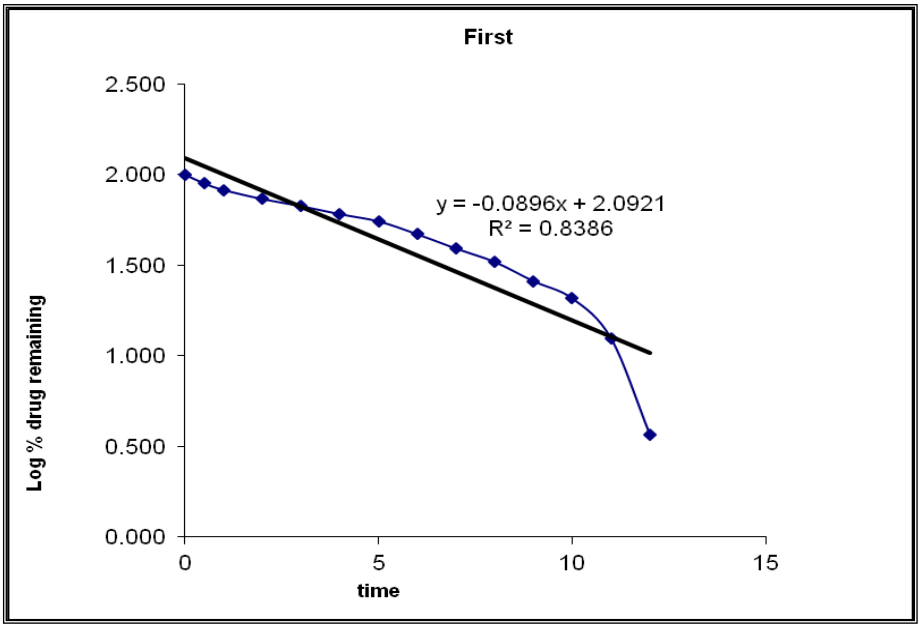

Fig8.10: First order release kinetics

Optimised formulation F6 was kept for release kinetic studies. From the above graphs it was evident that the formulation F6 was followed Zero order release mechanism.

CONCLUSION:

Development of Gastro retentive floating drug delivery of Alfuzosin tablets is to provide the drug action up to 12 hours.

Gastro retentive floating tablets were prepared by direct compression method using various various polymers like Xanthan gum, guar gum and Karaya Gum.

The formulated gastro retentive floating tablets were evaluated for different parameters such as drug excipient compatability studies, weight variation, thickness, hardness, content uniformity, *In vitro* Buoyancy studies, *In vitro* drug release studies performed in 0.1N HCL for 12 hrs and the data was subjected to zero order, first order, Higuchi release kinetics and karsmayer peppas graph.
The following conclusions could be drawn from the results of various experiments

- ✓ FTIR studies concluded that there was no interaction between drug and excipients.
- ✓ The physico-chemical properties of all the formulations prepared with different polymers Xanthan gum, guar gum and Karaya Gum were shown to be within limits.
- ✓ Quality control parameters for tablets such as weight variation, Hardness, Friability, thickness, drug content and floating lag time were found to be within limits.
- ✓ *In-vitro* drug release studies were carried out for all prepared formulation and from that concluded F6 formulation has shown good results.
- ✓ Finally concluded release kinetics to optimised formulation (F6) has followed Zero order kinetics.
- ✓ Present study concludes that gastro retentive floating system may be a suitable method for Alfuzosin administration.

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