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Research Article

Formulation and Evaluation of Floating Tablet Containing Solid Dispersion of Cefixime Trihydrate

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Abstract

Floating systems are low-density systems that remain in the gastric region for several hours and hence prolong the gastric residence time of drug. It is important for the drugs that are degraded in intestine or for drugs like antacids, or antiulcer, antibiotics that should act locally in the stomach. Cefixime Trihydrate a third generation cephalosporin and BCS class IV drug is used in local stomach infection. Hence to make it bioavailable and effective, the floating tablets are prepared to achieve stomach specific drug delivery. In the present study, Solid dispersion of cefixime trihydrate was prepared with polyvinyl pyrrolidone (PVP) K-30 by solvent evaporation method to improve the solubility and dissolution rate of this drug. This physical complex in ratio 1:1 exhibits the highest solubility in water (>90 %). The floating tablet containing solid dispersion of cefixime trihydrate was compressed using hydroxy propyl methyl cellulose (HPMC) K 100M for sustaining the release of drug, total 6 batches (F1-F6) was compressed and evaluated for various pre-compression and post-compression parameters. The optimized batch F5 shows sustained release of cefixime trihydrate upto 12 h, have the minimum lag time (3.0-3.5 min) and maximum floating time (>10 h). The released kinetics followed first order kinetics. The stability study of optimized batch was carried out at 40ºC and 75% RH, for 1 month which shows no drastic change as compared to room temperature. Thus, it can be concluded that this formulation can be used to achieve site specific drug delivery for drug having narrow absorption window, and low bioavailability.

Keywords: Floating Tablet, Solid dispersion, solvent evaporation method, Cefixime Trihydrate.

Introduction

The oral route remains the most considered for administration of drugs. However, due to differences on physiology, preferential site of drug absorption, dosage forms must be tailored to a specific organ or even a part of the organ. Site controlled release is usually controlled by environmental factors, like the pH or enzymes present in the lumen, whereas the drug release from time controlled system is controlled primarily by the delivery system and ideally not by the environment. Knowledge of transit time allows the use of time controlled release system to deliver a drug to a specific location in the digestive system. In fact, the use of particular polymer or mixture of polymers may fine tune on release of a drug within the gastrointestinal tract. The Gastrointestinal Drug Delivery Systems categorizes into the following types; Floating Drug Delivery Systems, Pulsatile Drug Delivery Systems, Colon Targeted Drug Delivery Systems [1].

Control release implies the predictability and reproducibility to control the drug release, drug concentration in target tissue and optimization of the therapeutic effect of a drug by controlling its release in the body with lower and less frequent dose [2-4]. Under certain circumstances prolonging the gastric retention of a delivery system are desirable for achieving greater therapeutic benefit of the drug substances. For example, drugs (i) that are locally active in the stomach, (ii) that have an absorption window in the stomach or in the upper small intestine, (iii) that are less soluble or degraded by the alkaline pH , and/or (iv) have low solubility at high pH values. In addition, as the total gastrointestinal transit time of dosage forms is increased by prolonging the gastric residence time, these systems can also be used as local and sustained drug delivery to the stomach. Prolonging gastric retention of the therapeutic moiety may offer numerous advantages including improved bioavailability, therapeutic efficacy and possible reduction of the dose size with a reduced frequency of administration and, therefore, improved patient compliance [5-7].

Floating systems are low-density systems that remain in the gastric region for several hs and hence prolong the gastric residence time of the drug .While the system is floating on the gastric contents; the drug is released slowly at the desired rate from the system. This results in an increased gastric residence time and a better control of the fluctuations in plasma drug concentration. Many buoyant systems have been developed based on granules, powders, capsules, tablets, laminated films and hollow microspheres. Floating drug delivery system is important for the drugs that are degraded in intestine or for drugs like antacids, or antiulcer, antibiotics that should act locally in the stomach.

Antibiotics are the type of antimicrobial used in the treatment and prevention of bacterial infection. They may either kill or inhibit the growth of bacteria. Several antibiotics are also effective against fungi and protozoans, and some are toxic to humans and animals, even when given in therapeutic dosage. Antibiotics are not effective against viruses such as the common cold or influenza, and may be harmful when taken inappropriately. These antibiotics bind to specific penicillin binding proteins (PBPs) located inside the bacterial cell wall and inhibit the bacterial cell wall synthesis. Third generation cephalosporins and a class IV drug as per BCS is having poor solubility and poor dissolution rate are suitable for FDDS. For examples: Cefpodoxime, Cefixime, etc.

The enhancements of oral bioavailability of such poorly water-soluble drugs often show poor bioavailability because of low and erratic levels of absorption. Drugs that undergo dissolution rate limited gastrointestinal absorption generally show improved dissolution and bio availability as a result of reduction in particle size. However, micronizing of drugs often leads to aggregation and agglomeration of particles, which results in poor wettability. Solid dispersions of poorly water-soluble drugs with water-soluble carriers have reduced the incidence of these problems and enhanced dissolution. The development of solid dispersions as a practically viable method to enhance bioavailability of poorly water-soluble drugs overcome the limitations of previous approaches such as salt formation, solubilisation by cosolvents, and particle size reduction. The present

study deals with the formulation and evaluation of floating tablet containing solid dispersion of cefixime trihydrate to increase the solubility and bioavailability of cefixime trihydrate.

Materials and methods

Materials

Cefixime trihydrate was received as research gift sample from Zim Laboratories Pvt. Ltd, Nagpur, India. HPMC K100M, Sodium alginate and Sodium CMC were received as gift sample from Colorcon Private Ltd, Goa, India. Sodium Bi-carbonate was supplied by Merck, India and Citric acid was obtained from Rankem Ltd, India respectively.

Methods

Preformulation Studies

Identification and Drug polymer interaction study of drugs

Identification and confirmation of drug was done by matching the obtained FT-IR spectrogram and UV - spectrogram with the reference spectrograms respectively.

Fourier transformed infrared spectroscopy (FT-IR)

FTIR spectra of drug and polymer mixture were recorded by FT-IR spectrophotometer using KBr disc method. Each sample was gently triturated with KBr powder. KBr disc was prepared by pressing powders using a hydrostatic press at a pressure of 2.5 tons. The disc was placed in the sample holder and scanned from 4000 to 400 cm^{-1} at a resolution of 4 cm^{-1} at zero time. The physical mixtures of Cefixime Trihydrate , sodium alginate and HPMC K100M were prepared in proportion of 1:1:1 and kept at 40 ± 2ºC temperature and 75 ± 5 % relative humidity for 30 days . Then this physical mixture was examined by FT-IR spectroscopy and DSC for compatibility between the drug and excipient.

Preparation of calibration curve

The stock solution of Cefixime Trihydrate (1000ug/mL) was diluted suitably with acidic buffer solution of pH 1.2 in solutions to make concentration ranges from 2-10 μg/mL. Absorbance of each solution was measured at 286 nm using acidic buffer solution of pH 1.2 as blank. The calibration curve was plotted between Absorbance and Concentration on Y and X axis respectively.

Preparation of solid dispersion of Cefixime Trihydrate with PVPK-30

Solid dispersion of cefixime trihydrate was prepared with PVPK-30 by solvent evaporation method. Cefixime trihydrate and PVPK-30 was mixed in various proportions' 1: 0.25, 1:0.5, and 1:1 proportion in 100 ml glass beaker. Ethanol was added as a solvent in sufficient quantity so that the mixture gets just dissolved. Solvent was allowed to evaporate under vacuum, and then the prepared dispersion was passed through sieve no. 50 to get uniform dispersion. The obtained solid mass was further evaluated for its stability by keeping at 45 ± 2ºC temperature and 75% RH. Prepared Solid dispersion was evaluated for solubility of cefixime trihydrate, as shown in Table 1.

Table 1: Comparison of solubility study of cefixime with pvpk-30 in different ratio

Sr. No	Solid dispersion formulations	Ratio	Absorbance(nm)	Saturation solubility in distilled water (μg/ml)
1.	Cefixime + water		0.173	11.2 (22%)
2.	Cefixime + PVP K-30	1 : 0.25	0.244	34.0 (75%)
3.	Cefixime + PVP K-30	1 : 0.5	0.358	43.3 (80%)
4.	Cefixime + PVP K-30	1 : 1	0.590	48.6697%)

Evaluation parameters for powders

Bulk density (Db):[R]

Bulk density is the ratio of total mass of solid to the bulk volume of solid. It is calculated according to the formula mention below, it is expressed in g/cc.

Bulk density (Db) = m/vo ..... (1)

Where, M = mass of powder and V0 = initial volume of powder

Tapped density (D_t): [R]

Tapped density is a ratio of total mass of powder to the tapped volume of powder. It is calculated according to the eq. 2 which is expressed in g/cc.

Tapped density (Dt) = m/vt ..... (2)

Where, M = mass of powder and Vt = Tapped volume of powder

Carr's index : [R]

Compressibility index of the powder was determined by Carr's compressibility index as given by eq. 3:

Carr's index = (Tapped density-Bulk density)/Tapped density x 100 ..... (3)

Hausner's ratio : [R]

It is the ratio of tapped to bulk density and was calculated by using the eq. 4

Hausner's ratio = Tapped density / Bulk density ..... (4)

Angle of repose: [R]

Static angle of repose was measured according to the fixed funnel and free standing core method of Banker and Anderson. The angle of repose (θ) was calculated by eq. (5). Where h is the height of the pile and r being the radius of the base of the conical pile.

θ = tan-1 h/r ..... (5)

Formulation of floating tablet using solid dispersion of cefixime trihydrate

The six formulations of floating tablets of varying compositions of solid dispersion of Cefixime Trihydrate (CFXSD), polymer like sodium alginate (gelating agent) and HPMC K100M (for sustained release) were prepared by direct compression method. The detail of composition is exhibited in Table 2.

Table 2: Formulation of cefixime trihydrate floating tablet

Ingredients	Content in mg					
	F1	**F2**	**F3**	**F4**	**F5**	**F6**
Solid dispersion of Cefixime trihydrate	400	400	400	400	400	400
HPMC K-100M	50	75	100	125	100	150
Sodium alginate	15	15	15	15	15	15
Sodium bicarbonate	60	50	20	60	45	40
Citric acid	5	5	5	5	5	5
Magnesium stearate	10	10	10	10	10	10
Microcrystalline cellulose-102	110	95	100	35	75	30
Total	**650**	**650**	**650**	**650**	**650**	**650**

Evaluation of tablets

Weight Variation

Twenty tablets were weighed individually and the average weight was determined. Then percentage deviation from the average weight was calculated as per IP.

Tablet hardness

The crushing strength of prepared tablets was determined for ten tablets of each batch using Monsanto hardness tester.

Friability

Twenty tablets were weighed accurately and placed in the plastic chamber that revolves at 25 rpm for 4 minutes dropping the tablets through a distance of six inches with each revolution. After 100 revolutions the tablets were reweighed and the percentage loss in tablet weight was determined by eq. 6.

Friability (% w/w) = (Initial wt. of tablets-Final wt. of tablets)/Initial wt. of tablets x 100 ……. (6)

Tablet thickness/Diameter

Six tablets were examined for their thickness and diameter using Vernier callipers and the mean thickness and diameter value was calculated.

Floating or buoyancy test

The time taken for tablet to emerge on the surface of the medium is called the floating lag time (FLT) or buoyancy lag time (BLT) and duration of time the dosage form constantly remains on the surface of the medium is called the total floating time (TFT). The buoyancy of the tablets was studied in USP type II dissolution apparatus at 37.5 oC in 900 mL of simulated gastric fluid at pH 1.2. The time of duration of floatation was observed visually.

Drug content

For the drug content ten tablets were weight and crushed to a fine powder in a mortar pestle, weigh a powdered tablet equivalent to 100 mg of cefixime trihydrate and transfer to 100 ml volumetric flask. 5 ml of methanol was added and sonicated for 10 minutes, then diluted to 100 ml with 1.2 pH buffer solution. Solution was filtered; 1 ml of this solution was diluted to 100 ml with 1.2 pH buffer solution. The cefixime trihydrate content was determined by measuring the absorbance at 286 nm using UV spectrophotometer.

Drug content (% w/w) = conc. from graph x dilution factor x avg. wt. x 100 / wt. of sample x dose ……. (7)

Drug loading and Percentage Entrapment Efficiency

The prepared tablet was evaluated for percent drug loading and drug entrapment efficiency. An accurately weighed sample of powdered tablet (50 mg) was transferred to 50 ml volumetric flask and 50 mL of pH 1.2 buffer was added. This mixture was sonicated for 6 hrs. Then filtered, and analyzed spectrophotometrically at λmax 286 nm. The percent drug loading was calculated by dividing the amount of drug in the powdered sample taken by the weight of powdered tablet taken.

% Drug loading = actual drug contents / wt. of beads x 100 …….. (8)

Entrappment efficiency = actual drug content / theorotical drug content x 100 …….. (9)

***In vitro* drug release study**

The release of drug from floating tablet was determined using the USP type II dissolution test apparatus. The dissolution test was performed using 900 mL pH 1.2 acidic buffer at 37 ± 0.5 ºC and rotational speed of 50 rpm. 10 ml aliquots were withdrawn at an interval of 1 h for 12 hs. The samples were replaced by their equivalent volume of dissolution medium. The samples were analyzed at 286 nm by UV spectrophotometer. The % cumulative drug release was calculated using the equation generated from the standard curve.

Treatment of dissolution data with different kinetic equation

To describe the kinetics of drug release from the formulations, mathematical models zero-order, first order, Higuchi, Hixon-Crowell, Korsmeyer-Peppas were used.

Zero-order kinetic, $Q_t = K_o t$ ……1

First order kinetic, $Q_t = Q_o (1\text{-}e^{-K_1 t})$ ……2

Higuchi, $Q = K_h \sqrt{t}$ …….3

Hixson-Crowell, $3\sqrt{Q_o} - 3Q_t = K_{HCt}$ ……..4

Korsmeyer-Peppas, $Q_t/Q_\infty = K_K^{tn}$ 5

Where, Q_t – is the amount of drug released in time t, Q_o – is the initial amount of the drug, F – is the fraction of drug released in time t, n – exponent value. The K_o, K_1, K_H, K_{HC} and K_K are release rate constants for zero order, first order, Higuchi, Hixson-Crowell, Korsmeyer-Peppas model rate equations respectively.

Stability studies

Tablet was stored in an aluminium foil and placed in humidity chamber maintained at temperature and humidity condition of 40 ± 2 ºC/ 75 ± 5 % RH and at room temperature . Samples were withdrawn on 30th day and analyzed for drug loading, floating property, in-vitro drug release.

Result and Discussion

Fourier transform infrared spectroscopy (FT-IR)

From FT-IR spectra of Cefixime (Figure 1) and its blend with polymer, it can be seen that there is no significant change in the FT-IR spectra of cefixime, depicting that drug and polymer did not interact with each other. Similar results were obtained with cefixime and other ingredients of the formulation. The data are given in Table 3.

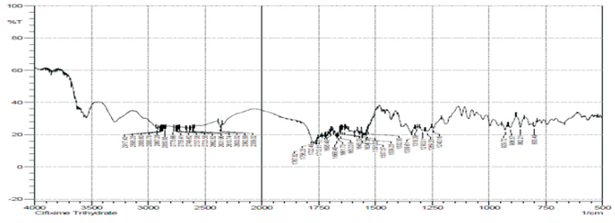

Figure 1: Infra-red (FT-IR) spectrum of cefixime trihydrate.

Table 3: FT-IR characterization of cefixime trihydrate

Frequency cm^{-1}	Group assigned	Peak assignment
3284	-Nh2	Primary amine
1771	-C=O	Non conjugated carboxylic acid
1667	N-H	Acyclic amide
1540	C-H	Stretching
1669	C=O	Stretching amide
1591	C=N	Stretching oxime
1382	N-O	Streatching

In order to characterize possible interaction between drug and polymer in a solid state FT-IR spectrum were recorded. The Figures 2 and 3 depicts the FT-IR spectrum of cefixime , PVP K-30 and physical mixture of drug , polymer in the ratio of 1:1 and its overlay of spectrum with other ingredients of formulation respectively.

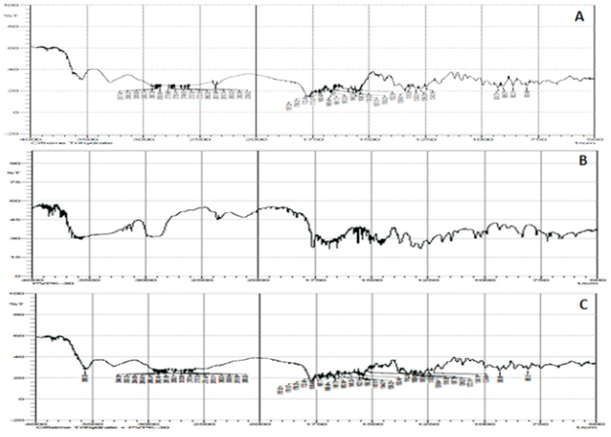

Figure 2: FT-IR spectrum of cefixime trihydrate (A), PVK-30 (B) and cefixime trihydrate+PVK-30(C)

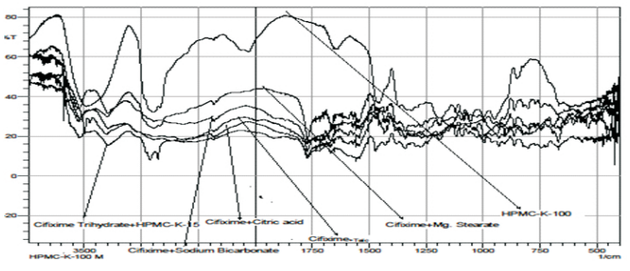

Figure 3: An overlay FT-IR spectrum of cefixime trihydrate and other excipients

The cefixime trihydrate is characterized by the 3284, 1771, 1667, 1540, 1591, and 1382 cm-1. These characteristic peaks were also present in the FT-IR spectra of physical mixture. A slight insignificant shift in bands towards lower frequencies at 3284, 1771, 1667, 1540, 1591, and 1382 cm-1 was noticed. From FT-IR spectra of cefixime and its blend with polymer, it can be seen that there is no significant change in FT-IR spectra of cefixime depicts that drug and polymer were not interacted with each other in this proportions. The same things were also seen with the other ingredients of formulations. The comparative evaluation of FT-IR data of cefixime and its excipients are given in Table 4.

Table 4: Comparison of peaks between FT-IR spectrum of cefixime and its blend with excipients

Sample	Group assigned						
	-Nh2	-C=O	N-H	C-H	C=O	C=N	N-O
Cefixime	√	√	√	√	√	√	√
Cefixime + PVK	√	√	√	√	√	√	√
Cefixime + HPMC K-100M	√	√	√	√	√	√	√
Cefixime + Citric acid	√	√	√	√	√	√	√
Cefixime + Sodium bicarbonate	√	√	√	√	√	√	√

DSC study

The DSC thermograms of pure drug and the composition of drug –polymers were recorded in DSC analyzer model Universal V4.5A at a heating rate of 20 oC per min from 0 to 350 oC in a nitrogen environment. The obtained DSC thermograms were shown in the Figures 4 and 5 respectively. The DSC thermograms shows well defined peak for drug in individual and combination with polymers. The onset, endset and peak point in both the thermograms were merely the same also indicating that there is no significant interaction between the drug and polymers.

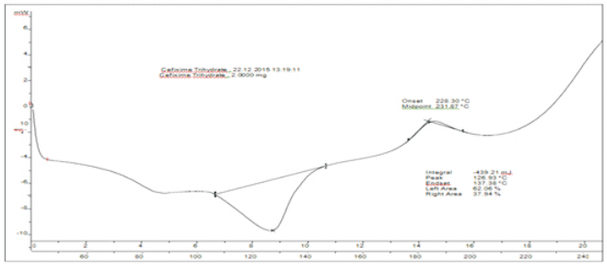

Figure 4: DSC thermogram of cefixime trihydrate

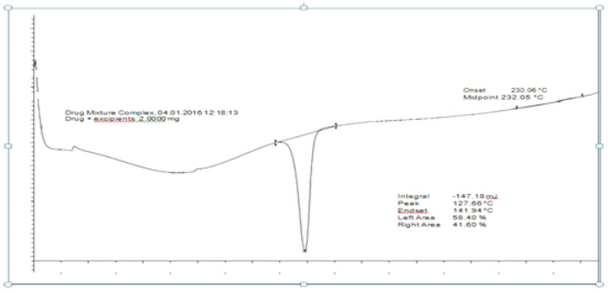

Figure 5: DSC thermogram of cefixime trihydrate with polymer

Calibration curve for Cefixime Trihydrate in pH 1.2 acidic buffer

The plot of absorption vs concentration of solutions in concentration range of 2-10μg/ml) measured at 286 nm is shown in Figure 6. The solution of pure drug obeyed Beer-Lambert's law within the above said concentration range in pH 1.2 acidic buffer. A linear relationship exists between the selected variable at these concentration range with correlation coefficient values (R^2) 0.997.

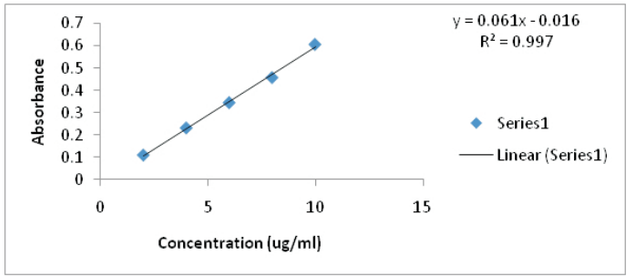

Figure 6: Calibration curve of cefixime trihydrate in pH 1.2 acidic buffer

Evaluation of Solid dispersion

The solid dispersion of cefixime with different polymers PVP, PEG, etc. were tried in equal proportion and were evaluated further for solubility. The solid dispersion prepared with PVP amongst the various polymers exhibits better solubility in water. Hence, this polymer was selected for the formulation of solid dispersion in various proportions as shown in Table 5 and 6. The significant alteration in solubility was observed with PVP-K 30 in various ratios. The physical complex of Cefixime with PVP-K in ratio 1:1 exhibits the highest solubility in water. Almost more than 90 % increment was noticed. Hereafter the solid dispersion of cefixime with PVP-K in 1:1 ratio was selected for preparation of different formulations and their evaluations.

Table 5: Evaluation of pre-compression studies

Formulation	Bulk density	Tapped density	Carr's index	Hausner's ratio	Angle of repose
F1	0.861 ± 0.01	0.988± 0.12	12.85± 0.21	1.14± 0.19	25.6°± 0.22
F2	0.912 ± 0.11	1.0312± 0.07	11.55± 0.06	1.13± 0.05	29.2°± 0.32
F3	0.810 ± 0.07	0.921± 0.17	12.05± 0.19	1.13± 0.22	24.5°± 0.27
F4	0.762 ± 0.13	0.861± 0.22	11.49± 0.14	1.12± 0.012	26.8°± 0.18
F5	0.669 ± 0.05	0.763± 0.14	12.31± 0.08	1.14± 0.10	24.1°± 0.20
F6	0.743 ± 0.21	0.844± 0.34	11.96± 0.24	1.13± 0.20	25.3°± 0.11

Table 6: Evaluation of post-compression studies

Formulation	Weight variation(g)	Hardness (Kg/cm^2)	Friability (%w/w)	Floating lag time(minute)	Floating time (Hr.)	Drug content (%w/w)
F1	651.0±0.04	4.0	0.87	4.5	5.0	96.42
F2	649.0±0.02	4.5	0.76	5.0	7.5	97.85
F3	652.0±0.012	5.0	0.83	4.0	4.0	97.66
F4	648.0±0.22	4.5	0.71	6.0	8.5	98.42
F5	650.0±0.27	6.5	0.22	3.5	>10	99.40
F6	651.0±0.22	6.0	0.33	5.5	8.0	97.22

In vitro drug release from different formulation batches

The drug release profiles were presented by plotting the amount of cefixime trihydrate released against time as shown in table 7. Figure 6 illustrates the release profiles of Floating Tablet of Cefixime Trihydrate containing varying concentration of polymer and their effect on drug release. The results show that a single polymer was sufficient to sustain the drug release. Almost 100% Cefixime was released within 12 h. Cumulative drug release of formulation F3 was more as compared to F5 batch but other evaluation parameters are not upto the mark. So, among the various formulations, batch F5 showed the better % drug loading, % drug entrapment efficiency, buoyancy period and in-vitro release profile.

Table 7: % Cumulative drug release from formulation batch F1-F6

Time	% cumulative drug released (mean ±SD, n=3)					
(h)	Batch F1	Batch F2	Batch F3	Batch F4	Batch F5	Batch F6
0	0	0	0	0	0	0
1	36.09±0.32	24.42±0.16	14.42±0.25	8.53±0.16	14.426±0.31	9.19±0.07
2	46.45±0.21	32.31±0.18	20.84±0.43	16.84±0.22	20.84±0.22	17.19±0.16
3	85.86±0.20	44.70±0.37	24.52±0.23	21.10±0.07	27.43±0.17	20.91±0.22
4	90.77±0.18	64.69±0.17	39.84±0.28	23.14±0.23	48.65±0.21	22.53±0.31
5	-	72.24±0.31	45.95±0.49	28.81±0.12	52.68±0.27	28.14±0.37
6	-	86.10±0.28	51.67±0.21	36.65±0.20	56.08±0.06	28.76±0.20
7	-	98.57±0.53	65.32±0.23	49.04±0.33	68.62±0.27	37.03±0.41
8	-	102.39±0.13	74.90±0.74	54.40±0.17	87.56±0.16	47.60±0.09
9	-	-	81.11±0.11	61.82±0.43	92.05±0.23	66.39±0.37
10	-	-	86.90±0.32	65.20±0.10	96.13±0.13	73.02±0.25
11	-	-	94.33±0.48	73.89±0.25	98.18±0.41	74.24±0.31
12	-	-	99.83±0.25	83.40±0.31	99.35±0.15	76.78±0.11

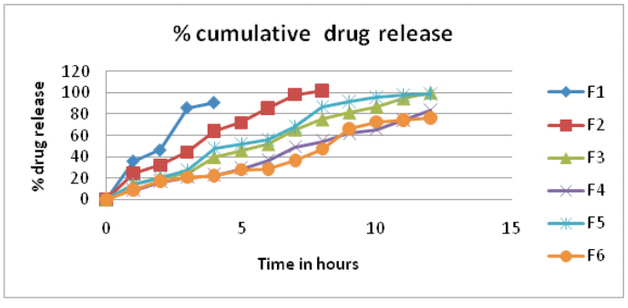

Figure 6: Drug release from batch F1, F2, F3, F4, F5, F6

Treatment of dissolution data with different kinetics equation

The result of kinetics treatment applied to dissolution profile of optimized formulation is shown in figure 7 and table 6. It is observed from the data that the value of regression coefficient of Zero order was found to be 0.981 which is close to 1 as compared to regression coefficient of Higuchi model which was 0.977. Therefore, the formulation F5 follows Zero order kinetics.

Table 6: Release kinetics of optimized formulation

Variables	Zero order	First order	Korsmeyer-Peppas	Higuchi
R^2	0.981	0.838	0.962	0.977

Best fit model-Zero order

Stability studies

The stability studies of the optimized formulation of beads revealed that there is no significant change in the physical parameters and released profile when stored at temperature and humidity conditions of 40±2ºC 75±5%RH and at room temperature. Drug content, *In vitro* buoyancy study and *In vitro* drug release studies of optimized formulation batch F5 at room temperature and at 40ºC

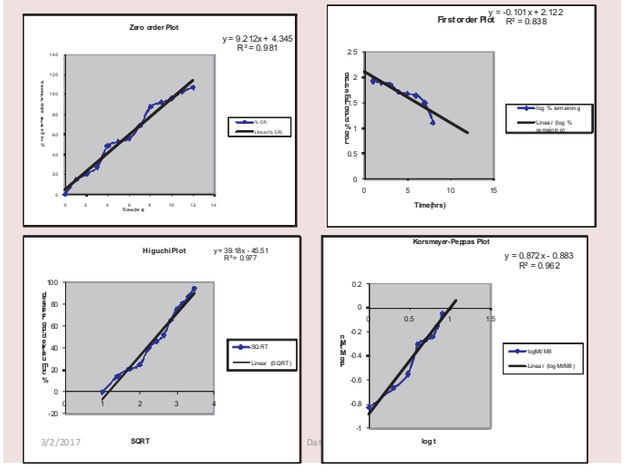

Figure 7: Release kinetics of optimized batch

Table 7: Drug content of optimized batch at room temperature and at 40ºC

Optimized batch	0 day at room temperature	30 days at room temperature	30 days at 40°C
F5	99.40± 0.73	99.21± 0.54	99.04± 0.81

Table 8: *In-vitro* buoyancy study of F5 at room temperature and 40ºC and 70% RH

Formulation batch	Temperature	Floating lag time (sec)	Total floating time (h)
F5	0 day at room temperature	3.5± 0.4	≥8
	30 days at room temperature	3.42±0.3	≥8
	30 days at 40°C	3.26±0.5	≥7

Table 9: *In vitro* drug release of optimized batch at room temperature 40ºC

Time (minute)	% cumulative drug released at room temperature		% cumulative drug released at 40ºC
	0 day	30 day	30 day
0	0	0	0
1 h	14.426±0.31	14.66±0.31	15.03±0.31
2 h	20.84±0.22	22.17±1.07	24.02±1.09
3 h	27.43±0.17	26.35±0.92	28.21±0.57
4 h	48.65±0.21	49.63±0.69	51.08±0.31
5 h	52.68±0.27	53.85±1.37	55.03±1.13
6 h	56.08±0.06	55.44±0.60	56.46±2.44
7 h	68.62±0.27	68.55±1.31	70.22±1.33
8 h	87.56±0.16	89.00±1.15	91.17±1.47
9 h	92.05±0.23	93.97±2.17	94.22±1.37
10 h	96.13±0.13	97.97±1.08	98.07±0.77
11 h	98.18±0.41	98.84±0.89	99.09±1.05
12 h	99.35±0.15	99.87±2.37	99.64±3.10

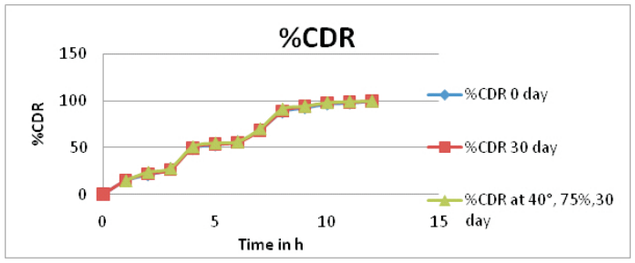

Figure 8: % CDR of optimized batch at room and 40ºC

Conclusion

Cefixime trihydrate is used in local stomach infection. It is mainly absorbed from the stomach. It has a half-life of about 3.0 – 4.0 h. It has a narrow absorption window and low bioavailabity (40-45%). Hence to make it bioavailable and effective, the floating tablets are prepared to achieve stomach specific drug delivery.

The present investigation shows that preformulation study for drug-polymer compatibility by FT-IR and DSC gave conformation about their purity and showed no interaction between the drug and selected polymers. Solid dispersion of Cefixime was prepared with PVPK-30 in various ratios, among which (1:1) shows the increase in solubility. As the solubility of Cefixime trihydrate was increased its bioavailability was also increased.

The floating tablet containing solid dispersion of Cefixime trihydrate was compressed using HPMC K 100M for sustaining the release of drug, total 6 batches (F1-F6) was compressed and evaluated for various pre-compression and post-compression parameters. From the results obtained the batch F5 was declared as optimized batch. The optimized batch F5 have excellent production yield, entrapment efficiency, buoyancy and sustained the release of drug upto 12 h.

It was concluded that the floating tablet was capable of sustaining release of Cefixime trihydrate upto 12 h, have the minimum lag time (3.0-3.5 min) and maximum floating time (more than 10 h). The released kinetics followed first order kinetics.

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Conflict of interest

The author declares no competing interest.

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