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Research Article

# FORMULATION AND INVITRO EVALUATION OF GASTRO RETENTIVE FLOATING TABLETS OF CEFIXIME TRIHYDRATE BY USING NATURAL POLYMERS

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## *ABSTRACT*

***Aim & Objective:*** *The study aimed to develop and evaluate gastro-retentive floating tablets of Cefixime Trihydrate using natural polymers to enhance the bioavailability and therapeutic efficacy of the antibiotic in the upper gastrointestinal tract.*

***Methodology:*** *Floating tablets of Cefixime Trihydrate were formulated using natural polymers, such as Gum Copal, Isapgol husk and Fenugreek extract, which are known for their mucoadhesive and gel-forming properties. The tablets were prepared by direct compression method, incorporating different ratios of these polymers to achieve optimal floating and release characteristics. The formulation was evaluated for various physicochemical properties of tablets and In-Vitro Evaluation.*

***Results:*** *The tablets 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 rate over the desired period. The swelling index was found to be proportional to the polymer concentration, and the mucoadhesive studies confirmed the tablets' ability to adhere to the gastric mucosa.*

***Conclusion:*** *Gastro-retentive floating tablets of Cefixime Trihydrate using natural polymers were successfully formulated and evaluated. The tablets demonstrated effective floating behaviour and controlled drug release, making them a promising formulation for improving the bioavailability and therapeutic efficacy of Cefixime Trihydrate in the treatment of infections.*

***Keywords:*** *Cefixime Trihydrate, Floating Tablets, Gastro-Retentive, Natural Polymers, Gum Copal, Isapgol husk and Fenugreek*

## 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. Oral drug delivery system is the most commonly used system for drug delivery because of its several advantage like easy administration, easy to formulate and high patient compliance. Oral controlled – release drug delivery system delivers the drug at a predetermined and controlled rate hence maintain optimum therapeutics concentration. Oral controlled release drug delivery system has a several merit enhancement of activity of duration for short half-life drug, elimination of side effect, reducing frequency of dosing and wastage of drug and high patient compliance[1-3]. Floating System (FDDS) are also known as hydro dynamically balanced system has a bulk density less than that of gastric fluid and so remains floating in the stomach without affecting gastric emptying rate for longer time. During floating period drug is slowly released at desired rate from the system. Floating system can be divided in to two types: effervescent and non – effervescent system[4-7]. The oral bioavailability of many drugs is limited by their

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unfavourable physicochemical characteristics or absorption in well-defined part of the gastrointestinal tract (GIT) referred as "absorption window". Prolonged gastric retention improves bioavailability, reduces drug waste, and improves the solubility for drugs that are less soluble in a high pH environment. Various approaches have been investigated to increase the retention of oral dosage form in the stomach, including floating systems, swelling and expanding systems, bioadhesive systems, modified shape systems, high density systems, and other delayed gastric emptying devices[8-10]. In this project work we hypothesized that natural polymers can be as effective as synthetic polymers in controlling the drug delivery from the gastro retentive drug delivery dosage forms.

## 2. MATERIALS & METHODOLOGY

**2.1 Materials:** Cefixime Trihydrate was purchased from CSC Pharmaceuticals, Mumbai, India. Talc & Magnesium Stearate was purchased from Apex chemicals, Ahmedabad, Gujarat, India. Isapgol husk was purchased from Shakti Isabgol Industries, Patan, Gujarat, India. Fenugreek extract was purchased from A M Nutratech Pvt. Ltd, New Delhi, India. Microcrystalline Cellulose was purchased from Merck Specialities Pvt. Ltd, Mumbai, India. sodium bicarbonate, citric acid, Psyllium Husk was purchased from Pioneer Chemical Industries, Fateh Nagar, Hyderabad, Telangana, India, Gum Copal was purchased from Shreeji Chemical Industries, Hyderabad, Telangana, India.

**2.2 Methods:**

**2.2.1 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 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 (R2) which determined by least-square linear regression analysis.

**2.2.2 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.

**2.2.3 Pre-formulation 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 Indian Pharmacopoeia.

**2.2.4 Formulation development of floating Tablets:**

**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 upto 15min.
3) The powder mixture was lubricated with talc.
4) The tablets were prepared by using direct compression method by using 8mm punch.

**2.2.5 Formulation of Tablets:**

**Table1: Formulation composition for 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 |
| Microcrystalline cellulose | 115 | 90 | 75 | 115 | 90 | 75 | 115 | 90 | 75 |
| Talc | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Total Weight | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |

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

**2.2.5 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 100ml volumetric flask containing 50ml 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.

**2.2.6 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

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floats on the dissolution medium was noted as Total Floating Time respectively (TFT).

**Table 2: In vitro drug release studies Sink conditions.**

| In-vitro drug release studies-Dissolution parameters | |
|---|---|
| **Apparatus** | USP-II,Paddle Method |
| **Dissolution Medium** | 0.1N HCL |
| **RPM** | 50 |
| **Samplingintervals (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 12hrs at50 rpm. At definite time intervals of 5 ml of the receptor's fluid was withdrawn, filtered and again 5mlreceptor fluid was replaced. Suitable dilutions were done with media and analyzed by spectrophotometrically at 288 nm using UV-Spectrophotometer.

**2.2.7 Application of Release Rate Kinetics to Dissolution Data:** Various models were tested for explaining the kinetics of drug release. 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= Kot

Where, 'F' is the drug release at time't', and 'Ko' 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=kt1/2
Where,'k'is the Higuchi constant.
Inhiguchi 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.

Mt/M∞=Ktn
Where, Mt/ 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-orderrelease (case I Itransport), n=1;and for supercase II transport, n > 1. In this model, a plot of log (Mt/ M∞) versus log (time) is linear.

## 3. RESULTS AND DISCUSSION

### 3.1 Analytical Method

**Determination of absorption maxima**

The standard curve is based on the spectrophotometer. The maximum absorption was observed at 288nm. Calibration curve Graphs of Cefixime Trihydrate was taken in 0.1N HCL (pH1.2).

**Table 3: Observations for graph of Cefixime Trihydrate in 0.1N HCL**

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

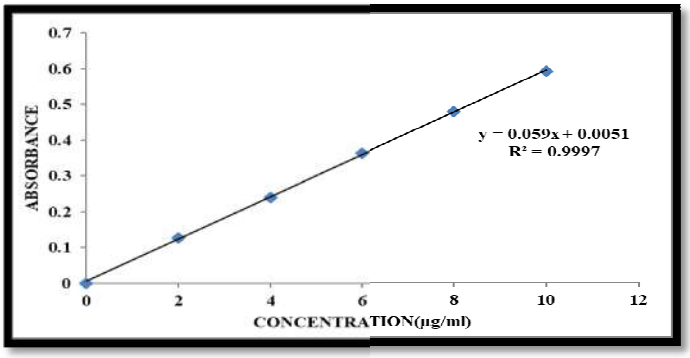


**Fig.1: Standard graph of Cefixime Trihydrate in 0.1N HCL**

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 R2 of 0.999, which indicates that it obeys "Beer-Lamberts" law.

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### 3.1.1 Drug – Excipient compatibility studies Fourier Transform-Infrared Spectroscopy:

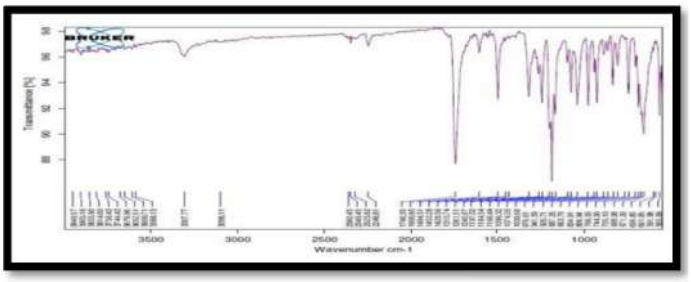


**Fig 7 FTIR Spectrum of pure drug**

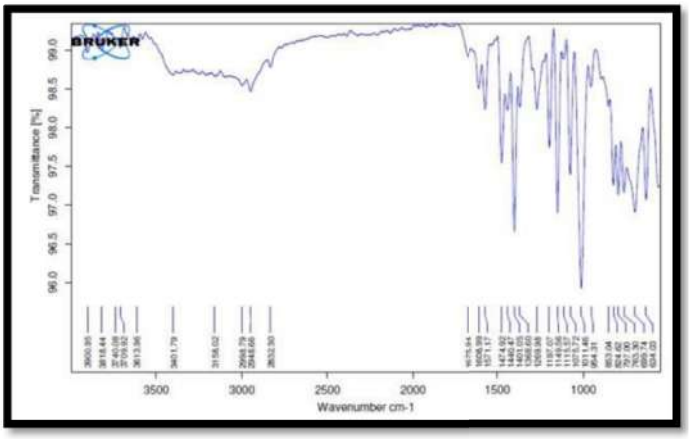


**Fig 8 FTIR Spectrum of optimized formulation**

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.

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.

**Table 4 Pre-formulation parameters of powder blend**

| Formulation Code | Angleof Repose | Bulk Density (gm/mL) | Tapped Density(gm/mL) | Carr'sindex (%) | 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 |

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/cm3) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of0.52 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.

### 3.1.2 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.

**Table 5. Results of In-vitro quality control parameters**

| Formulation codes | Weight variation (mg) | Hardness (kg/cm2) | Friability (%loss) | Thickness (mm) | Drug content (%) | Floating lagtime (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 |

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

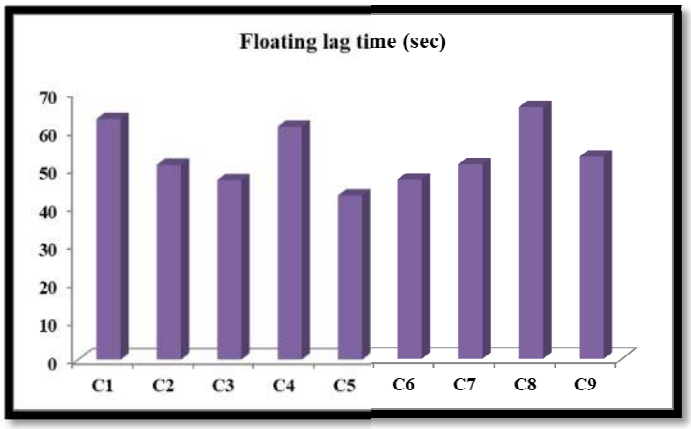


**Fig 2: Floating lag time (sec)**

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### 3.1.3 In vitro drug release studies

**Table 6. Dissolution data of Floating tablets**

| TIME | CUMULATIVE PERCENT DRUG DISSOLVED | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| (HRS) | C1 | C2 | C3 | C4 | C5 | C6 | C7 | C8 | C9 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.5 | 21.13 | 18.15 | 14.67 | 11.59 | 9.11 | 17.55 | 17.89 | 12.35 | 10.78 |
| 1 | 28.89 | 22.72 | 21.62 | 16.83 | 14.96 | 21.74 | 32.42 | 24.01 | 15.31 |
| 2 | 34.21 | 28.43 | 25.89 | 21.02 | 19.53 | 28.26 | 44.65 | 29.95 | 25.95 |
| 3 | 38.15 | 34.11 | 31.65 | 27.46 | 25.72 | 34.74 | 48.21 | 37.11 | 32.52 |
| 4 | 47.88 | 41.86 | 35.43 | 36.17 | 31.12 | 42.21 | 54.26 | 43.45 | 35.68 |
| 5 | 59.63 | 46.95 | 42.81 | 48.28 | 39.98 | 46.58 | 61.21 | 49.72 | 43.82 |
| 6 | 66.74 | 58.15 | 53.67 | 56.69 | 46.61 | 51.14 | 65.28 | 58.02 | 51.67 |
| 7 | 71.97 | 69.52 | 61.74 | 64.07 | 56.72 | 55.56 | 68.56 | 64.98 | 57.28 |
| 8 | 86.05 | 73.34 | 67.22 | 72.24 | 68.94 | 62.21 | 77.19 | 76.09 | 63.03 |
| 9 | 98.26 | 89.68 | 79.78 | 77.71 | 75.67 | 67.65 | 81.78 | 81.28 | 68.16 |
| 10 | 98.28 | 95.23 | 86.21 | 85.32 | 79.41 | 74.41 | 83.42 | 85.53 | 75.01 |
| 11 | 98.32 | 95.25 | 91.95 | 94.91 | 81.94 | 79.18 | 97.11 | 89.37 | 82.28 |
| 12 | 98.36 | 95.29 | 94.37 | 99.68 | 86.57 | 85.23 | 97.24 | 92.14 | 91.92 |

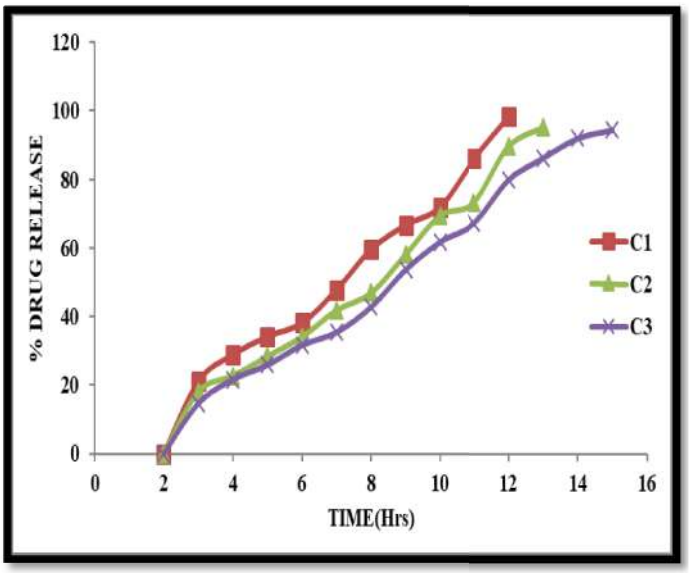


**Fig: 3 Dissolution data of Cefixime Trihydrate Floating tablets containing Gum Copal**

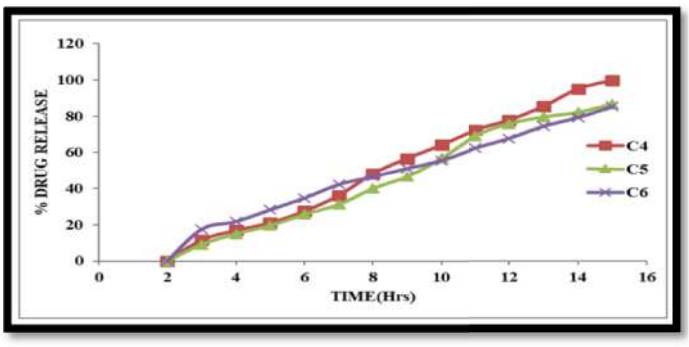


**Fig: 4 Dissolution data of Cefixime Trihydrate Floating tablets containing Isapgol husk**

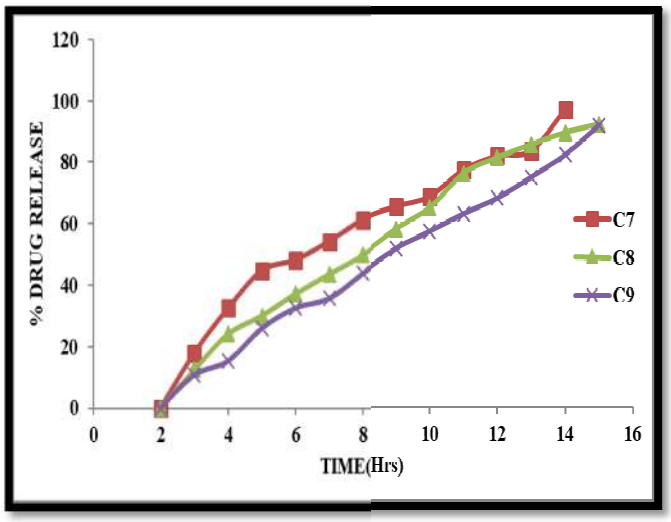


**Fig: 5 Dissolution data of Cefixime Trihydrate Floating tablets containing Fenugreek extract**

Whereas 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. 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. Whereas the formulations prepared with Fenugreek extract were retarded the drug release in the concentration of 25 mg (C7 Formulation) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 97.11 % in 11 hours with good retardation.

Hence from the above dissolution data it was concluded that C4 formulation was considered as optimized formulation because good drug release (99.68%) in 12 hours.

Application of release rate kinetics to Dissolution data for optimized formulation.

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**Table 7 Application kinetics for optimized formulation**

| CUMULATIVE (%) RELEASE Q | TIME (T) | ROOT(T) | LOG (%) RELEASE | LOG (T) | LOG (%) REMAIN | RELEASE RATE (CUMULATIVE % RELEASE/t) | 1/CUM% RELEASE | PEPPAS logQ/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** |

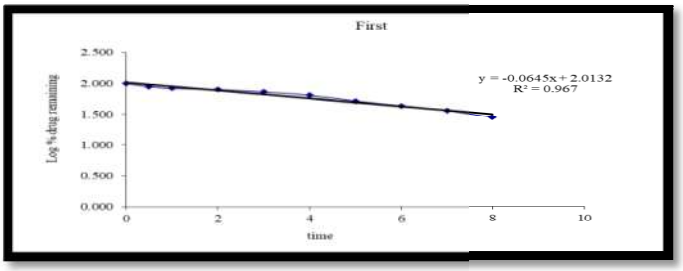


**Fig 6 First order release kinetics**

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

## 4. CONCLUSION

The formulation and in vitro evaluation of gastro-retentive floating tablets of Cefixime Trihydrate utilizing natural polymers have demonstrated significant advancements in enhancing drug delivery and bioavailability. The natural polymers selected, such as Gum Copal, Isapgol husk and Fenugreek extract, effectively contributed to the formulation of gastro-retentive floating tablets. The optimized formulations exhibited the ability to float in simulated gastric fluid, ensuring prolonged gastric residence time. The floating tablets exhibited a controlled release profile, with a sustained release of Cefixime Trihydrate over an extended period. This controlled release was attributed to the high viscosity and gel-forming properties of the natural polymers, which contributed to the slow erosion and dissolution of the tablets. In vitro evaluations confirmed that the studies demonstrated a consistent and prolonged release of Cefixime Trihydrate, aligning with the goal of extending the drug's residence time in the stomach. In conclusion, the development of gastro-retentive floating tablets of Cefixime Trihydrate using natural polymers has been successful, amongst them Isapgol Husk found with promising in vitro results that support their potential for improved drug delivery.

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