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Formulation and *in-vitro* evaluation of Gastro retentive floating tablets of Cefixime Trihydrate by using Natural Polymers

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Abstract: *The Floating drug delivery system is a novel approach in the Gastro retentive drug delivery systems (GRDDS). Floating system is needed for those drugs having a stomach or upper small intestine absorption window. This process does not affect on the rate of gastric emptying over an extended time as it a less dense method and therefore stay buoyant in the stomach and slowly release the drug. System floats on the gastric contents thereby releasing the drug slowly at a desired rate from the system which results in an increased gastric residence time (GRT) and a better control of the fluctuations in plasma drug concentration. Floating systems utilize highly swellable and gel forming hydrocolloids like HPMC, CMC and Carbopol being widely used for their desirable properties. Excellent bioavailability, enhanced reliability, little incompatibility are the benefits of this technology. Floating tablets of Cefixime Trihydrate using natural polymers like Gum Copal, Isapgol husk and Fenugreek extract containing 25mg of Cefixime Trihydrate was prepared successfully using direct compression method. All the prepared formulations were evaluated for preformulation and post compression parameters. The floating behaviour and drug release study was assessed using USP dissolution apparatus and results exhibited satisfactory floating properties with a floating lag time of less than 2 minutes and remained buoyant for 12 hours. The drug release profile showed a controlled release pattern with a sustained release pattern. Of all the formulations, formulation (C4) prepared with Isapgol husk was considered best with a release of 99.68% in 12 hours. The release kinetics was also analysed to determine the drug release mechanism and follows a zero-order kinetic profile. Hence Gastro-retentive floating tablets of Cefixime Trihydrate using natural polymers were successfully formulated and found to be a promising formulation to improve the bioavailability and therapeutic efficacy of Cefixime Trihydrate in the treatment of infections.*

Key Words: *Floating Tablet, Natural polymers, Cefixime Trihydrate*

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I. INTRODUCTION

The main motive of any drug delivery system is to deliver a sufficient concentration of drug to the specific target (cell, organ, tissue) in the body to achieve therapeutic concentration and maintain optimum concentration.[1] Oral administration is the most comfortable route of medication delivery and is associated with improved patient compliance when compared to other modes of drug consumption. Oral drug delivery systems account for around half of all drug delivery systems on the market, and they offer more benefits owing to patient acceptability and simplicity of administration.

Gastro retentive Drug Delivery system (GRDDS)

These are the drug delivery system in which can specifically targeted at the site of GI tract. It releases the drug at the site of abdomen/stomach. This type of drug delivery is an approach used to prolong gastric residence time so that the drug remains in the stomach for prolonged time and shows required pharmaceutical action.[2]

The floating drug delivery system is a novel approach in the GRDDS. They float in the stomach and do not slow down gastric emptying since their bulk density is lower than that of gastric fluids. The drug is gradually removed from the system at the desired rate while the body floats on the stomach contents.[3] Floating process does not affect on the rate of gastric emptying over an extended time. It is a less dense (less than gastric liquid) method. Therefore, it stays buoyant in the stomach and slowly release the drug.[4]

The foremost effective strategy is to carry the formulation within the stomach. When a medicine is prepared with gel-forming hydrocolloids like hydroxyl propyl methylcellulose (HPMC) and carbon dioxide-

generating substances like citric acid and sodium hydrogen carbonate, it swells. within the gastric fluid because it gets contact with the aqueous medium. Formation of carbon dioxide (CO2) and entrapment of that gas into the polymeric gel causes swelling of the dosage resulting a bulk density less than 1. It then remains buoyant and floats in the gastric fluid that is accountable for prolonged gastric duration. FDDS having a lower bulk density than gastric fluid, therefore they remain buoyant in the stomach for longer periods of time without influencing gastric emptying time. FDDS offers fundamental advantages approximating they are a smaller amount prone to gastric emptying resulting in summary intra and inter subject variability in plasma drug levels, successful for delivery of drugs by thin absorption windows, reduced dosing and enhanced patient compliance, reduced Cmax and expanded drug levels and better safety profile for drugs with side effects linked with high Cmax [3, 5, 6]

Floating tablets are a type of sustained release drug delivery device that floats on stomach contents for an extended period of time by creating CO 2 gas or swelling, allowing the medicine to be released for a longer period. Various polymers, including different grades of HPMC, Eudragit, chitosan, Carbopol, guar gum, and xanthium gum, can be employed to extend drug release. Drugs that are rapidly absorbed from the stomach and have a short half-life are quickly removed from the bloodstream, necessitating repeated administration. To address this issue, oral Gastro retentive formulations have been created in an effort to gradually release the medicine into the Gastric area.[7]

II. MATERIALS AND METHODS

Cefixime Trihydrate was received as a gift sample from the **SURA LABS, Dilsukhnagar, Hyderabad, India.** Gum Copal, Isapgol husk, Fenugreek extract was received as a gift sample from Degussa India Ltd. (Mumbai, India), Arvind Remedies Ltd, Tamil nadu, India, Merck Specialities Pvt Ltd, Mumbai, India. Citric acid was obtained from Laser Chemicals, Ahmedabad, India. Sodium bicarbonate and Micro crystalline cellulose from Merck Specialities Pvt Ltd, Mumbai, India. Magnesium Stearate is from Apex Chemicals, Ahmedabad, India. Talc is from S.D. Fine Chem., Mumbai, India. All other materials and chemicals used were of pharmaceutical and analytical grade.

1. Analytical method Development:

a) 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.

b) Preparation calibration curve:

10mg Cefixime Trihydrate 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, 10µg /ml of per ml of solution. The absorbance of the above dilutions was measured at 288 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.

2. Formulation Development of Gastro retentive Floating Tablets: -

Floating tablets of Cefixime Trihydrate were prepared by using direct compression method according to the formulae as shown in the table 1. The method involves a basic procedure of passing the individual ingredients along with the drug and subjected to direct compaction. Procedure involves by taking the required ingredients into a mortar and the powder blend was mixed for a time period of 15min by using mortar and pestle. Then each mixture was individually passed through sieve no 60 The resulted mixture was lubricated with talc and subjected to compression by using a tablet punching machine (Lab Press Limited, India.) to get 8mm size of tablet each weighing 200mg.

Table No 1: - Formulation of Cefixime Floating Tablets

INGREDIENTS (mg)	**FORMULATION CODE**								
	C1	**C2**	**C3**	**C4**	**C5**	**C6**	**C7**	**C8**	**C9**
Cefixime Trihydrate	25	25	25	25	25	25	25	25	25
Gum Copal	25	50	75	-	-	-	-	-	-
Isapgol husk	-	-	-	25	50	75	-	-	-
Fenugreek extract	-	-	-	-	-	-	25	50	75
Citric acid	15	15	15	15	15	15	15	15	15
Sodium bicarbonate	10	10	10	10	10	10	10	10	10
Micro crystalline	115	90	75	115	90	75	115	90	75

Magnesium Stearate	5	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5	5
Total Weight	200	200	200	200	200	200	200	200	200

3. Evaluation Parameters

3.1: Pre-compression parameters of powder blends: -

The characterization of flow properties of powder blends is a must in tablet compression. The powder blends with good flow properties gives uniformity in die filling and gives uniform tablet weight. 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. The designed compression tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability and drug content.

Bulk density:

Density is defined as weight per unit volume. Bulk density, is defined as the mass of the powder divided by the bulk volume and is expressed as gm/cm^3. Bulk density is very important in the size of containers needed for handling, shipping, and storage of raw material and blend.

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.

Carr's Index:

The Compressibility Index (Carr's Index) is a measure of the propensity of a powder to be compressed. It is determined from the bulk and tapped densities. In theory, the less compressible a material the more flowable it is. As such, it is measures of the relative importance of interparticulate interactions.

Angle of repose:

The frictional force in a loose powder can be measured by the angle of repose. It is defined as, the maximum angle possible between the surface of the pile of the powder and the horizontal plane. If more powder is added to the pile, it slides down the sides of the pile until the mutual friction of the particles producing a surface angle, is in equilibrium with the gravitational force.

Hausner's ratio

The Hausner's ratio is another parameter indicating the flow properties. The value of ratio below 1.25 indicates good flow while above 1.25 indicates the poor flow.

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 0.42 to 0.57 (gm/cm^3) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.52 to 0.63 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 18.05 which show that the powder has good flow properties. All the formulations has shown the Hausner ratio below 1.50 indicating the powder has good flow properties.

3.2. Evaluation Of Quality Control 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:

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 weight variation test would be a satisfactory method of deter mining the drug content uniformity. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the following table and none deviate by more than twice the percentage. The mean and deviation were determined. The percent deviation was calculated using the following formula.

Hardness:

Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its 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:

Tablet thickness is an important characteristic in reproducing appearance. Tablet thickness is an important characteristic in reproducing appearance. Average thickness for core and coated tablets is calculated and presented with deviation.

Friability:

It is measured of mechanical strength of tablets. Roche friabilator was used to determine the friability by following procedure. Pre weighed tablets were placed in the friabilator. The tablets were rotated at 25 rpm for 4 minutes (100 rotations). 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 Cefixime Trihydrate 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. 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)	--	0.5,1,2,3,4,5,6,7,8,10,11,12
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.

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 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 receptor's fluid was withdrawn, filtered and again 5ml receptor fluid was replaced. Suitable dilutions were done with media and analysed by spectrophotometrically at 288 nm using UV-Spectrophotometer.

3.3. FTIR (Fourier Transform-Infrared Spectroscopy) RESULT:

FTIR studies were conducted and the spectrum was recorded in the range of 4000-400cm^{-1}. 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. Cefixime Trihydrate is 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.

III. RESULTS AND DISCUSSION

The present work was aimed to developed floating tablets of Cefixime Trihydrate using natural polymers and all the formulations were evaluated for physicochemical properties, in-vitro drug release and release kinetic data.

1. Analytical Method

Standard graph of Cefixime Trihydrate was plotted as per the procedure in experimental method and its linearity is shown in Table 8.1 and Fig 8.1. The standard graph of Cefixime Trihydrate showed good linearity with R^2 of 0.999, which indicates that it obeys "Beer- Lamberts" law.

Table no 2: Observations for graph of Cefixime Trihydrate in 0.1N HCL

Conc. [µg/mL]	Abs
0	0
2	0.127
4	0.241
6	0.364
8	0.478
10	0.591

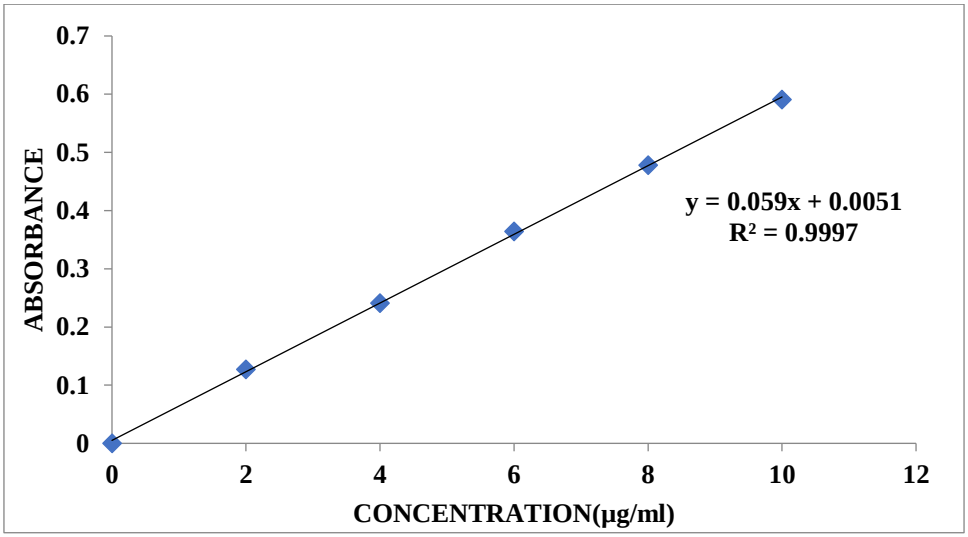

Figure No 1: - Standard graph of Cefixime Trihydrate in 0.1N HCL

2. EVALUATION PARAMETERS

2.1. Pre-compression parameters

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 0.42 to 0.57 (gm/cm^3) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.52 to 0.63 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 18.05 which show that the powder has good flow properties. All the formulations have shown the Hausner ratio below 1.50 indicating the powder has good flow properties.

Table No 3: - Evaluation (Pre-formulation) parameters of all formulation (C1-C9)

Formulation Code	Angle of Repose	Bulk density (gm/mL)	Tapped density (gm/mL)	Carr's index (%)	Hausner's Ratio
C1	28.36	0.46	0.54	14.81	1.19
C2	25.64	0.42	0.63	30.15	1.50
C3	27.02	0.44	0.54	18.05	1.22
C4	24.22	0.52	0.57	8.77	1.09
C5	31.38	0.57	0.63	9.52	1.10
C6	24.22	0.46	0.57	19.29	1.23
C7	30.11	0.42	0.52	19.23	1.23
C8	22.29	0.52	0.60	13.33	1.15

C9	27.02	0.48	0.57	18.75	1.08

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

Table No 4: - In-vitro quality control parameters of prepared formulations

Formulation codes	**Weight variation (mg)**	**Hardness (kg/cm^2)**	**Friability (%loss)**	**Thickness (mm)**	**Drug content (%)**	**Floating lag time (sec)**	**Total Floating Time (Hrs)**
C1	198.22	4.2	0.43	2.15	99.36	63	9
C2	199.88	4.9	0.52	2.69	98.14	51	10
C3	197.43	4.2	0.58	2.81	97.34	47	12
C4	200.89	4.3	0.62	2.79	100.02	61	12
C5	201.63	4.0	0.44	2.56	99.47	43	12
C6	196.44	4.7	0.63	2.11	99.33	47	12
C7	201.67	4.6	0.43	2.29	97.20	51	11
C8	198.28	4.8	0.39	2.50	98.47	66	12
C9	199.37	4.3	0.57	1.74	99.83	53	12

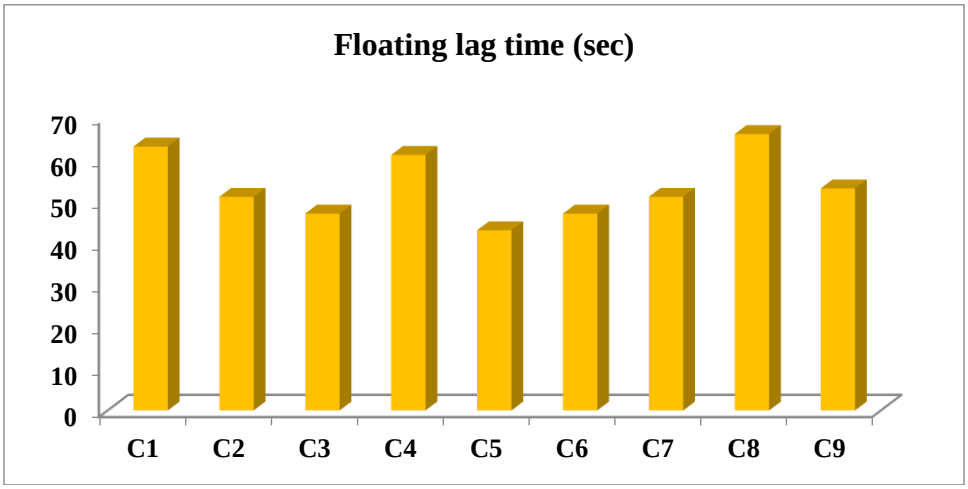

Figure No 2: - Floating lag time (sec)

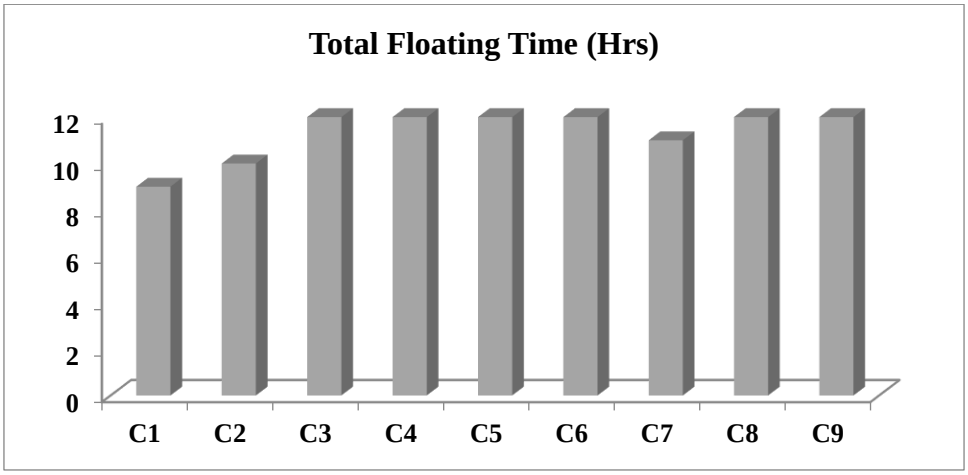

Figure No 3: - Total Floating Time (Hrs)

***In-vitro* Drug Release Studies:**

The formulations were prepared with different polymers by direct compression method. Dissolution studies were carried out using USP II paddle type Dissolution apparatus using 0.1N HCL for 12 hrs at 50rpm.

Table No 5: - Dissolution Profiles of Formulations C1-C3

INGREDIENTS (MG)	FORMULATION CODE		
	C1	C2	C3
Cefixime Trihydrate	25	25	25
Gum Copal	25	50	75
Isapgol husk	-	-	-
Fenugreek extract	-	-	-
Citric acid	15	15	15
Sodium bicarbonate	10	10	10
Micro crystalline cellulose	115	90	75
Magnesium Stearate	5	5	5
Talc	5	5	5
Total Weight	200	200	200

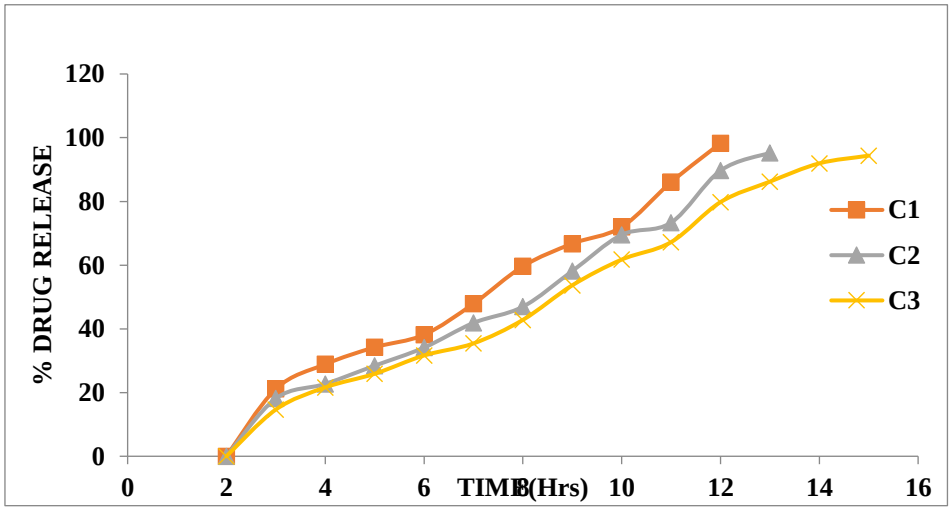

Figure No 4: - Percentage drug release for Formulations C1-C3

The formulations prepared with Gum Copal were retarded the drug release in the concentration of 25 mg (C1 Formulation) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 98.26 % in 9 hours with good retardation.

Table No 6: - Dissolution Profiles of Formulations C4-C6

INGREDIENTS (MG)	FORMULATION CODE		
	C4	C5	C6
Cefixime Trihydrate	25	25	25
Gum Copal	-	-	-
Isapgol husk	25	50	75
Fenugreek extract	-	-	-
Citric acid	15	15	15
Sodium bicarbonate	10	10	10
Micro crystalline cellulose	115	90	75
Magnesium Stearate	5	5	5
Talc	5	5	5

Total Weight	200	200	200

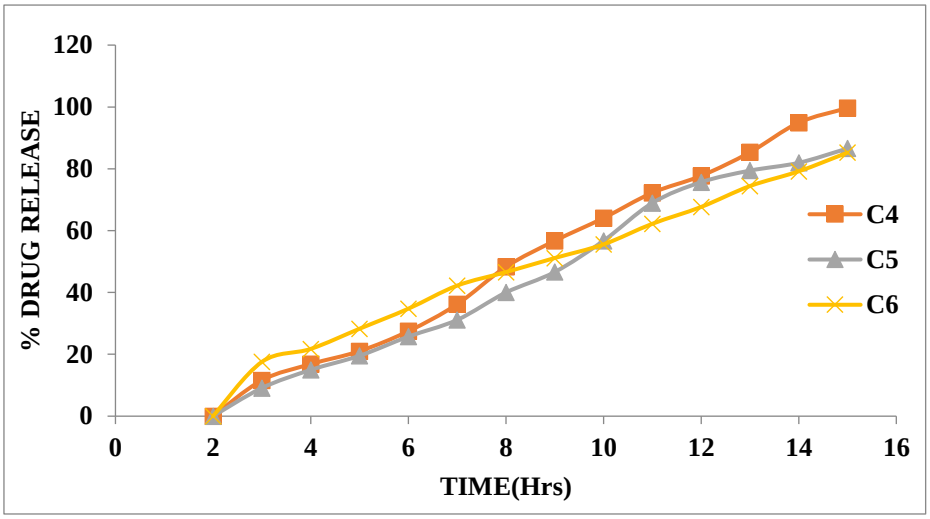

Figure No 5: - Percentage drug release for Formulations C4-C6

Whereas the formulations prepared with Isapgol were retarded the drug release in the concentration of 25 mg (C4 Formulation) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 99.68 % in 12 hours with good retardation.

Table No 7: - Dissolution Profiles of Formulations C7-C9

INGREDIENTS (MG)	**FORMULATION CODE**		
	C7	**C8**	**C9**
Cefixime Trihydrate	25	25	25
Gum Copal	-	-	-
Isapgol husk	-	-	-
Fenugreek extract	25	50	75
Citric acid	15	15	15
Sodium bicarbonate	10	10	10
Micro crystalline cellulose	115	90	75
Magnesium Stearate	5	5	5
Talc	5	5	5
Total Weight	200	200	200

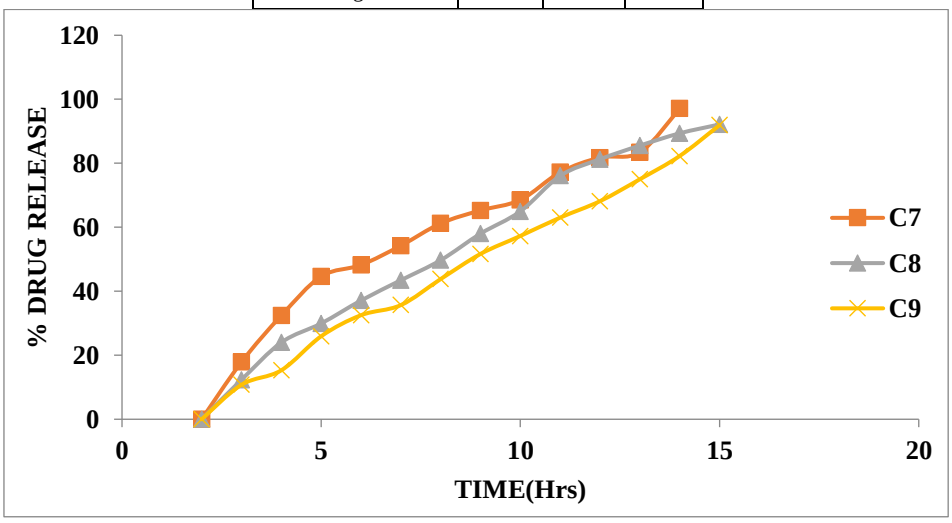

Figure No 6: - Percentage drug release for Formulations C7-C9

While the formulations made with fenugreek extract showed the desired release pattern, i.e., retarded the drug release up to 12 hours and showed a maximum of 97.11 percent in 11 hours with good retardation, the formulations made with fenugreek extract showed retarded drug release at a dose of 25 mg (C7 Formulation).Therefore, based on the dissolution statistics above, it was determined that the C4 formulation was deemed optimal due to its good drug release (99.68%) during a 12-hour period.

Table No 8: - Kinetic release fit model of all Formulations

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
11.59	0.5	0.707	1.064	-0.301	1.947	23.180	0.0863	-0.936	88.41	4.642	4.455	0.187
16.83	1	1.000	1.226	0.000	1.920	16.830	0.0594	-0.774	83.17	4.642	4.365	0.277
21.02	2	1.414	1.323	0.301	1.898	10.510	0.0476	-0.677	78.98	4.642	4.290	0.351
27.46	3	1.732	1.439	0.477	1.861	9.153	0.0364	-0.561	72.54	4.642	4.171	0.471
36.17	4	2.000	1.558	0.602	1.805	9.043	0.0276	-0.442	63.83	4.642	3.996	0.645
48.28	5	2.236	1.684	0.699	1.714	9.656	0.0207	-0.316	51.72	4.642	3.726	0.916
56.69	6	2.449	1.754	0.778	1.637	9.448	0.0176	-0.246	43.31	4.642	3.512	1.130
64.07	7	2.646	1.807	0.845	1.555	9.153	0.0156	-0.193	35.93	4.642	3.300	1.342
72.24	8	2.828	1.859	0.903	1.443	9.030	0.0138	-0.141	27.76	4.642	3.028	1.614
77.71	9	3.000	1.890	0.954	1.348	8.634	0.0129	-0.110	22.29	4.642	2.814	1.827
85.32	10	3.162	1.931	1.000	1.167	8.532	0.0117	-0.069	14.68	4.642	2.449	2.193
94.91	11	3.317	1.977	1.041	0.707	8.628	0.0105	-0.023	5.09	4.642	1.720	2.921
99.68	12	3.464	1.999	1.079	-0.495	8.307	0.0100	-0.001	0.32	4.642	0.684	3.958

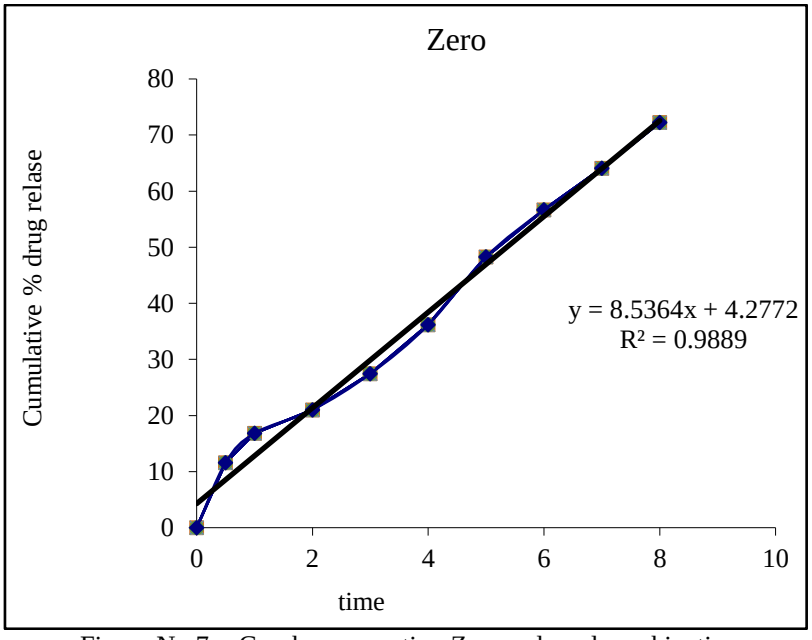

Figure No 7: - Graph representing Zero order release kinetics

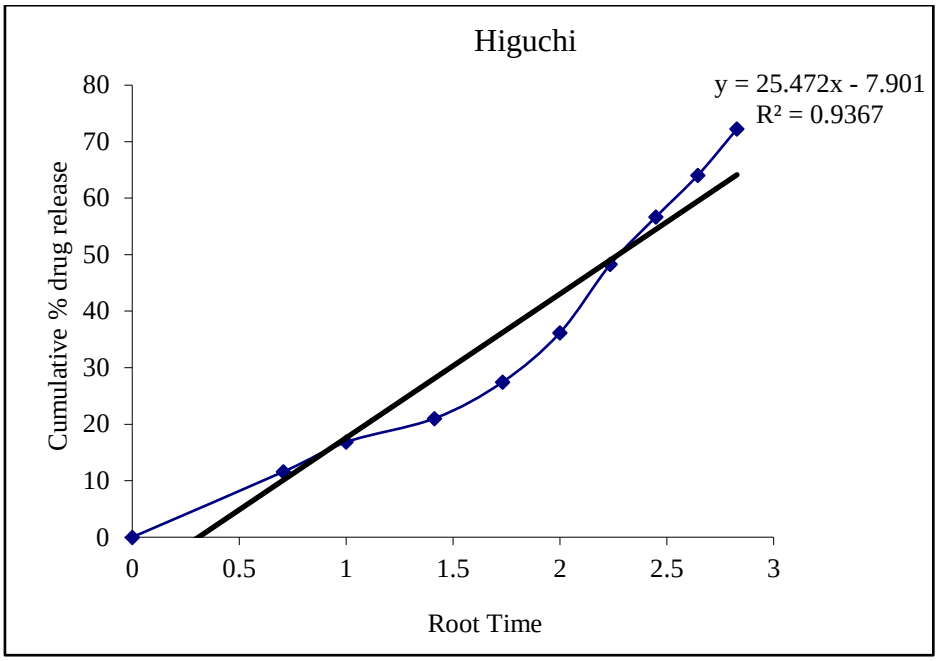

Figure No 8: - Graph representing Higuchi release kinetics

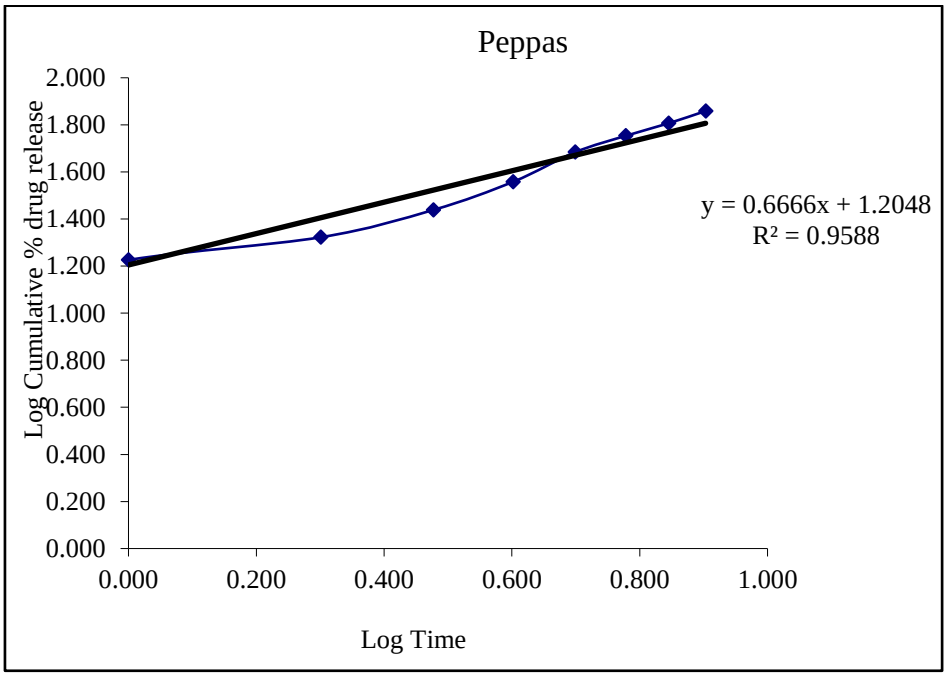

Figure No 9: - Graph representing Kors mayer peppas release kinetics

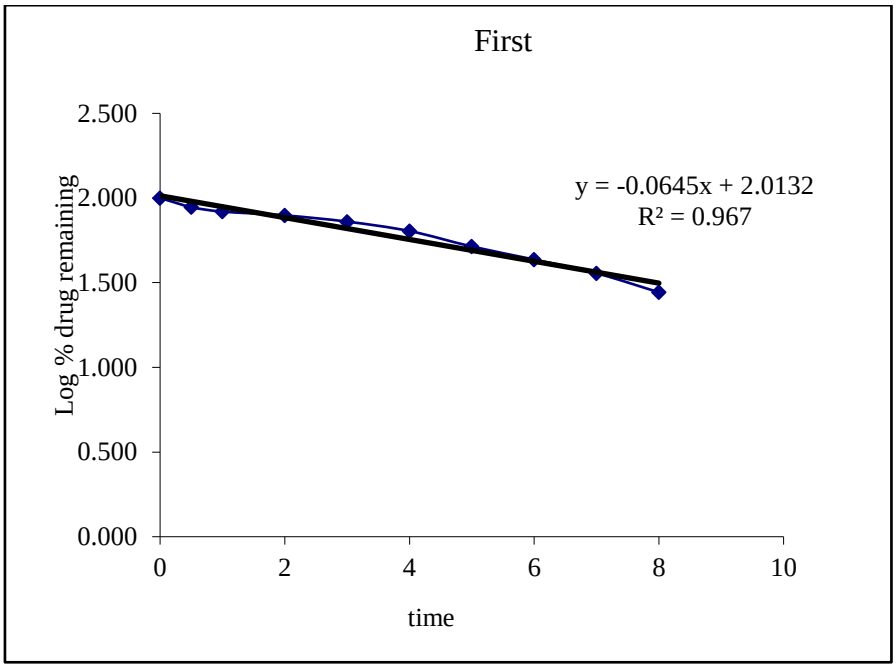

Figure No 10: - Graph representing First order release kinetics

Optimised formulation C4 was kept for release kinetic studies. From the above graphs it was evident that the formulation C4 was followed Zero order release kinetics mechanism.

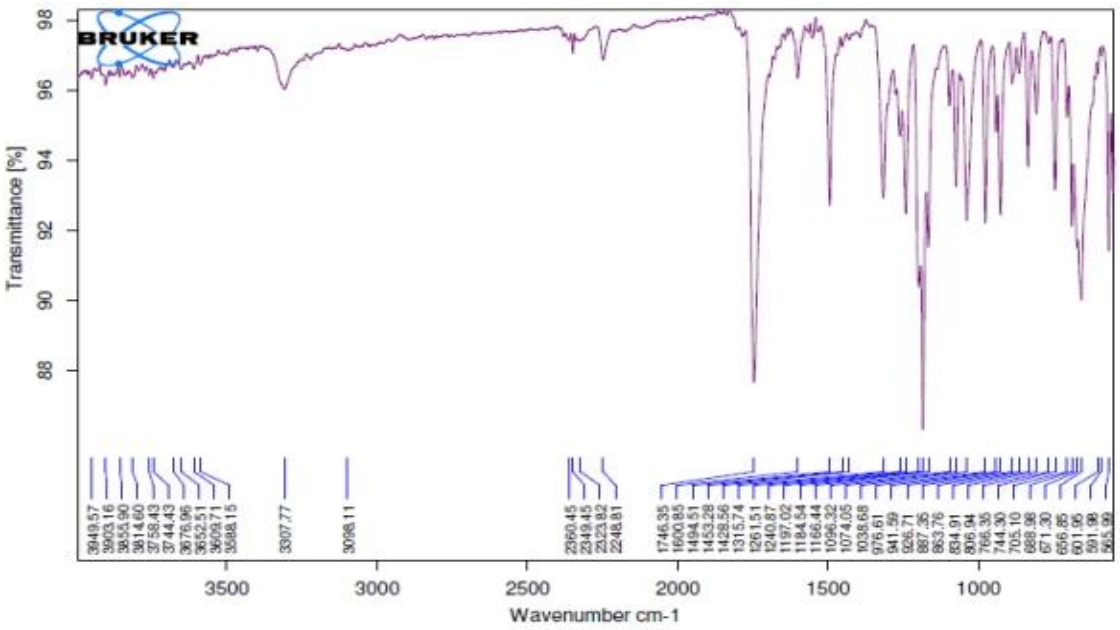

Figure 11: - FTIR Spectrum of pure drug

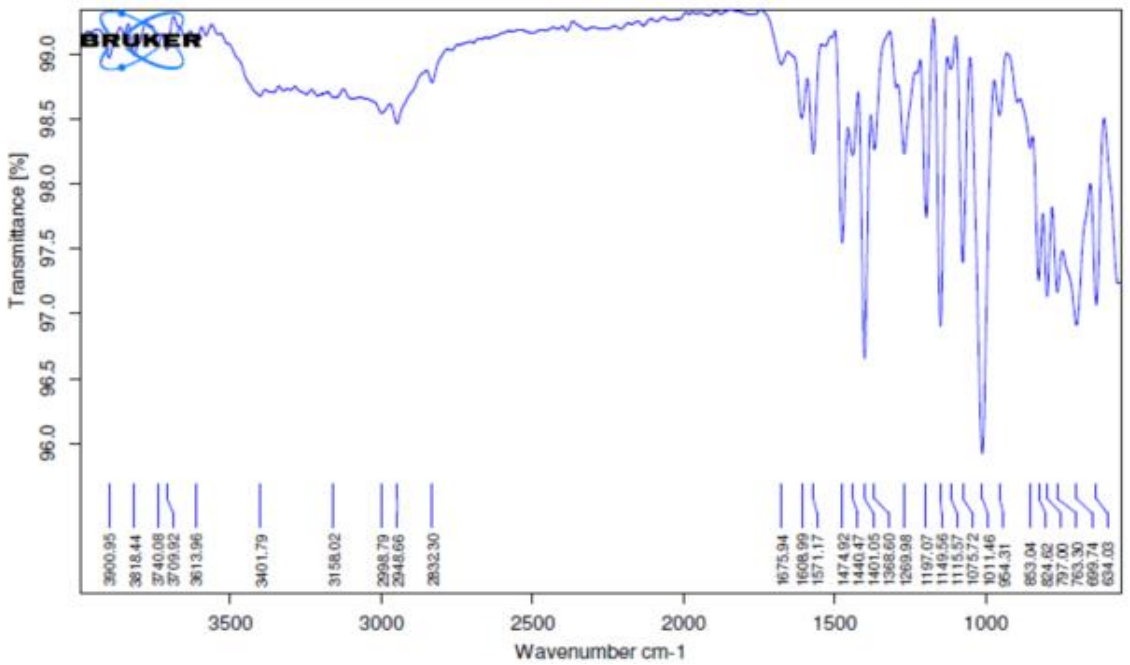

Figure No 12: - FTIR Spectrum of optimised formulation

IV. CONCLUSION

Gastro-retentive floating tablets of Cefixime Trihydrate using natural polymers like Gum Copal, Isapgol husk, and fenugreek extract were chosen and successfully added to the creation of the gastro-retentive floating tablets.

Cefixime Trihydrate was continuously released from the floating tablets for a considerable amount of time, demonstrating a regulated release profile. This controlled release was ascribed to the natural polymers' high viscosity and gel-forming qualities, which aided in the tablets' gradual erosion and dissolving. *In vitro* evaluations confirmed that the floating tablets-maintained buoyancy for a desirable duration, adhering to the desired gastro-retentive properties. The drug release studies demonstrated a consistent and prolonged release of Cefixime Trihydrate, aligning with the goal of extending the drug's residence time in the stomach. While the formulations made with fenugreek extract showed the desired release pattern, i.e., retarded the drug release up to 12 hours and showed a maximum of 97.11 percent in 11 hours with good retardation, The formulations made with fenugreek extract showed retarded drug release at a dose of 25 mg (C7 Formulation).Therefore, based on the dissolution statistics above, it was determined that the C4 formulation was deemed optimal due to its good drug release (99.68%) during a 12-hour period.

In conclusion, the development of gastro-retentive floating tablets of Cefixime Trihydrate using natural polymers has been successful, with promising in vitro results that support their potential for improved drug delivery.

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