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Formulation and *in vitro* evaluation of ofloxacin gastro retentive floating tablets

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ABSTRACT

In the present research work gastro retentive floating matrix formulation of Ofloxacin by using polymers were developed. Initially analytical method development was done for the drug molecule. Absorption maxima was determined based on that calibration curve was developed by using different concentrations. Gas generating agent sodium bicarbonate concentration was optimized. Then the formulation was developed by using different concentrations of polymers Gum Acacia, Sodium CMC as polymeric substances. The formulation blend was subjected to various preformualation studies, flow properties and all the formulations were found to be good indicating that the powder blend has good flow properties. Among all the formulations, the formulations prepared with Gum Acacia were also retarded the drug release up to 24 hours (F2=99.32). The optimized formulation dissolution data was subjected to release kinetics; from the release kinetics data it was evident that the formulation followed first order mechanism of drug release.

Keywords: Ofloxacin, Gum Acacia, Sodium Ccarboxy Methyl Cellulose, Floating Tablets

INTRODUCTION

Oral drug delivery systems have progressed from immediate release to site-specific delivery over a period of time. Every patient would always like to have a ideal drug delivery system possessing the two main properties that are single dose or less frequent dosing for the whole duration of treatment and the dosage form must release active drug directly at the site of action [1].

Thus the objective of the pharmacist is to develop systems that can be as ideal system as possible. Attempts to develop a single- dose therapy for the whole duration of treatment have focused attention on controlled or sustained release drug delivery systems. Attention has been focused particularly on orally administered sustained drug delivery systems because of the ease of the administration via the oral route as well as the ease and economy of manufacture of oral dosage forms. Sustained release describes the delivery of drug from the dosage forms over an extended period of time. It also implies delayed therapeutic action and sustained duration of therapeutic effect. Sustained

release means not only prolonged duration of drug delivery and prolonged release, but also implies predictability and reproducibility of drug release kinetics. A number of different oral sustained drug delivery systems are based on different modes of operation and have been variously named, for example, as dissolution controlled systems, diffusion controlled systems, ion-exchange resins, osomotically controlled systems, erodible matrix systems, pH- independent formulations, swelling controlled systems, and the like.

Gastric Floating Drug Delivery systems (GFDDS)

The various buoyant preparations include tablets, pills, granules, powders, capsules, hollow, Microspheres (micro balloons) and laminated films. Based on the mechanism of buoyancy, two distinctly different technologies i.e., noneffervescent and effervescent systems have been utilized in the development of GFDDS.

Non-Effervescent GFDDS [2]

The approach involved in the formulation of floating dosage forms is intimate mixing of drug with a gel forming hydrocolloid, which swells in contact with gastric fluid after oral administration and maintains a relative integrity of shape and a bulk density of less than one within the outer gelatinous barrier. The air entrapped by the swollen polymer confers buoyancy to these dosage forms. The gel structure acts as a reservoir for sustained drug release since the drug is slowly released by a controlled diffusion through the gelatinous barrier. Commonly used excipients, here are gel-forming or highly swellable cellulose type hydrocolloids, polysaccharides and matrix forming polymers such as polycarbonate, polyacrylate, polymethacrylate and polystyrene.

Effervescent GFDDS

The floating drug delivery systems utilize matrices prepared with swellable polymers such as methocel, polysaccharides, effervescent components like sodium bicarbonate, citric acid and tartaric acid or chambers containing a liquid that gasifies at body temperature. The optimal stoichiometric ratio of citric acid and sodium bicarbonate for gas generation is reported to be 0.76:1 carbon dioxide is released, causing the beads to float in the stomach[9] The matrices are fabricated so that upon contact with gastric fluid, carbon dioxide is liberated by the acidity of gastric contents and is entrapped in the gellyfied hydrocolloid. This produces an upward motion of the dosage form and maintains its buoyancy. The carbon dioxide generating components may be intimately mixed within the tablet matrix to produce a single-layered tablet or a bilayered tablet may be compressed which contains the gas generating mechanism in one hydrocolloid containing layer and the drug in the other layer formulated for the Sustained Release effect [3] . This concept has also been exploited for floating capsule systems.

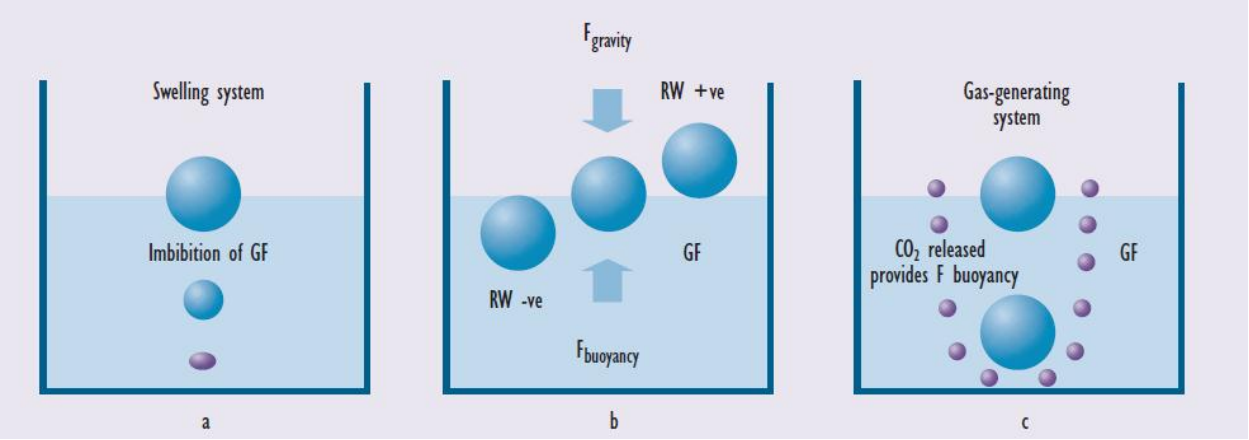

Figure 1.1: Mechanisms of a) Swelling system b) Non-Effervescent and c) Effervescent GFDDS

Other approaches and materials that have been reported are highly swellable hydrocolloids and light mineral oils, a mixture of sodium alginate and sodium bicarbonate, multiple unit floating pills that generate carbon dioxide when ingested, floating mini capsules with a core of sodium bicarbonate, lactose and polyvinyl pyrrolidone coated with hydroxyl propyl methyl cellulose (HPMC), and floating systems based on ion exchange resin technology, etc [2].

Advantages of GFDDS [4]

- Floating drug delivery offers several applications for drugs having poor Bioavailability because of the narrow absorption window in the upper part of the gastrointestinal tract. It retains the dosage forms at the site of absorption and thus enhances the Bioavailability. These are summarized as follows.
- Sustained Drug Delivery
- Site Specific Drug Delivery
- Absorption or Bioavailability Enhancement
- Fewer Doses
- Improved plasma levels
- Better Bioavailability.
- Less Irritation
- Fewer side effects
- Low risk inactive ingredients
- Manufacturing ease
- Low cost

Aim & objective

The aim of the present work is to formulate gastro retentive floating tablets of Ofloxacin using various polymers by direct compression and in vitro investigation

METHODOLOGY

Analytical method development

Determination of absorption maxima

A solution containing the concentration 10 µg/ mL drug was prepared in 0.1N HCL UV spectrum was taken using Double beam UV/VIS spectrophotometer. The solution was scanned in the range of 200 – 400 nm.

Preparation calibration curve

10mg Ofloxacin pure drug was dissolved in 10ml of methanol (stock solution1) from stock solution 1ml of solution was taken and made up with10ml of 0.1N HCL (100µg/ml). From this 1ml was taken and made up with 10 ml of 0.1N HCL (10µg/ml). The above solution was subsequently diluted with 0.1N HCL to obtain series of dilutions Containing 2, 4, 6, 8, 10 µg /ml of per ml of solution. The absorbance of the above dilutions was measured at 294 nm 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.

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}.

Preformulation parameters

The quality of tablet, once formulated by rule, is generally dictated by the quality of physicochemical properties of blends. There are many formulations and process variables involved in mixing and all these can affect the characteristics of blends produced. The various characteristics of blends tested as per Pharmacopoeia.

Angle of repose

The fixed funnel method was employed to measure the angle of repose. A funnel was secured with its tip at a given height (h), above a graph paper that is placed on a flat horizontal surface. The blend was carefully pored through the funnel until the apex of the conical pile just touches the tip of the funnel. The radius (r) of the base of the conical pile was measured. The angle of repose was calculated using the following formula:

$\tan \theta = h / r$

$\tan \theta$ = Angle of repose

h = Height of the cone,

r = Radius of the cone base

Table 2.1: 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

10 gm powder blend was sieved and introduced into a dry 20 ml cylinder, without compacting. The powder was carefully leveled without compacting and the unsettled apparent volume, Vo, was read. The bulk density was calculated using the formula:

Bulk Density = M / V_o

Where, M = weight of sample

V_o = apparent volume of powder

Tapped density

After carrying out the procedure as given in the measurement of bulk density the cylinder containing the sample was tapped using a suitable mechanical tapped density tester that provides 100 drops per minute and this was repeated until difference between succeeding measurement is less than 2 % and then tapped volume, V measured, to the nearest graduated unit. The tapped density was calculated, in gm per L, using the formula:

Tap = M / V

Where, Tap= Tapped Density

M = Weight of sample

V= Tapped volume of powder

Measures of powder compressibility

The Compressibility Index (Carr's Index) is a measure of the propensity of a powder to be compressed. For poorer flowing materials, there are frequently greater interparticle interactions, and a greater difference between the bulk and tapped densities will be observed. These differences are reflected in the Compressibility Index which is calculated using the following formulas:

Carr's Index = [(tap - b) / tap] × 100

Where, b = Bulk Density

Tap = Tapped Density

Table 2.2: 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

Formulation development of floating Tablets

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

Procedure for direct compression method

Drug and all other ingredients were individually passed through sieve no ≠ 60, mixed thoroughly by triturating up to 15 min and powder mixture was lubricated with talc. The tablets were prepared by using direct compression method by using 12 mm punch.

Optimisation of Sodium bicarbonate

Various concentrations of sodium bicarbonate were employed; floating lag time and floating duration were observed. Based on the concentration of sodium bicarbonate was finalised and preceded for further formulations.

Table 2.3: Optimisation sodium bicarbonate concentration

Ingredients	DO1	DO2	DO3
Ofloxacin	200	200	200
Gum Acacia	200	200	200
PVP K 30	7.5	7.5	7.5
$NaHCO_3$	15	30	45
Citric Acid	7.5	7.5	7.5
Mg.Stearate	4	4	4
Talc	4	4	4
MCC pH 102	162	162	162
Total weight	600	600	600

All the quantities were in mg.
Based on the floating lag time and floating duration the concentration of sodium bicarbonate was optimised.

FORMULATION OF TABLETS

Table 2.4: Formulation composition for Floating tablets

Formulation Code	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Ofloxacin	200	200	200	200	200	200	200	200	200
Gum Acacia	50	100	150	200	-	-	-	-	100
Sodium CMC	-	-	-	-	50	100	150	200	50
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	4	4	4	4	4	4	4	4	4
Talc	4	4	4	4	4	4	4	4	4
MCC PH 102	312	262	212	162	312	262	212	162	212
Total weight	**600**	**600**	**600**	**600**	**600**	**600**	**600**	**600**	**600**

All the quantities were in mg

Evaluation of post compression parameters for prepared Tablets [6, 7, 8]

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

Weight variation test

To study the weight variation, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The percent deviation was calculated using the following formula.

% Deviation = (Individual weight – Average weight / Average weight) × 100

Table 2.5: 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

Hardness

For each formulation, the hardness of three tablets was determined using Monsanto hardness tester and the average is calculated and presented with deviation.

Thickness

Average thickness for core and coated tablets is calculated and presented with deviation.

Friability

The tablets were rotated at 25 rpm for 4 minutes (100 rotations) on Roche friabilator. At the end of test, the tablets were re- weighed, and loss in the weight of tablet is the measure of friability and is expressed in percentage as

% Friability = [W1-W2) / W1] × 100

Where, W1 = Initial weight of tablets

W2 = Weight of the tablets after testing

Determination of drug content

Both compression-coated tablets of were tested for their drug content. Ten tablets were finely powdered quantities of the powder equivalent to one tablet weight of clopidogrel were accurately weighed, transferred to a 100 ml volumetric flask containing 50 ml water and were allowed to stand to ensure complete solubility of the drug. The mixture was made up to volume with water. The solution was suitably diluted and the absorption was determined by UV –Visible spectrophotometer. The drug concentration was calculated from the calibration curve.

In vitro Buoyancy studies

The in vitro buoyancy was determined by floating lag time, and total floating time (As per the method described *by Rosa et al*). The tablets were placed in a 100ml beaker containing 0.1N HCL. The time required for the tablet to rise to the surface and float was determined as floating lag time (FLT) and duration of time the tablet constantly floats on the dissolution medium was noted as Total Floating Time respectively (TFT).

In vitro drug release studies

Dissolution parameters

Apparatus -- USP-II, Paddle Method
Dissolution Medium -- 0.1 N HCL
RPM -- 50
Sampling intervals (hrs) -- 1, 2,4,6,8,10,12,24
Temperature -- 37°c $\pm$ 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 $\pm$ 0.5°c. Tablet was placed in the vessel and the vessel was covered the apparatus was operated for 24 hours and then the medium 0.1 N HCL was taken and process was continued from 0 to 24hrs 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 294 nm using UV-spectrophotometer.

Application of Release Rate Kinetics to Dissolution Data

To analyze the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Zero order release rate kinetics

To study the zero–order release kinetics the release rate data are fitted to the following equation.

$F = K_o t$

Where, 'F' is the drug release at time't', and 'K_o' is the zero order release rate constant. The plot of % drug release versus time is linear.

First order release rate kinetics

The release rate data are fitted to the following equation

Log (100-F) = kt

A plot of log cumulative percent of drug remaining to be released vs. time is plotted then it gives first order release.

Higuchi release model

To study the Higuchi release kinetics, the release rate data were fitted to the following equation.

F = k t1/2

Where, 'k' is the Higuchi constant.

In higuchi model, a plot of % drug release versus square root of time is linear.

Korsmeyer and Peppas release model

The mechanism of drug release was evaluated by plotting the log percentage of drug released versus log time according to Korsmeyer- Peppas equation. The exponent 'n' indicates the mechanism of drug release calculated through the slope of the straight Line.

$M_t / M_\infty = K t^n$

Where, M_t / M_∞ is fraction of drug released at time 't', k represents a constant, and 'n' is the diffusional exponent, which characterizes the type of release mechanism during the dissolution process. For non-Fickian release, the value of n falls between 0.5 and 1.0; while in case of Fickian diffusion, n = 0.5; for zero-order release (case I I transport), n=1; and for supercase II transport, n > 1. In this model, a plot of log (M_t / M_∞) versus log (time) is linear.

RESULTS AND DISCUSSION

Analytical Method

Determination of absorption maxima

The standard curve is based on the spectrophotometry. The maximum absorption was observed at 294 nm.

Calibration curve

Graphs of Ofloxacin was taken in 0.1N HCL (pH 1.2)

Table 3.1: Observations for graph of Ofloxacin in 0.1N HCl

Conc [µg/mL]	Abs
0	0
5	0.139
10	0.284
15	0.44
20	0.578
25	0.702

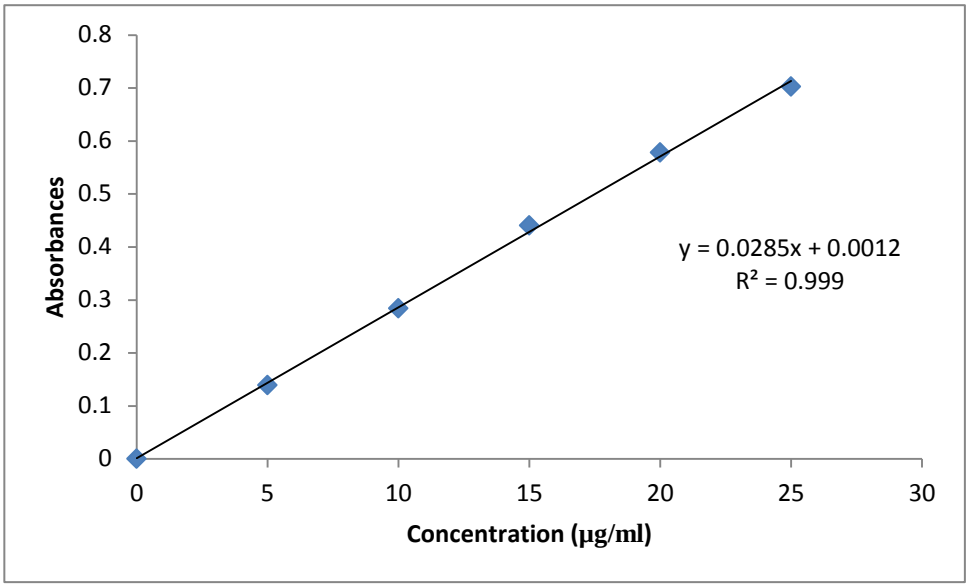

Fig 3.1: Standard graph of Ofloxacin in 0.1N HCL

Standard graph of Ofloxacin was plotted as per the procedure in experimental method and its linearity is shown in Table and Fig. The standard graph of Ofloxacin showed good linearity with R^2 of 0.999, which indicates that it obeys "Beer-Lamberts" law.

Drug – Excipient compatibility studies

Fourier Transform-Infrared Spectroscopy

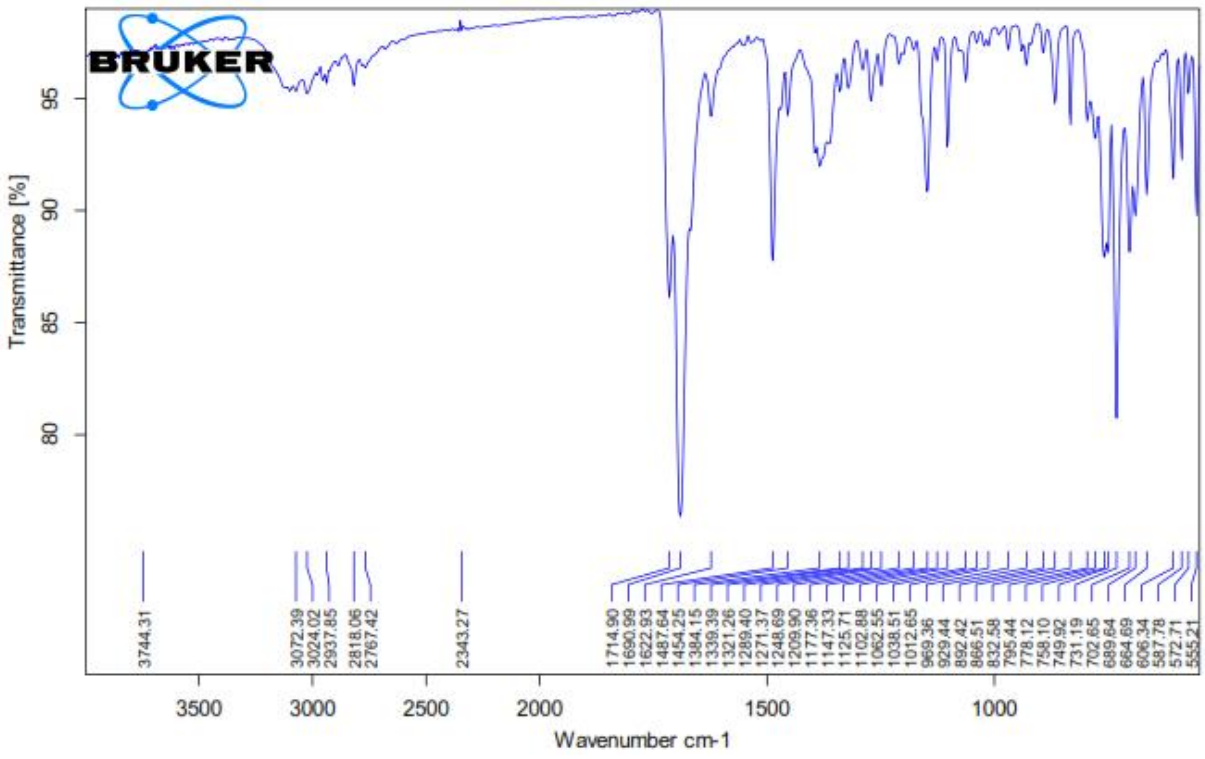

Figure 3.2: FTIR Spectrum of pure drug

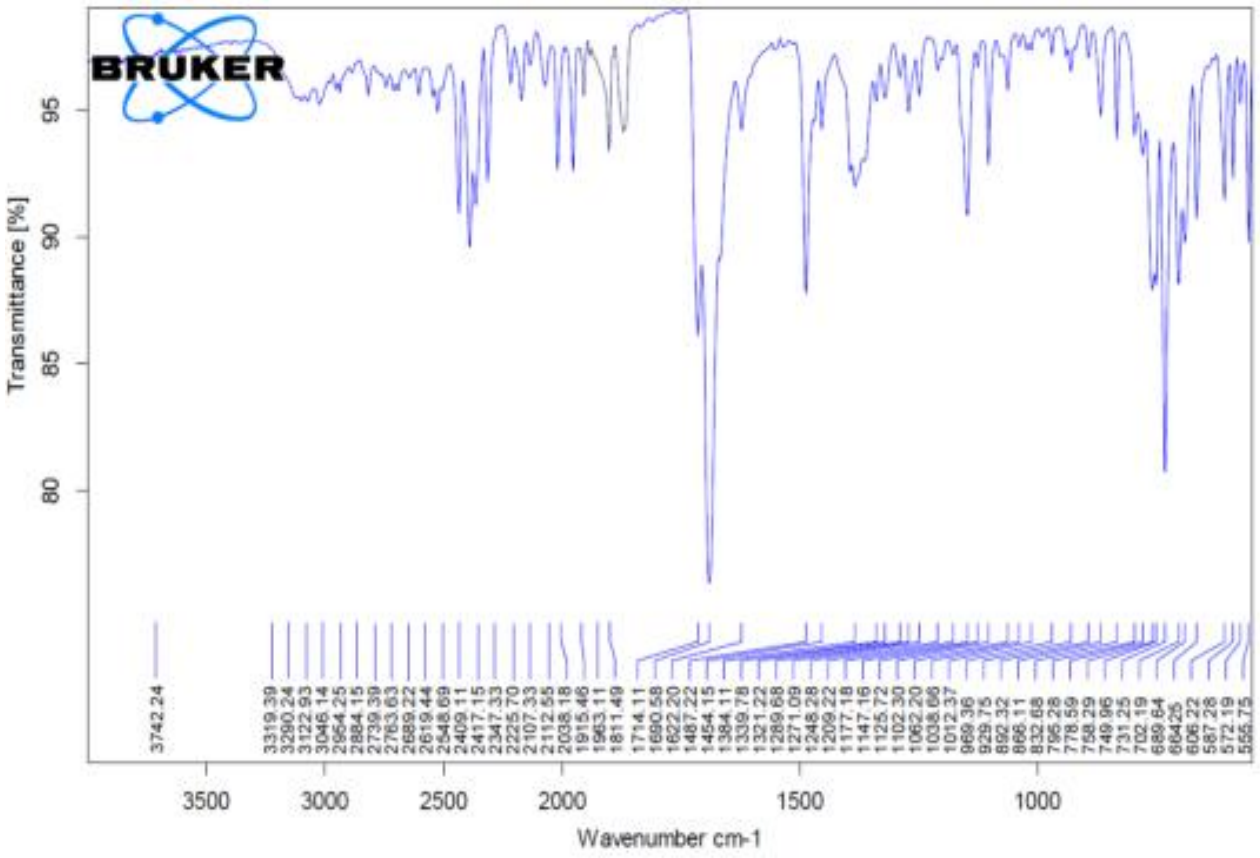

Fig 3.3: FTIR Spectrum of optimised formulation

There was no disappearance of any characteristics peak in the FTIR spectrum of drug and the polymers used. This shows that there is no chemical interaction between the drug and the polymers used. The presence of peaks at the expected range confirms that the materials taken for the study are genuine and there were no possible interactions. Ofloxacin 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.

Preformulation parameters of powder blend

Table: 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 show 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.

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.

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.

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	600.4	5.1	0.61	3.3	98.42	5.5	4
F2	599.2	5.2	0.58	3.2	99.65	4.2	6
F3	599.3	5.5	0.45	3.4	99.12	5.0	12
F4	598.3	5.1	0.61	3.3	98.42	5.1	6
F5	600.6	5.3	0.59	3.5	99.65	4.0	8
F6	601.4	5.5	0.65	3.4	99.12	3.2	12
F7	600.6	5.3	0.62	3.6	98.16	4.5	5
F8	599.9	5.2	0.59	3.4	98.11	3.6	12
F9	598.7	5.4	0.60	3.3	98.25	4.7	12

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

In Vitro Drug Release Studies

Table no 3.4: 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
1	15.3	6.6	4.3	5.6	18.96	13.64	12.3	13.2	4.87
2	26.5	22.4	11.6	12.4	28.77	23.71	21.34	29.63	19.7
4	46.8	37.4	35.8	34.6	39.02	33.47	29.58	38.47	39.19
6	69.65	48.3	42.6	41.11	58.13	45.66	39.15	47.63	41.35
8	88.9	65.6	58.7	56.4	66.51	65.69	47.96	51.72	60.35
10	99.82	74.8	66.3	62.8	81.06	75.79	58.31	58.13	74
12		88.6	73.4	72.14	85.88	86.34	66.84	64.6	88.87
24		99.62	87.1	85.26	98.08	89.21	76.78	75.69	90.76

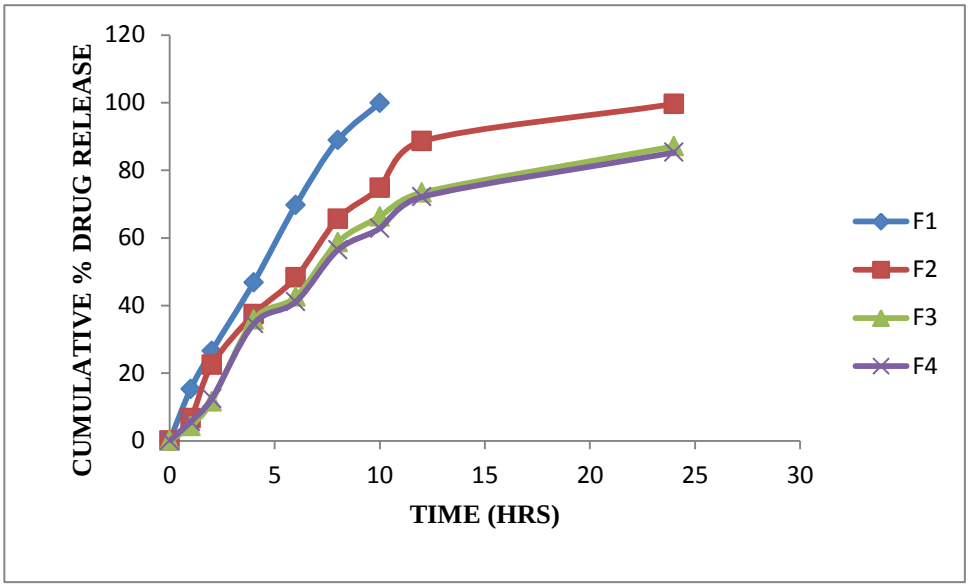

Fig 3.4: Dissolution data of Ofloxacin Floating tablets containing Gum Acacia

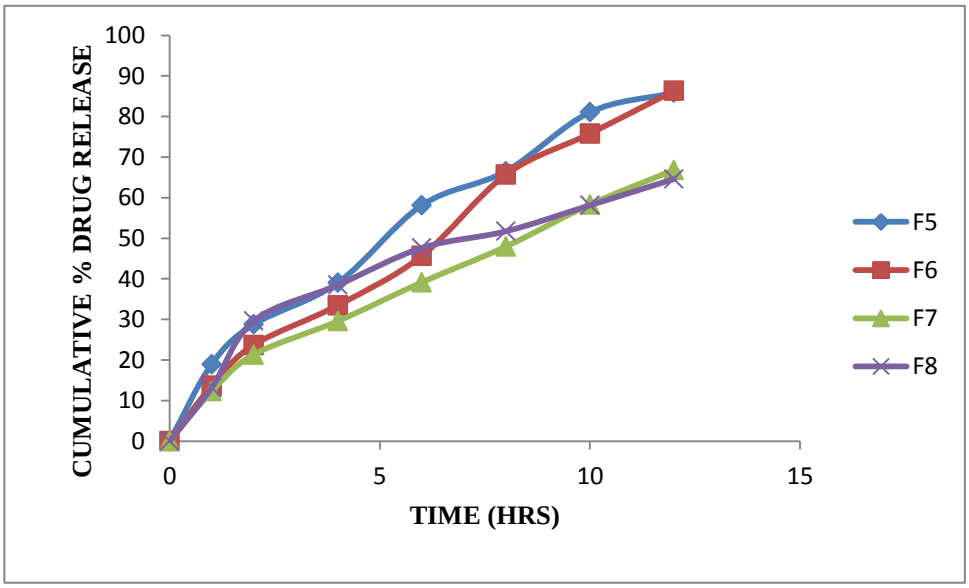

Fig: 3.5: Dissolution data of Ofloxacin Floating tablets containing Sodium CMC

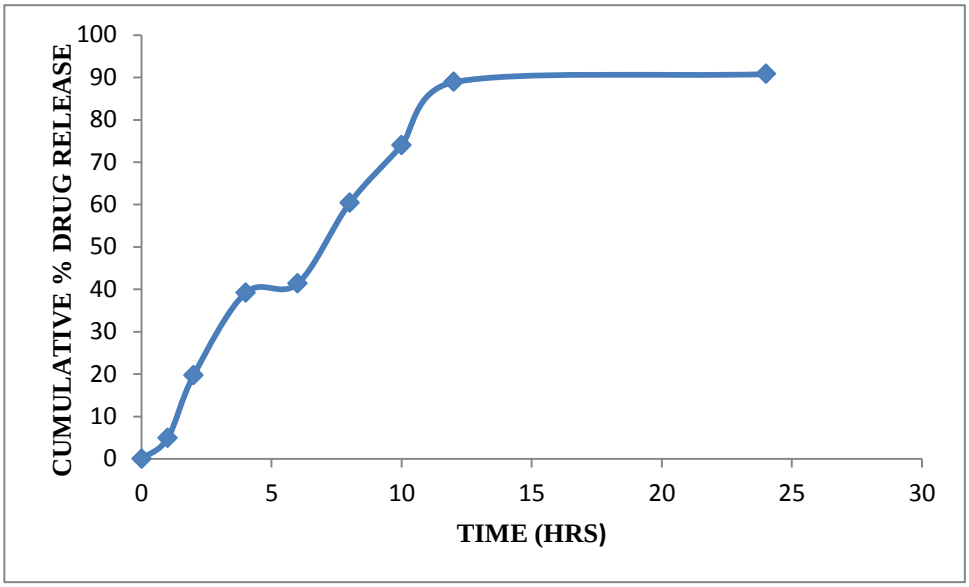

Fig: 3.6 Dissolution data of Ofloxacin Floating tablets containing Gum Acacia and Sodium CMC both

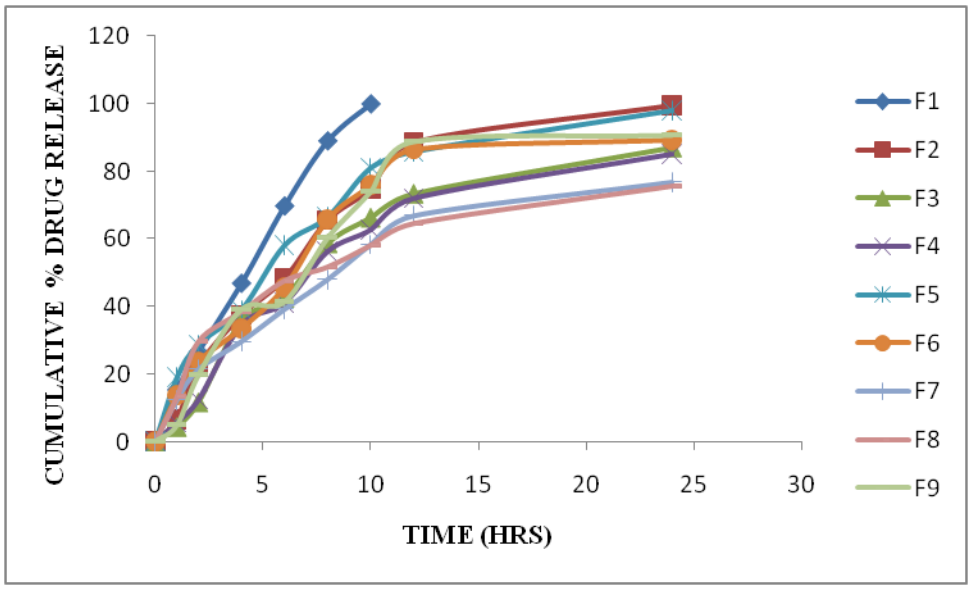

Fig: 3.7 Dissolution data of Ofloxacin Floating tablets containing all formulations (Gum Acacia, Sodium CMC and Both)

From the dissolution data it was evident that the formulations prepared with Gum Acacia as polymer was retarded the drug release up to 10 hrs at the concentration of 50 mg. But F2 formulation was retard the drug release required 24 hours. While increasing the concentration of Gum Acacia polymer, decrease the drug release in the case of F3, F4 Formulations.

Whereas the formulations prepared with Sodium CMC release good drug release up to 24 hours in the concentration 50 mg. In higher concentrations the polymer was able to retard the drug release (F6, F7, F8).

The formulations prepared with Gum Acacia, Sodium CMC better release amounts of polymer included in the F9 Formulation. Then that formulation showed more retardation capacity when compared to F2 and F5. Hence they were not considered.

Hence from the above dissolution data it was concluded that F2 formulation was considered as optimised formulation because good drug release (99.62%) in 24 hours.

Application of Release Rate Kinetics to Dissolution Data for optimised formulation

Table 3.5: 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	Q0 1/3	Qt1 /3	Q01 /3- Qt1/ 3
0	0	0			2.000				100	4.642	4.642	0.000
6.6	1	1.000	0.820	0.000	1.970	6.600	0.1515	-1.180	93.4	4.642	4.537	0.104
22.4	2	1.414	1.350	0.301	1.890	11.200	0.0446	-0.650	77.6	4.642	4.265	0.376
37.4	4	2.000	1.573	0.602	1.797	9.350	0.0267	-0.427	62.6	4.642	3.971	0.671
48.3	6	2.449	1.684	0.778	1.713	8.050	0.0207	-0.316	51.7	4.642	3.725	0.916
65.6	8	2.828	1.817	0.903	1.537	8.200	0.0152	-0.183	34.4	4.642	3.252	1.389
74.8	10	3.162	1.874	1.000	1.401	7.480	0.0134	-0.126	25.2	4.642	2.932	1.710
88.6	12	3.464	1.947	1.079	1.057	7.383	0.0113	-0.053	11.4	4.642	2.251	2.391
99.62	24	4.899	1.998	1.380	-0.420	4.151	0.0100	-0.002	0.38	4.642	0.724	3.917

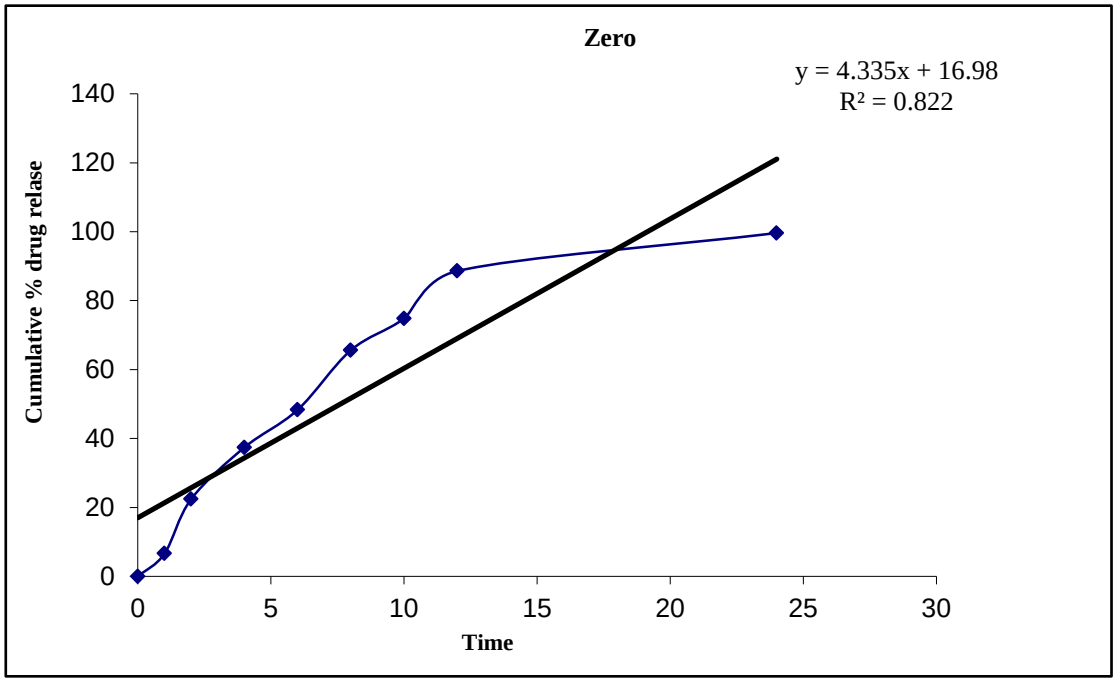

Fig 3.7: Zero order release kinetics

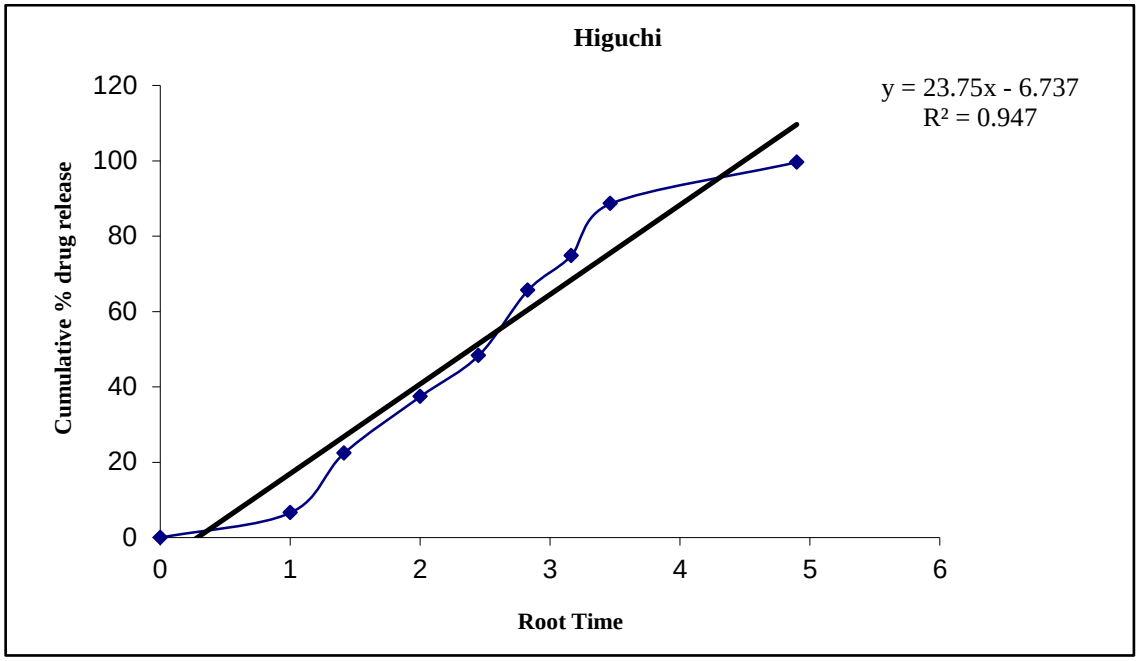

Fig 3.8: Higuchi release kinetics

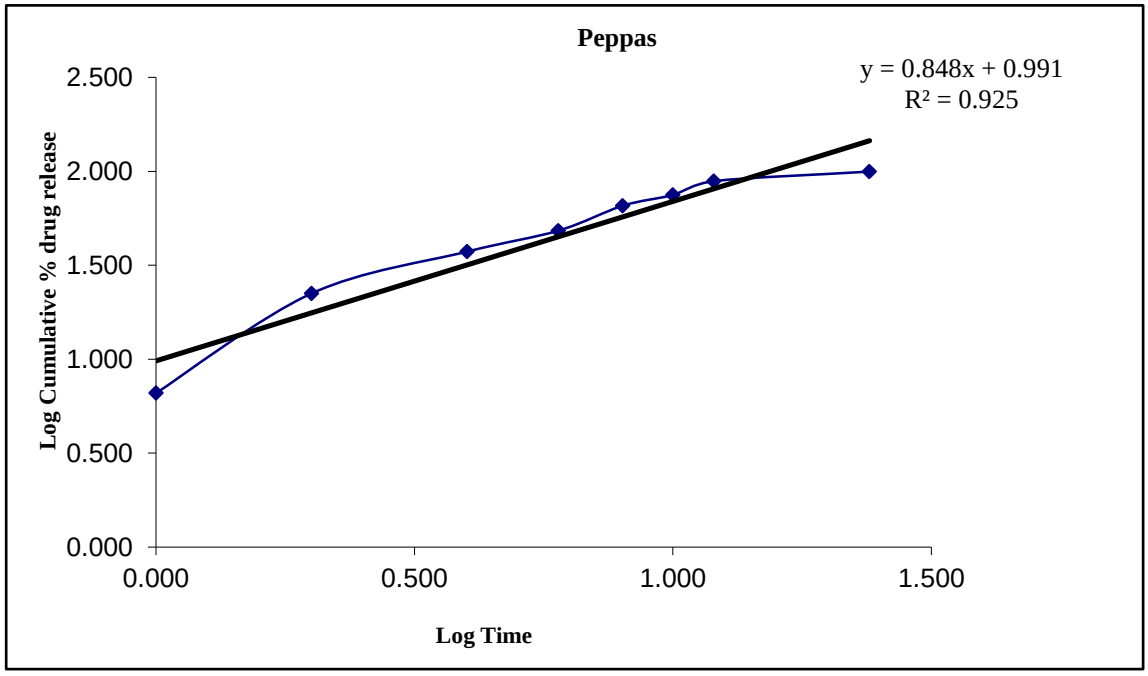

Fig 3.9 : Kors mayer peppas release kinetics

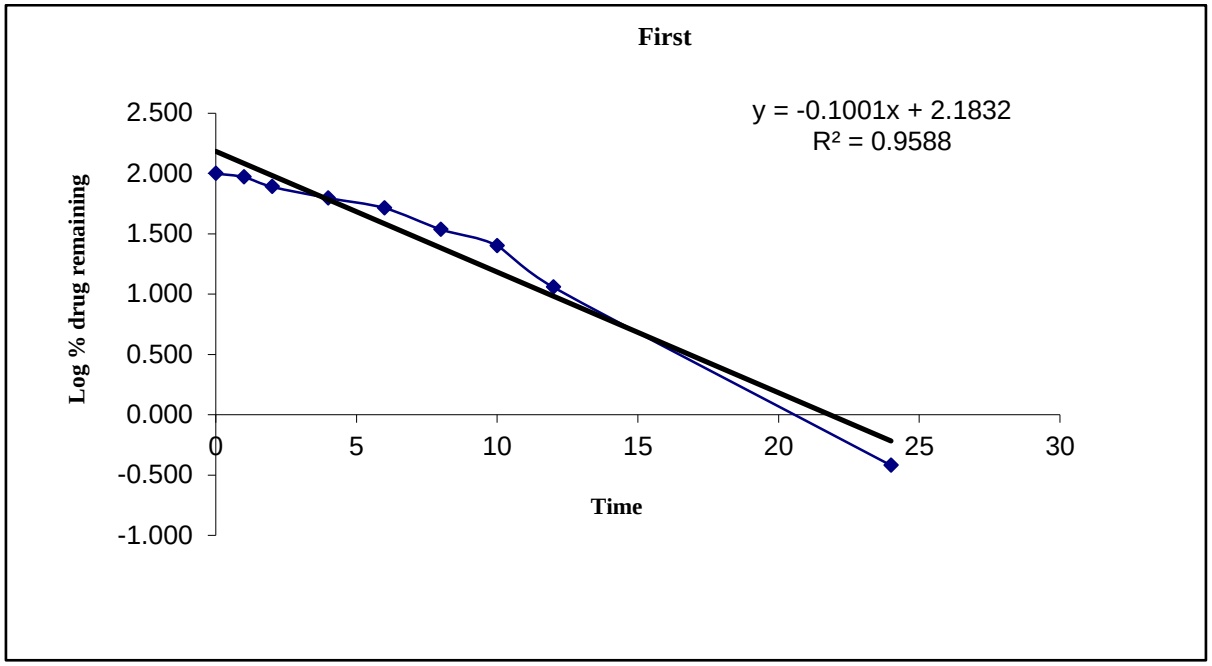

Fig 3.10: First order release kinetics

Optimised formulation F2 was kept for release kinetic studies. From the above graphs it was evident that the formulation F2 was followed First order release mechanism.

CONCLUSION

Development of Gastro retentive floating drug delivery of Ofloxacin tablets is to provide the drug action up to 24 hours.

Gastro retentive floating tablets were prepared by direct compression method using various polymers like Gum Acacia, Sodium CMC.

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 24 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 Xan Gum Acacia, Sodium CMC 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 F2 formulation has shown good results.
- ✓ Finally concluded release kinetics to optimised formulation (F2) has followed First order kinetics.
- ✓ Present study concludes that gastro retentive floating system may be a suitable method for Ofloxacin administration.

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