Formulation and In-Vitro Evaluation of Effervescent Floating Tablet of Ofloxacin Using Hpmc and Badam Gum

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ABSTRACT:
The aim of present research work is to "formulation and in vitro evaluation of effervescent floating tablet of ofloxacin using HPMC And Badam gum". The composition of effervescent floating tablet is Ofloxacin And Excipients. Oral route is the most preferred route of administration that delivers drugs in a non-invasive manner. However, it faces several limitations of administering drugs. To overcome these limitations, gastro-retentive drug delivery systems (GRDDS) came into the scenario. GRDDS approach has been used for site-specific drug release and ensuring local or systemic action in the upper GI tract specially for the drugs having absorption window in the stomach region. These systems help increase the drug's gastric residence time, thus increase bioavailability. GRDDS increases the drug release duration by retaining the drugs in stomach for a longer period of time. They also increase the solubility of the drugs which are less soluble at intestinal pH. Thus, these delivery systems are of great importance nowadays and a lot of work is being carried out as evident from various recent reports. Understanding of the physiology and anatomy of the GIT is necessary for the evolution of different types of gastro retentive technologies derived from the respective understandings. Therefore, the main aim should be towards equalizing this number, which will result in a huge benefit to the mankind. (1) Conventional oral dosage forms provide a specific drug concentration in systemic circulation without offering any control over drug delivery. Controlled-release drug delivery systems (CRDDS) provide drug release at a predetermined, predictable, and controlled rate.

I. INTRODUCTION:

Oral route is the most preferred route of administration that delivers drugs in a non-invasive manner. However, it faces several limitations of administering drugs. Drugs that have narrow absorption window are absorbed only if these are in close proximity with their absorption window. Crossing through the absorption window, drugs face lesser/negligible amount of the absorption and hence show decreased bioavailability as the time of absorption is very less in such conditions. Another major problem associated with some of the drugs is first-pass metabolism. After getting absorbed through the GI tract, drug has to pass through the liver where it gets metabolized and the maximum amount of the dose gets depleted in this step. Some of the other limitations are short gastric residence time, unpredictable gastric emptying time, and frequent dosing of the drugs (with short biological half-lives).

To overcome these limitations, gastro-retentive drug delivery systems (GRDDS) came into the scenario. GRDDS approach has been used for site-specific drug release and ensuring local or systemic action in the upper GI tract specially for the drugs having absorption window in the stomach region. These systems help increase the drug's gastric residence time, thus increase bioavailability. GRDDS increases the drug release duration by retaining the drugs in stomach for a longer period of time. They also increase the solubility of the drugs which are less soluble at intestinal pH. Thus, these delivery systems are of great importance nowadays and a lot of work is being carried out as evident from various recent reports. Understanding of the physiology and anatomy of the GIT is

necessary for the evolution of different types of gastro retentive technologies derived from the respective understandings.

Many of them have already entered into the huge pharmaceutical market, whereas others need attention for gaining their access into the global market. Clinical studies are to be envisaged in a more efficient way for overcoming trial failures. Several combination therapies are being studied for their enhanced efficacy, reduced side effects, and extended gastro-retention than the individual therapies Several reports are getting published daily but the number of technologies which are getting market access is much lower as compared to the investigations published day by day. Therefore, the main aim should be towards equalizing this number, which will result in a huge benefit to the mankind Conventional oral dosage forms provide a specific drug concentration in systemic circulation without offering any control over drug delivery. Controlled-release drug delivery systems (CRDDS) provide drug release at a predetermined, predictable and controlled rate.

Table : GRDDs vs. Conventional drug delivery systems

SR.NO.	FACTOR	GRDDS	CONVENTIONAL DDS
1)	Toxicity	Low risk of toxicity	High risk of toxicity
2)	Patient compliance	Improves patient compliance	Less
3)	Drug with narrow absorption window in small intestine	Suitable	Not suitable
4)	Drugs having rapid absorption through GIT	Very much advantageous	Not much advantageous
5)	Drug which degrades in the colon	Very much advantageous	Not much advantageous
6)	Drugs acting locally in the stomach	Very much advantageous	Not much advantageous
7)	Drugs which are poorly soluble at an alkaline pH	Very much advantageous	Not much advantageous

1. Advantages of GRDDS:
Sustained drug delivery/reduced frequency of dosing: Drugs having shorter biological half-life, prolonged and low ingestion through CRGRDF can minimize dosing intervals. This is associated to better patient adherence and therefore upgrades the treatment.

Minimize drug concentration fluctuations: Constant drug consumption following administration of GRDDS induces narrower amounts of blood drugs relative to immediate dosage forms. As a result, variations in drug effects are reduced and harmful symptoms linked with maximum amounts can be concentration-dependent can be avoided. This function emphasis for drugs having a small therapeutic index. Reduce variation to achieve a sure acumen in pharmacological effect of drugs which trigger various receptor forms at various stages.

Improves Bioavailability of drug: Drugs with low bioavailability because of upper site-definitive absorption of the GI tract are pre-qualified for

formulation as floating dosage form, thus enhances absorption. Bioavailability increases after the first pass effect as a result of variations in the concentration of plasma drugs; the necessary concentration of plasma drugs is preserved by continuous drug release.

Site specific drug delivery: Long-term and continuous administration of GRDDS could be useful for site action/site peculiar in stomach. This administration form results in local concentrations of therapeutic drugs, however systemic levels, following absorption and distribution of drugs, are limited. A buoyant dosage form is a workable solution, particularly for drugs with restricted places of absorption in the upper bowel. Sustained release of drugs to stomach provides enough inhabitant therapeutic scale and reduces systemic access to the medication. It eliminates adverse effects of the drug in the circulation of the blood.

Minimize adverse reaction: Constant maintenance the drug concentration at therapeutic level and below toxic level over longer period resulting in adverse effect reduction.

2. Disadvantages of GRDDS:
Drugs with stability problems in the highly acidic condition cannot be formulated as GRDDS.
Drugs with low pH solubility can experience problems of dissolution and may not fully release the drug.
This only works if the fluid level is high enough in the stomach.
Some drugs cause irritation to the gastric mucosa.
Drugs which undergo equal absorption throughout all the regions and sites of gastrointestinal tract are not desired candidates.
Aim :
To formulate and in vitro evaluation of effervescent floating tablet of Ofloxacin.

Objective :
i. Comparative study between Badam gum and HPMC on floating tablet of ofloxacin.
ii. To study the effect of polymers on buoyancy studies, swelling studies and drug release.
iii. To retain drug in stomach for longer period of time.

II.   MATERIAL AND EQUIPMENT:
Materials:
1.   Ofloxacin- Fresenius kabi India Pvt Ltd, Pune.

2.   Badam Gum- Yarrow Chem.
3.   Hydroxypropyl Methyl Cellulose- Loba Chem Laboratory.
4.   Magnesium Stearate- Loba Chemie Laboratory.
5.   Sodium Bicarbonate- Loba Chem Laboratory.
6.   Lactose- Loba Chemie Laboratory

Equipment:
1.   Electronic Weighing Balance- Schimadzu.
2.   Tablet Compression Machine- Jaguar
3.   Sieves- Kumar Standard Sieve
4.   Vernier Caliper Scale- Aerospace
5.   Hardness Tester- Omega Scientific Company
6.   PH Meter- Hanna Instrument
7.   Friabilator- Electrolab
8.   Dissolution Test Apparatus- Electrolab
9.   UV Spectrophotometer- Schimadzu
10. FTIR- Bruker optics

PRE-FORMULATION STUDIES:
Identification of drug by FTIR:
FTIR study was carried out to identify drug. Infrared spectrum of Ofloxcain was determined on Fourier transform Infrared Spectrophotometer using KBr dispersion method. The base line correction was done using dried potassium bromide. Then the spectrum of dried mixture of drug and potassium bromide was run followed by using Parkin elmer-Pharmaspec-1 FTIR spectrophotometer. The absorption maximums in spectrum obtained with the substance being examined correspond in position and relative intensity to those in the reference spectrum.

Characterization of Drug:
a) Colour And Appearance: The sample was observed vissualy.
b) Melting Point: Melting point of drug was determined by Melting point test apparatus.
c) Solubility study: Solubility study was carried out as per the I.P.2007.In this maximum amount of solvent required to dissolve the solute was determined.

Spectral Analysis of Ofloxacin:
A) Determination of absorption maximum in 0.1 N HCl
Stock solution of Ofloxacin (1000 μg/ml) was prepared by dissolving 50 mg of Ofloxacin in 50

ml of 0.1 N HCl. Dilutions of (3-15 μg/ml) were performed. The solution was scanned in range of wavelength 210-400 nm, for determining absorption maxima (λmax) of Ofloxacin by drug by using Shimadzu-1700 Pharmaspec UV-Visible spectrophotometer.

B) Preparation of Standard Curve of Ofloxacin.
Stock solution of Ofloxacin (1000 μg/ml) was prepared by dissolving 50ml of drug of 0.1 N HCl. The dilutions of 3-15 μg/ml were prepared from stock solution. The UV absorbances of these solutions were determined spectrometrically at λmax 293.2 nm using UV-visible Spectrophotometer.

Assay of Ofloxacin:
Accurately weighed 50 mg of Ofloxacin was dissolved in little quantity of 0.5 N acetic acid and volume was adjusted to 50 ml with the same to prepare standard solution having concentration of 1000 μg/ml and the volume was adjusted with 0.5 N acetic acid to get a concentration of 100 μg/ml. From this stock solution, 0.5 ml was pipette out and transferred to 10 ml volumetric flask and final volume was adjusted with 0.5N acetic acid. Absorbance values of these solutions were measured against blank at 294 nm using UV-Visible spectrophotometer. The percentage purity of drug was calculated by using calibration graph method.

Loss on drying:
Loss on drying is the loss of weight expressed as percentage w/w resulting from volatile matter of any kind that can be driven off under specified condition. The test can be carried out on the well mixed sample of the substance.

Drug - polymers compatibility studies:
Drug polymers studies holds great importance in designing a formulation In drug formulation it is essential to evaluate the possible interactions between the active principle and the polymers, as the choice of the polymers should be performed in relation to the drug delivery, to their compatibility with the same drug and to the stability of the final product.
The compatibility checking for active molecule and selected polymers is confirmed by FTIR, the absorption of various infrared radiations by the drug and polymers, to produce an IR spectrum that can be used to identify functional groups deviation if any and to analyse molecular structure in the sample is done before to the development of ofloxacin floating tablet.
Individual spectra of drug, polymers and physical mixture were taken to study compatibility. Selection of polymers places an important role in formulation and deigning of a drug product. The compatibility study will give an idea of possible physical and chemical interactions between active pharmaceutical ingredient and polymers. Early Identifying incompatibilities will be helpful in preparing the strategies for development and it also helps us in solving stability problems.

PREPARATION AND EVALUATION OF POWDER BLENDS:
1.Preparation of powder blends:
All ingredients were weighed and passed through mesh #40 separately. The drug and polymer were blended first in mortar and pestle then the remaining ingredients are added in that and blended for 20 min. Finally the blend is passed through mesh # 20 and used for evaluation of flow characteristics.

2.Evaluation of micromeritic properties of powders:
i. Angle of Repose:
The angle of repose was determined by the funnel method. The accurately weighed (10 gms) powder was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touched the apex of the heap of powder. The powder was allowed to flow through the funnel freely onto a clean surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation :

$$\tan = h/r$$

Where h is the height of powder cone and r is the radius of the powder cone. Relationship between angle of repose (θ) and flowability.

ii. Bulk Density and Tapped Bulk Density:
An accurately weighed (10 gms) powder from each formula was lightly shaken to break any agglomerates formed and it was introduced into a measuring cylinder. The volume occupied by the powder was measured which give bulk volume. The measuring cylinder was tapped until no further change in volume was noted which gave the tapped volume. Both Bulk Density (BD) and Tapped Bulk Density (TBD) of powder were determined using the following formula ,
BD = Weight of the powder/Volume of the powder

TBD = Weight of the powder/Tapped volume of the powder.

iii.Carr's Compressibility Index:
The compressibility index of the powder was determined using following Carr's compressibility index formula.

Carr's Compressibility Index (%) = [(TBD-LBD)/ TBD] x100

iv.Hausner's ratio:
Hausner's ratio is the ratio between tapped density and bulk density.
Hausner's ratio less than 1.25 indicates good flow properties while.
Hausner's ratio greater than 1.25 shows poor flow of powder.

FORMULATION OF FLOATING TABLETS:
Table: Composition of floating Tablets of Ofloxacin:

SR.NO.	INGREDIENT	F1	F2	F3	F4	F5	F6
1)	Ofloxacin	400	400	400	400	400	400
2)	HPMC	40	50	60	-	-	-
3)	Badam Gum	-	-	-	40	50	60
4)	Sodium Bicarbonate (10%)	30	30	30	30	30	30
5)	Magnesium Stearate (1%)	6	6	6	6	6	6
6)	Lactose	24	14	4	24	14	4
	Total	500	500	500	500	500	500

Compression of powder blends into tablets:
After evaluation of powder blend, the floating tablets were prepared by direct compression method using (9 mm diameter, round flat faced punches) multiple punch tablet compression machine. Each tablet contained 400 mg of Ofloxacin; the batch size for each formulation was 100 tablets.

EVALUATION OF TABLETS:
1. Physicochemical Properties of Tablet:
a) Appearance:
The tablets were visually observed for any capping, chipping and lamination.

b) Size and Thickness:
The size and thickness of tablet can vary with no change in weight due to difference in Density of granulation, the pressure applied to the tablets and speed of the tablet compression machine. The thickness of the tablets was determined using a Vernier caliper. Three tablets from each type of formulation were used and average values were calculated.

c) Hardness :
There is a certain requirement of hardness in tablets so as to withstand the mechanical shocks during handling, manufacturing, packaging and shipping. Hardness tester (Monsanto tester) was used to measure hardness of tablets. The tablet was held along its oblong axis in between the two jaws of the tester.At this point, reading should be taken as a zero kg/cm2 . Then constant force was applied by rotating the knob until the tablet fractured. The value at this point was noted in kg/cm2 .

d) Friability:
Friability is the measure of tablet strength. This test subjects a number of tablets to the combined effect of shock abrasion by utilizing a plastic chamber which revolves at a speed of 25 rpm for four minutes, dropping the tablets to a distance of 6 inches in each revolution. A sample of pre-weighed tablets was

placed in Roche friabilator which was then operated for 100 revolutions.
The tablets were then dedusted and reweighed. Percent friability (% F) was calculated as follows,
% Friability = (Initial weight - Final weight / Initial weight) x 100.

e) Weight Variation :
The weight variation test is done by taking 20 tablets randomly and they were weighed individually. The composite weight divided by 20, provides an average weight of tablet. Not more than two of the individual weight deviates from the average weight by % deviation allowed and none should deviate by more than twice its percentage.

f) Drug Content :
Twenty tablets were weighed and finely powdered. An accurately weighed quantity of powder equivalent to 50 mg of Ofloxacin was taken in 50 ml volumetric flask and dissolved in 25 ml of 0.5 N Acetic acid; it was further diluted up to the mark with same solvent. The solutions were then filtered and filterate gets diluted to get 5 µg/ml concentration of Ofloxacin. The solution was then read at 294 nm by using UV visible spectrophotometer

g) Swelling Index of Tablets :
The extent of swelling was measured in terms of percentage weight gain by the tablet. The swelling behaviour of formulation F1-F9 was studied. One tablet from each formulation was kept in a petritdish containing 0.1N HCl. The tablet was withdrawn in time intervals, soaked with tissue paper, and weighed. Weights of the tablet were noted and the process was continued till the end 12 hrs. Percentage weight gain by the tablet was calculated by formula.

Loss on Drying = (Initial Weight of Substance- Final Weight of Substance) **/** Initial Weight of Substance × 100

h) In vitro Buoyancy Studies :
The time taken for tablet to emerge on the surface of the medium is called the floating lag time or buoyancy lag time and duration of time the dosage form constantly remains on the surface of the medium is called total floating time. The buoyancy of the tablets was performed by using 0.1 N HCl.
The time of duration of floatation was observed visually**.**

i) In vitro Drug release studies of Tablets :
The release rate of Ofloxacin from floating tablets was determined using USP Dissolution Testing Apparatus type-II (paddle method; Electrolab TDT-08-L). The dissolution test was performed using 900 ml of 0.1N HCl, at $37 \pm 0.5°C$ and 50 rpm. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus hourly and the samples were replaced with fresh dissolution medium. The samples were filtered through a 0.45 µ membrane filter and diluted to a suitable concentration with 0.1N HCl. Absorbance of these solutions was measured at 293.2 nm using a Shimadzu-1800 UVvisible spectrophotometer. For each formulation, the experiments were carried out in triplicate.

III.   RESULTS:

a) Colour and Appearance :
The drug (Ofloxacin) colour is "Off-white to pale yellow" as same as the reported reference.

b) Melting Point :
The Melting point of Ofloxacin was found to be 256.056 ± 0.040. The reported melting point of Ofloxacin is 250-2570C. Hence, observed values are complies with USP.

a) Solubility Study :
The Solubility of Ofloxacin in different solvents is given   below   :

Table: Solubility of Ofloxacin in Different Solvents.

SR.NO.	SOLVENT	PARTS OF SOLVENT REQUIRED PER PART OF SOLUTE	INFERENCE
1)	Acetic acid	10	Soluble.

2)	Water	460	Slightly soluble.
3)	0.1 N HCl	28	Soluble.

Identification of drug :
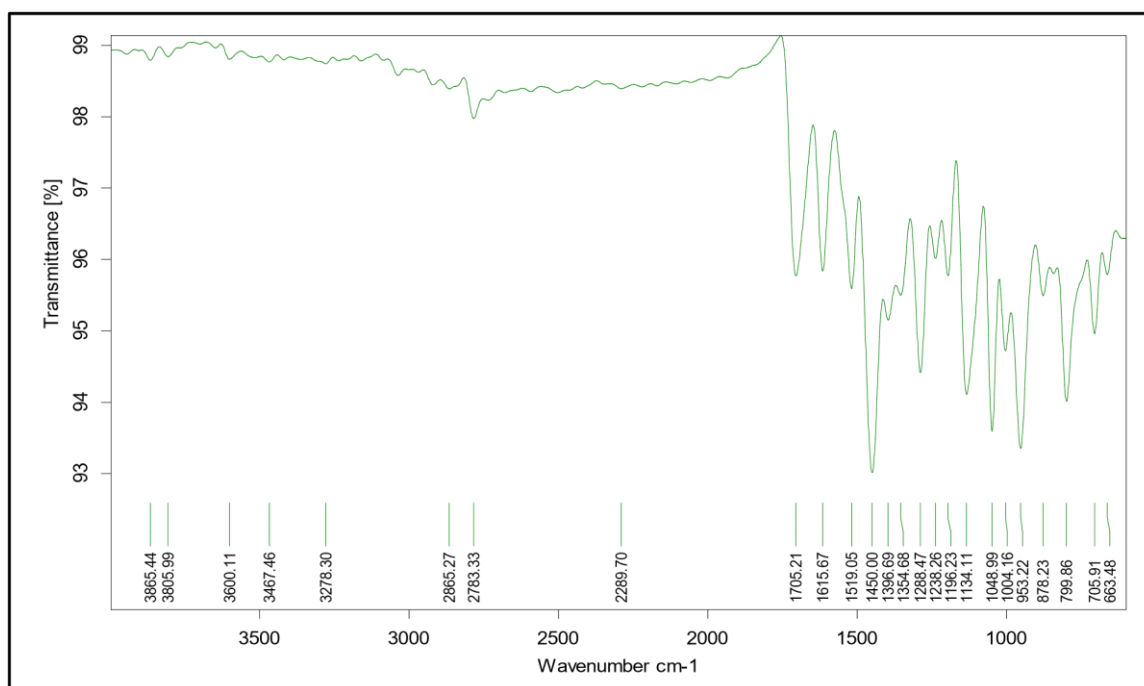Identification of drug was performed by FTIR spectroscopic method

Figure: FTIR of ofloxacin

Fourier Transform Infra-Red Spectroscopy (FTIR) :
The IR spectrum of Ofloxacin is shown in figure 17. The Interpretation of IR frequencies are show.
Interpretation of FTIR Spectrum :

shows the peaks observed at different wave numbers and the functional group associated with these peaks. The major peaks are identical to functional group of Ofloxacin. Hence, the sample was confirmed as Ofloxacin.

Table: Characteristic Frequencies in FTIR Spectrum of Ofloxacin.

FUNCTIONAL GROUPS	WAVE NO. (cm-1)
C-H out of plane bending	799

C-O-C stretching ether group	1050
C-F stretching	1130
C-O stretching COOH	1291
C-C stretching	1459
C=O aromatic stretching	1531
C=O stretching ketones	1620

Spectroscopic studies:

UV Spectroscopy :

Determination of λmax and Preparation of Calibration Curve of Ofloxacin by using 0.1N HCl UV absorption spectrum of Ofloxacin in 0.1N HCl shows λmax at 293.2 nm. Absorbance obtained for various concentrations of Ofloxacin in 0.1N HCl are given in Table 16. The graph of absorbance versus concentration for Ofloxacin was found to be linear in the concentration range of 3-15 μg /ml. The drug obeys Beer- Lambert's law in the range of 3-15 μg /ml.

Table : Concentration and Absorbance data for Calibration Curve of Ofloxacin in 0.1N HCL.

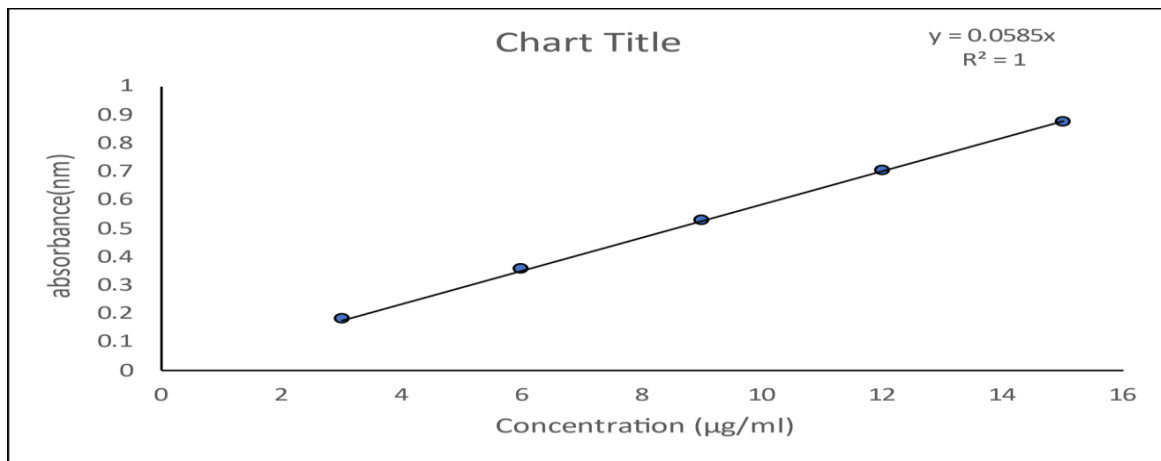| SR.NO.	CONCENTRATIONS (mg/ml)	ABSORBANCE AT 293.2nm
1)	3	0.182
2)	6	0.355
3)	9	0.529
4)	12	0.701
5)	15	0.875

Figure: Calibration curve of Ofloxacin in 0.1N HCl

The values of Correlation coefficient (R), Slope, Intercept obtained from the calibration curve

Table: Data for Calibration Curve parameters of Ofloxacin in 0.1N HCl.

Sr.No.	Parameters	Values
1)	Slope	0.0585
2)	Intercept	0.0089
3)	Correlation coefficient (R)	0.9999

Assay of Ofloxacin:

Table: Assay of Ofloxacin

SR.NO.	PERCENTAGE PURITY	AVERAGE PERCENTAGE PURITY(%)
1)	99.86	
2)	100.10	100.38±0.714
3)	101.20	

The official percentage purity of Ofloxacin is not less than 98.5% and not more than 101.5%. So it can be declared as pure drug. The percentage purity of raw material Ofloxacin was found to be 100.38±0.714. Hence, the sample was concluded as pure.

Loss on drying:
The percentage loss on drying after 5 hours was found to be 0.0797%. The sample passes test for loss on drying as per the limits specified in USP. (NMT 0.2%).

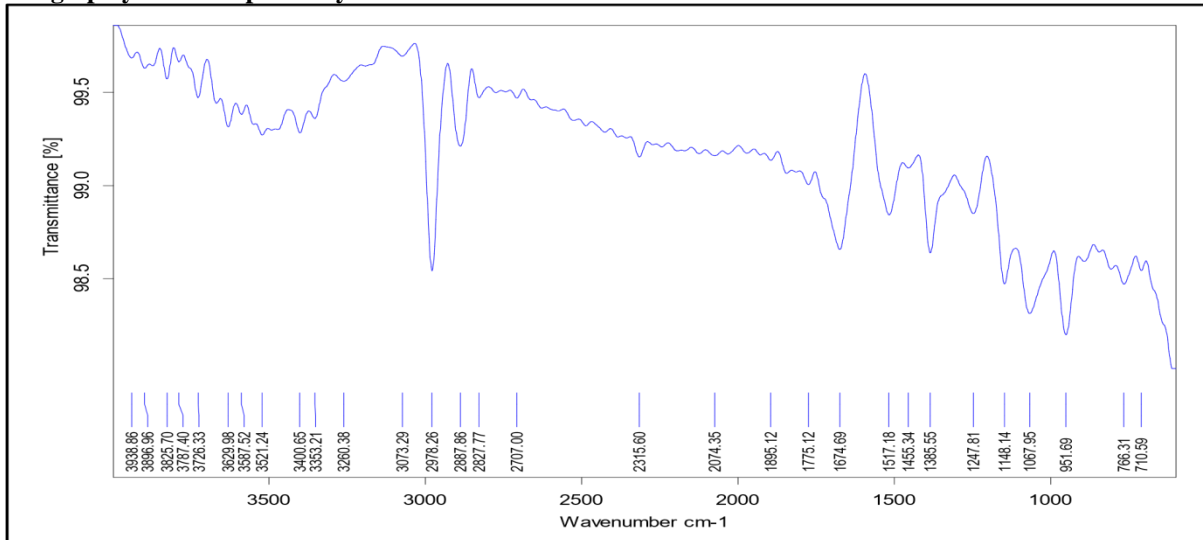**Drug - polymers compatibility studies:**
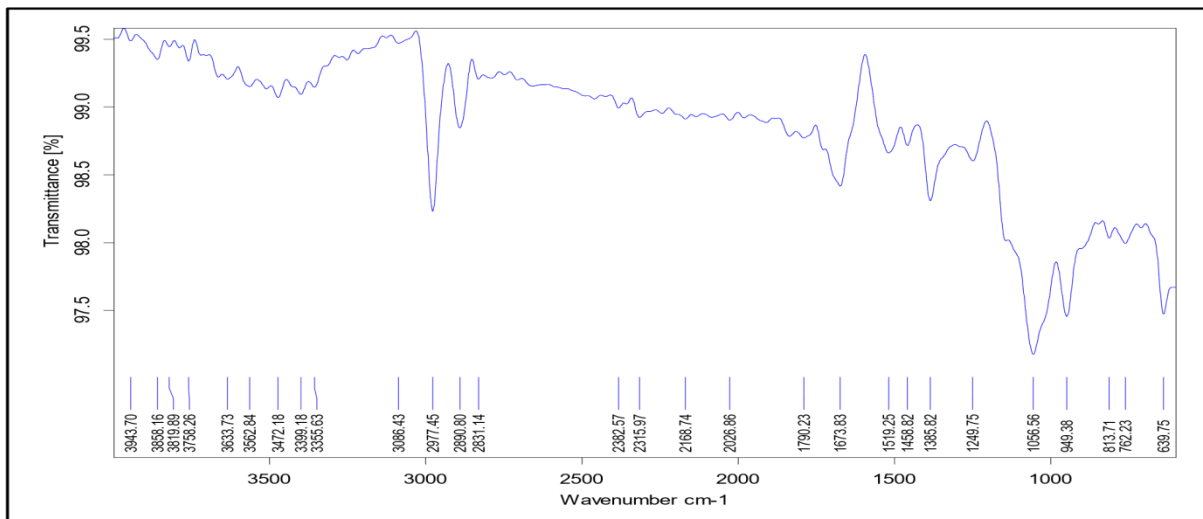

Figure: FTIR Spectrum of HPMC.

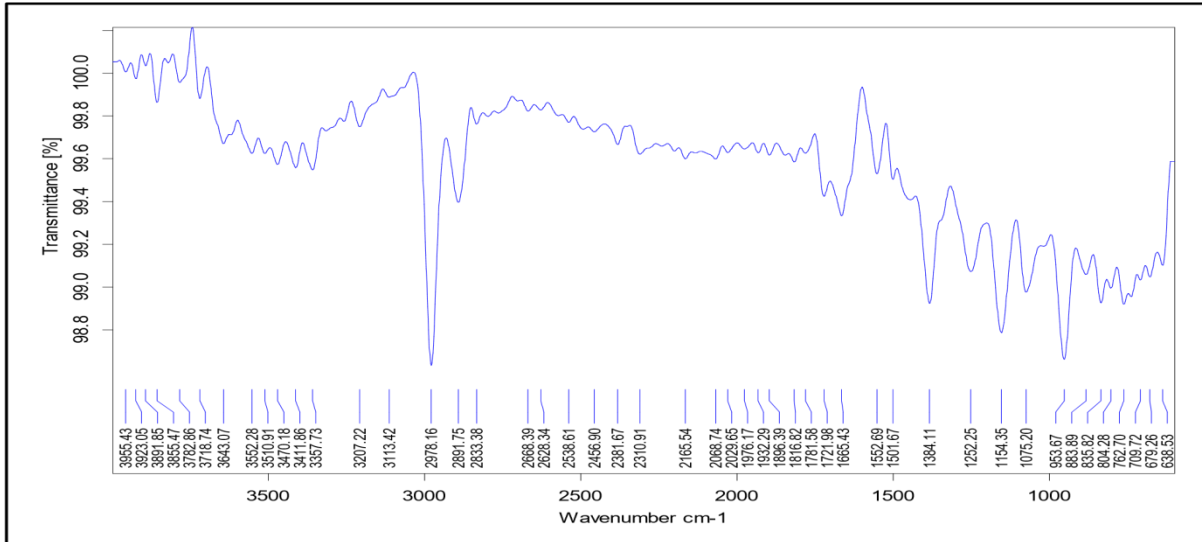Figure: FTIR Spectrum of HPMC and Ofloxacin.

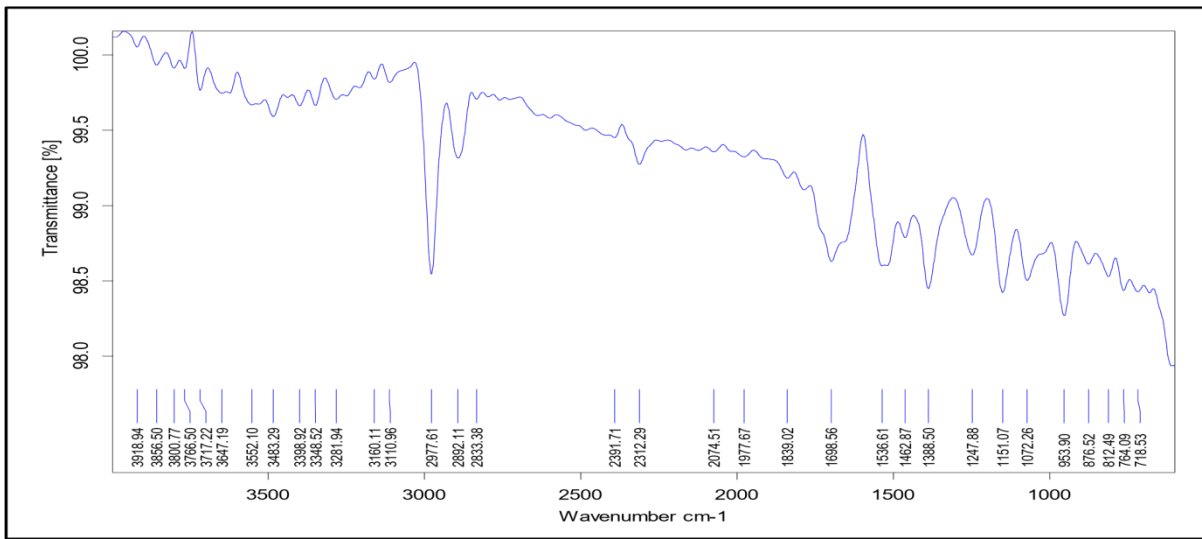Figure: FT-IR Spectrum of Badam Gum.

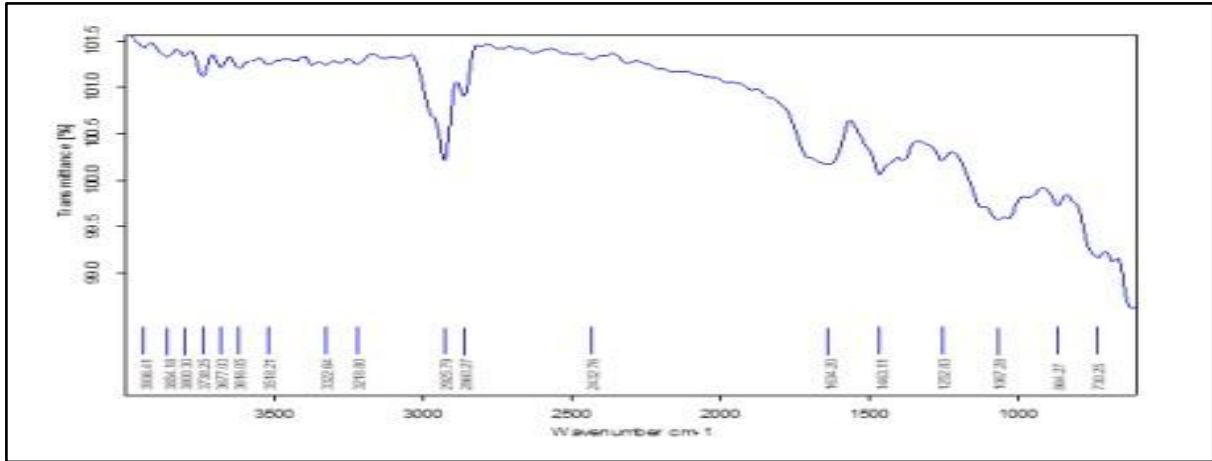Figure: FT-IR Spectrum of Badam Gum and Ofloxacin.
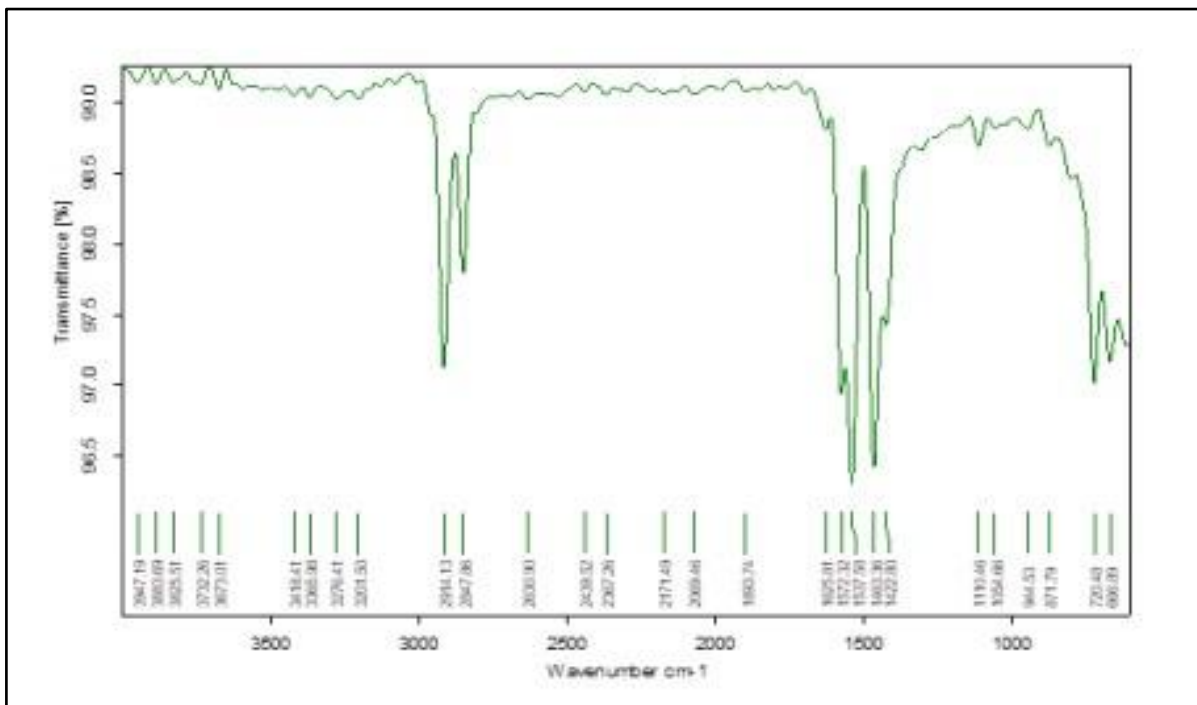
Figure : Magnesium Sterate

Figure: FTIR Spectrum of Lactose.

FTIR studies were carried out for Ofloxacin , Polymer and Excipients mixture. The recorded FTIR spectrum of the spectrum shows the presence of principle peaks of Ofloxacin which indicates that there was no interaction between Ofloxacin , Polymer and Excipients. Therefore it was confirmed the absence of incompatibilities between. Ofloxacin, Polymer and Excipients.

Swelling index study:

Table: Swelling Index data of formulations

SR.NO.	TIME (HRS)	SWELLING INDEX					
		F1	F2	F3	F4	F5	F6
1)	0	0.000	0.000	0.000	0.000	0.000	0.000
2)	1	1.25±0.031	1.59±0.035	1.74±0.152	0.76±0.033	0.97±0.043	1.12±0.030
3)	2	1.53±0.042	1.91±0.030	1.91±0.0301	0.92±0.030	1.21±0.031	1.49±0.042
4)	3	1.69±0.030	2.19±0.053	2.04±0.151	1.02±0.040	1.34±0.072	1.76±0.040
5)	4	1.91±0.022	2.40±0.041	2.21±0.030	1.26±0.076	1.63±0.025	1.89±0.030
6)	5	2.13±0.030	2.53±0.032	2.59±0.112	1.42±0.129	1.70±0.030	2.02±0.033
7)	6	2.63±0.041	2.92±0.030	3.02±0.054	1.66±0.030	1.95±0.021	2.17±0.030
8)	7	2.91±0.072	2.99±0.073	3.10±0.042	2.04±0.040	2.18±0.150	2.45±0.029
9)	8	2.64±0.032	3.21±0.022	3.35±0.030	1.95±0.051	2.74±0.030	2.93±0.040
10)	9	2.49±0.030	3.03±0.040	3.23±0.070	1.83±0.050	2.58±0.054	2.82±0.031
11)	10	2.27±0.031	2.87±0.030	2.97±0.091	1.62±0.030	2.27±0.031	2.69±0.030
12)	11	2.08±0.053	2.71±0.052	2.81±0.031	1.54±0.021	2.03±0.044	2.46±0.034

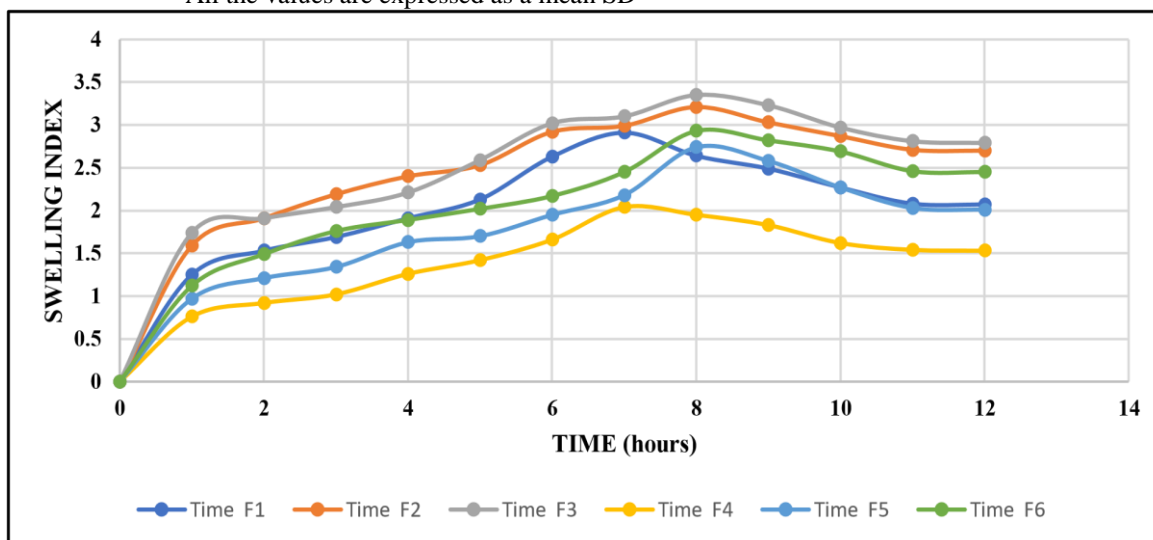| 13)	12	2.07±0.030	2.70±0.031	2.79±0.040	1.53±0.040	2.01±0.041	2.45±0.032

All the values are expressed as a mean SD

Figure: Swelling index of formulations (F1 – F6)

The floating and drug release profile are dependent upon swelling behaviour of the tablets. Swelling index increased as the weight gained by the tablet increased proportionally with the rate of hydration. Swelling is also a vital factor to ensure buoyancy and drug dissolution of matrix tablet.

The comparative swelling Index data of all the formulations were showed in Figure 26 . From this Figure, it can be observed that the swelling Index of different formulations decreased in the following order; F1>F2 > F3 > F4 > F5 > F6

In vitro drug release studies:
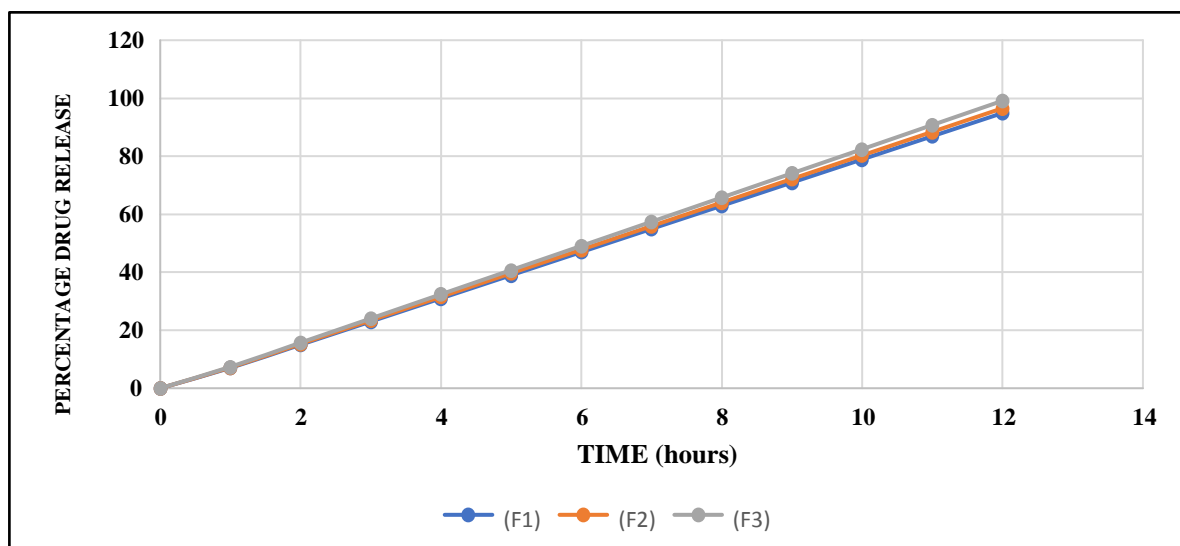**In vitro drug release profile of tablets:**

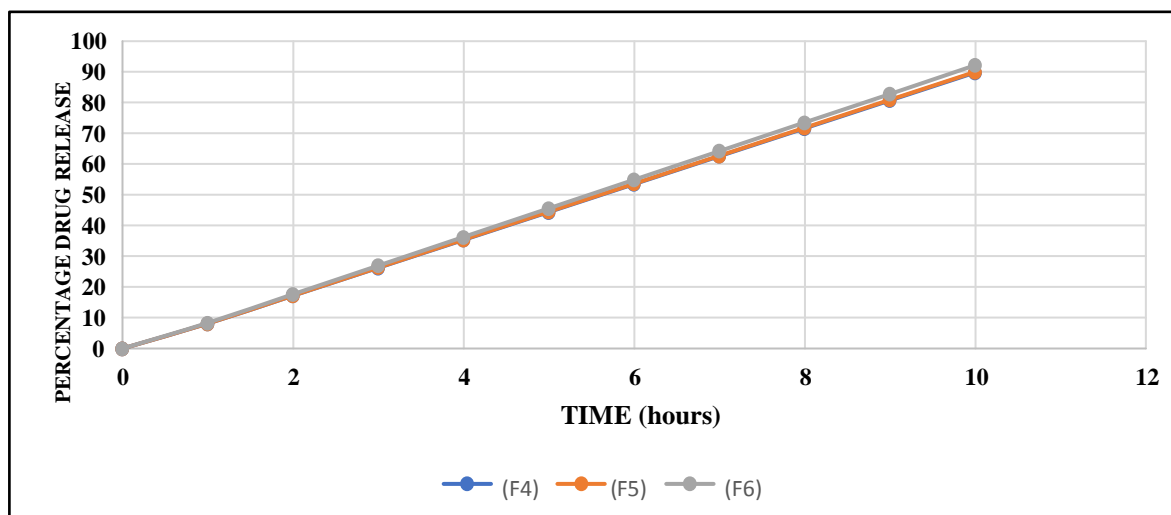Figure: Percentage drug release profile of formulation. (F1-F3)

Figure: Percentage drug release profile of formulation. (F4-F6)

In-vitro dissolution studies of all the formulation of Ofloxacin floating tablets were carried out in 0.1 N HCl. The study was performed for 12 hrs and cumulative drug release was calculated at different time interval. This showed that HPMC hydrated more rapidly in 0.1 N HCl. The formulation F1, F2 and F3 showed the drug release 94.91, 96.52 and 99.12 % up to 12 hrs but F4, F5 and F6 showed the drug release 89.80, 90.06 and 92.12 % up to 10 hrs. The comparison graph for all formulations F1-F6

IV. CONCLUSION:

The formulation of floating tablet was successfully done. From above data we conclude that the Ofloxacin was successfully done by using Badam gum and HPMC as release retardant polymer.

On the basis of invitro evaluation studies it shown that Badam gum have complete drug release, good floating and swelling ability at appropriate concentration hence due to appropriate concentration formulation F6 shows good result and Hence, we can say that by keeping appropriate concentration of Badam gum in ofloxacin floating tablet, shows good results as compared to HPMC.

Formulation F3 and Formulation F6 have shown good results with 99.12 and 92.19 % drug release, both have 12hrs floating time and Swelling index - 2.79% and 2.45%.

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