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FORMULATION DEVELOPMENT AND EVALUATION OF FLOATING TABLET OF LEVOFLOXACIN

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ABSTRACT

Floating systems or hydrodynamic controlled systems are low-density systems that have sufficient buoyancy to float over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. Levofloxacin pure drug is yellowish odorless, bitter crystalline powder, sparingly soluble in water and ethyl acetate, soluble in 0.1 N NaOH and 0.1N HCl and freely soluble in methanol, having melting point 218^{o}C. λ_{max} of levofloxacin was determined at 290 nm. Pre-compression Evaluation parameters were within the acceptable limit. The angle of repose of all the formulation was within 30^{0}. Post-compression Evaluation parameters were such as hardness, thickness, friability, drug content (%) and weight variation. The hardness value found between 4.8-5.3 Kg/cm^{2}. The dissolution study of all formulations was found as the percentage drug release were F1- 88.53%, F2- 81.09%, F3- 95.74%, F4-83.12%, F5-82.12%, F6- 92.33 %, in 12 hrs. From all the formulation F3 showed excellent drug release with 95.74% release. F3 was considered as optimized formulation and subjected for kinetic modeling and stability studies. Formulations F3 was follow Zero Order release and diffusion mechanism with continuous drug release. Stability studies were carried out for the formulation F3 at 4±2^{0}C, 27± 2 ^{0}C and 45 ±2 ^{0}C for 45 days.

KEYWORDS: Floating tablet, Levofloxacin, Pre-compression, Dissolution studies.

INTRODUCTION

Floating systems or hydrodynamic controlled systems are low-density systems that have sufficient buoyancy to float over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time.[1,2,3] While the system is floating on the gastric contents, the drug is released slowly at the desired rate from

the system.[4,5] After release of drug, the residual system is emptied from the stomach. This results in an increased GRT and a better control of the fluctuations in plasma drug concentration.[6] The Floating systems are advantageous for drugs meant for local action in the stomach e.g. antacids.[7,8] Application of Floating Drug Delivery Systems Floating drug delivery offers several applications for drugs having poor bioavailability because of the narrow absorption window in the upper part of the gastrointestinal tract.[9]

Levofloxacin is a synthetic broad-spectrum antibacterial agent for oral administration. Gastro retentive floating tablets have been emerged as an efficient means of enhancing the bioavailability of many drugs. The increasing sophistication of delivery technology will ensure the development of increasing number of Gastro-retentive drug delivery systems to optimize the delivery of molecules that exhibit an absorption window, low bioavailability and extensive first pass metabolism.[10]

Development of a Levofloxacin floating oral formulation would be a significant advantage for patient compliance accompanied by minimization of the drug side effects as a result of reduction in the drug blood concentration fluctuations, especially in long-term therapy.[11]

MATERIAL AND METHODS

Levofloxacin was obtained from Ranbaxy, Devas, Sodium Bicarbonate, Citric Acid and HPMC K100M was purchased from Rankem, Mumbai, talc, Magnesium stearate, and PVP were purchased from Sulab, Varodara (India). All used solvents and chemicals were laboratory grade.

Preformulation studies

Preformulation study was the first step in the rational development of dosage form of a drug substance. The objective of preformulation study was to develop a portfolio of information about the drug substance, which is useful to develop formulation.

Solubility Determination: A fixed amount of drug was taken then solvent e.g. water, methanol, 0.1N NaOH, 0.1N HCl, Ethyl acetate was added and observes the solubility visually. The solubility of the drug was obtained by dissolving amount of drug in individual solvent to the saturation and then concentration of prepared solution was measured using UV spectrophotometer.

Melting Point: The Melting point was determined by the capillary method using Digital Melting point apparatus. The capillary tube was fused and filled by pressing the open end gently into pure drug sample and packed by tapping the bottom of the capillary on a hard surface so that the drug packed down into the bottom of the tube. When the drug was packed into the bottom of the tube, the tube was placed into the slot of the apparatus, the apparatus was started and the temperature was noted at which the drug melt.

Preparation of calibration curve by U V- spectrophotometer

Determination of Wavelength of Maximum Absorbance (λ_{max})

10 mg of drug was weighed accurately and transferred to 10 ml of volumetric flask then 0.1N HCl, was added to dissolve the drug completely. The volume was made up to 10 ml with 0.1N HCl, The prepared sample was 1000 µg/ml. 1ml of above solution was then transferred to another 10 ml volumetric flask and diluted it upto the mark with 0.1N HCl results 100 µg/ ml. 1ml of above solution was then transferred to another 10 ml volumetric flask and diluted it upto the mark with 0.1N HCl results 10µg/ ml. This concentration was scanned from 200-400nm by UV- spectrophotometer.

Preparation of Calibration Curve

Stock solution: Levofloxacin (10 mg) was dissolved in 10ml of 0.1 N HCl in 10 ml volumetric resulted solution was 1000µg/m. this prepared solution was stock solution, it is used for preparation of various dilutions.

Preparation of dilutions: From this stock solution, aliquots of 2, 4, 6, 8 and 10 µg/ml concentration was prepared form stock solution using serial dilution method. The absorbance of these solutions was taken by double beam U.V. spectrophotometer using λ_{max} of 290 nm.

Preparation of calibration curve: The absorbance values of different dilutions were plotted against respective concentration (µg/ml) and obtained the standard calibration curve. MS-excel tool was used to prepare calibration curve, linearity equation and regression (R^2) value.

Partition coefficient

In chemistry and the pharmaceutical sciences, a partition- (P) or distribution coefficient (D) is the ratio of concentrations of a drug in the two phases of a mixture of two immiscible solvents at equilibrium. 25mg of pure drug was added in 25ml of water in a 100 ml separating funnel then 25ml of octanol was added, sacked it well for 15 min. separating funnel was

allowed to stand until both water and octenol layer was separated. Each layer collected separately in different beakers and absorbance taken by UV spectrophotometer then partition coefficient was calculated.

Drug - Excipients Compatability Study FT-IR

FT-IR Spectroscopy can be used to investigate and predict any physicochemical interactions between different components, in a formulation and therefore it can be applied to selection of suitable chemically compatible excipients. While selecting the ingredients, we would choose those which are stable, compatible and therapeutically acceptable. The aim of compatibility study was to test, whether there is any interaction between the excipients and the drug and compatibility between the drug and excipients.

Preparation of formulation

Tablets were prepared by conventional wet granulation method. The various excipient used were listed in table. Ingredients except gliding agent and lubricant were thoroughly mixed and passed through sieve no. 16. Granulation was done with a solution of calculated quantity of HPMC K4M in sufficient isopropyl alcohol. The wet mass was passed through sieve no. 60 and dried at 50°C for 2 h. The dried granules were lubricated with magnesium stearate and talc and compressed into tablets using single station tablet punch machine.

Table no.1: formulation composition of floating tablet of levofloxacin.

Formulation Code	F1	F2	F3	F4	F5	F6
Levofloxacin	250	250	250	250	250	250
Polymer Ratio	5%	10%	15%	5%	10%	15%
HPMC K4M	12.5	25	37.5	--	--	--
Carbopol	--	--	--	12.5	25	37.5
Sodium bicarbonate	50	50	50	50	50	50
Citric acid	20	20	20	20	20	20
Talc	5	5	5	5	5	5
Magnesium stearate	10	10	10	10	10	10
PVP	30	30	30	30	30	30

Evaluation of prepared formulations

Pre-Compression Parameter

Angle of Repose: Angle of Repose was determined using funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) was obtained. Radius of the heap(r) was measured and the angle of repose (θ) was calculated using the formula.

$$\Theta = \tan^{-1} (h/r)$$

Bulk Density: Apparent bulk density (ρ_b) was determined by pouring the blend into a graduated cylinder. The bulk volume (V_b) and the weight of the powder (M) were determined. The bulk density was calculated using the formula.

$$\rho_b = M/ V_b$$

Tapped Density: The measuring cylinder filled with known mass of blended granules tapped for a fixed time. The minimum volume (V_t) occupied in the cylinder and the weight (M) of the blend was measured. The tapped density (ρ_t) was calculated using the following formula:

$$\rho_t = M/ V_t$$

Compressibility Index: The simplest way for measurement of free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by (I) calculated as follows:

$$I = \{(V_b - V_t)/ V_b\} \times 100$$

The value below 15% indicates a with good flow characteristics and above 25% indicate poor flowability.

Post- Compression Parameter

Weight uniformity test: In weight uniformity test 20 tablets were selected at random and average weights were determined. Then individual tablets weighed and the individual weight was compared with the average.

$$\text{Calculate the average weight of tablets} = \frac{\text{Total weight of tablet}}{\text{Numbers of tablets}}$$

Hardness uniformity studies: The hardness of prepared formulation was measured by using Pfizer hardness tester. Five floating tablets were used for hardness uniformity studies. The hardness data used to calculate mean and standard deviation.

Thickness and Diameter: Tablet thickness is important for tablet packaging; very thick tablets affect packaging either in blister or plastic containers. The tablet thickness is determined by the diameter of the die, the amount of fill permitted to enter the die and the force or pressure applied during compression. The thickness of the tablet may be measured

manually or by automatic equipment. The thickness and diameter of the tablets was measured by Vernier's Calipers.

Friability (F): The friability of the tablet was determined using Roche Friabilator. It is expressed in percentage (%).20 tablets were initially weighed (w initial) and transferred into the friabilator. The friabilator was operated at 25 rpm per min for 4 min (100 revolutions). The tablets were weighed again (w final). The % friability was then calculated by:

$$F = W_{initial} - W_{final} / W_{initial}$$

% Drug content: Twenty tablets were taken and amount of drug present in each tablet was determined. The tablets were crushed in a mortar and the powder equivalent to 100 mg of drug was transferred to 100 ml standard flask. The powder was dissolved in a suitable solvent and make up the final volume with the suitable buffer solution. The sample was mixed thoroughly and filtered through a 0.45µ membrane filter. The filtrate was diluted suitably and analyzed for drug content by UV spectrophotometer, using buffer solution as a blank.

***In-vitro* buoyancy/floating study:** *In-vitro* buoyancy studies were performed for all the formulations. The randomly selected tablets from each formulation were kept in 100ml beaker containing simulated gastric fluid, pH 1.2 as per USP. The time taken for the tablet to rise to the surface and float was taken as floating lag time. The duration of time the dosage form constantly remained on the surface of medium was determined as the total floating time (TFT).

In vitro dissolution studies: The release rate of Levofloxacin from floating tablet was determined using United States Pharmacopoeia (USP) Dissolution Testing Apparatus 2 (paddle method).The dissolution test was performed using 900 ml of 0.1N HCl buffer for 2 hrs. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus hourly and the samples were replaced with fresh dissolution medium. The sample were filtered through a 0.45µ membrane filter and diluted to a suitable concentration with of ph 0.1N HCl buffer for 2 hrs. Absorbance of these solutions was measured at 290 nm using a UV/Visible spectrophotometer.

Drug release kinetics: To analyze the mechanism of drug release from the prepared formulation, the data obtained from in vitro release studies were subjected to Higuchi's model, Zero order model and First order model.

Stability Studies: Stability studies were aimed at determining the result of ageing and storage under various conditions on the formulated floating release tablet. It was carried out to evaluate the stability of Levofloxacin in formulated tablet after storing in different temperature for 45 days. The prepared tables were kept at three different temperature $4^0C\pm2^0C$, 27 ± 2^0C and 45 ± 2^0C for 45 days at RH 75±5%. The percentage of Levofloxacin content and *in-vitro* drug release studies were determined by double beam UV visible spectrophotometer.

RESULTS

Preformulation Study

Organoleptic properties of Levofloxacin

Table no. 2: Organoleptic properties of pure drug Levofloxacin.

S. no.	Properties	Reported	Observation
1	Color	Yellowish	Complies
2	Odor	Odorless	Complies
3	Taste	Bitter	Complies
4	Physical state	Crystalline powder	Complies

Solubility

Table No.3: Solubility profile of Levofloxacin.

Sr. No.	Compound	Solubility
1	Water	Sparingly soluble
2	Methanol	Freely soluble
3	0.1N NaOH	Soluble
4	Ethyl Acetate	Slightly soluble
5	0.1N HCl	Soluble

Melting Point

Table no.4: Melting Point of Levofloxacin.

Name of Compound	Reported Melting Point	Observed Melting Point
Levofloxacin	220 ^0C	218 ^0C

Partition Coefficient

Table no.5: Partition coefficient of Levofloxacin.

S.NO.	Solvent	Wave Length	Absorbance
1.	n-Octenol	290.0	1.213
2.	Distill water	290.0	1.367

$$Partition\ Coefficient = \frac{1.213}{1.367} = 0.887$$

Partition coefficient was obtained as 0.887

Determination of λ_{max} of levofloxacin

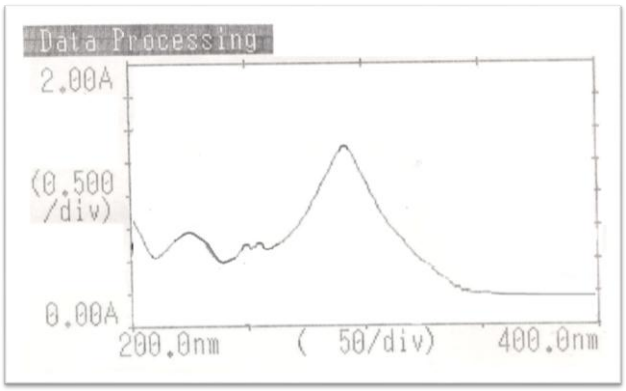

Figure no. 1: Scanning UV- spectrogram of levofloxacin from 200-400nm.

Calibration Curve in 0.1 N HCl

Table no. 6: Absorbance of drug at different concentrations in 0.1N HCl.

S. no.	Concentration (µg/ml)	Wave length (nm)	Absorbance
1.	2	290.0	0.218
2.	4	290.0	0.429
3.	6	290.0	0.611
4.	8	290.0	0.759
5.	10	290.0	0.935

The calibration curve for Levofloxacin in 0.1N HCl is in the concentration range of 2-10 µg/ml as shown in figure below:

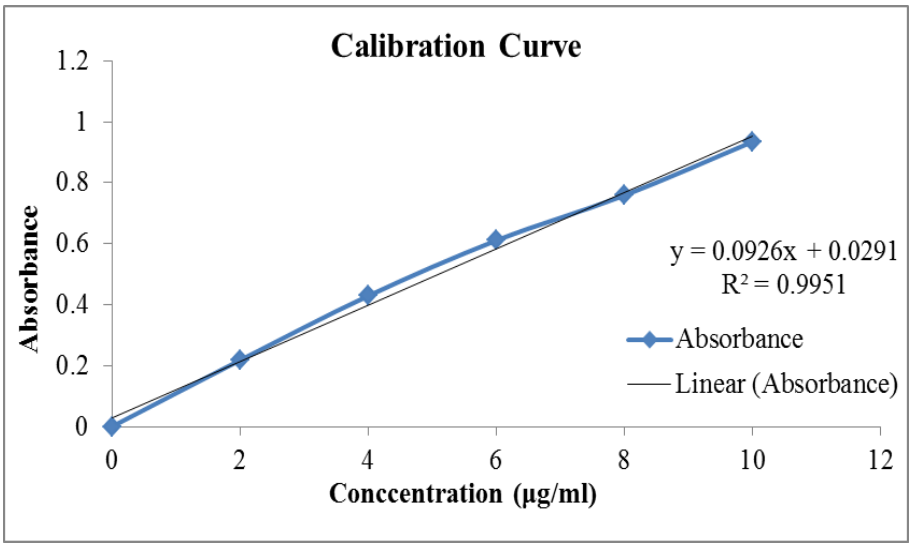

Figure no. 2: Calibration curve of Levofloxacin in 0.1N HCl.

Drug – excipient Compatibility by FT-IR

FT-IR Spectrum of Levofloxacin pure Drug

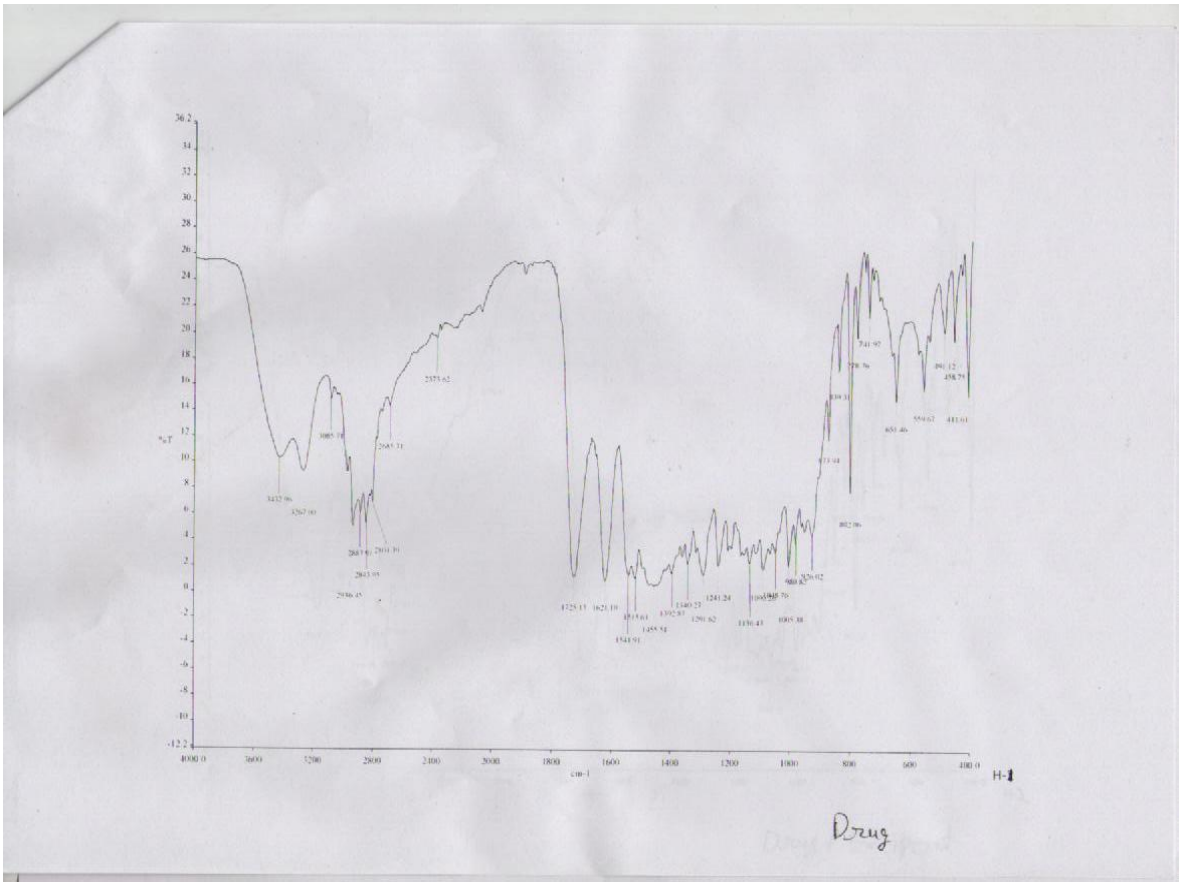

Figure no. 3: IR spectrum of pure drug (Levofloxacin).

FT-IR spectrum of levofloxacin + excipients

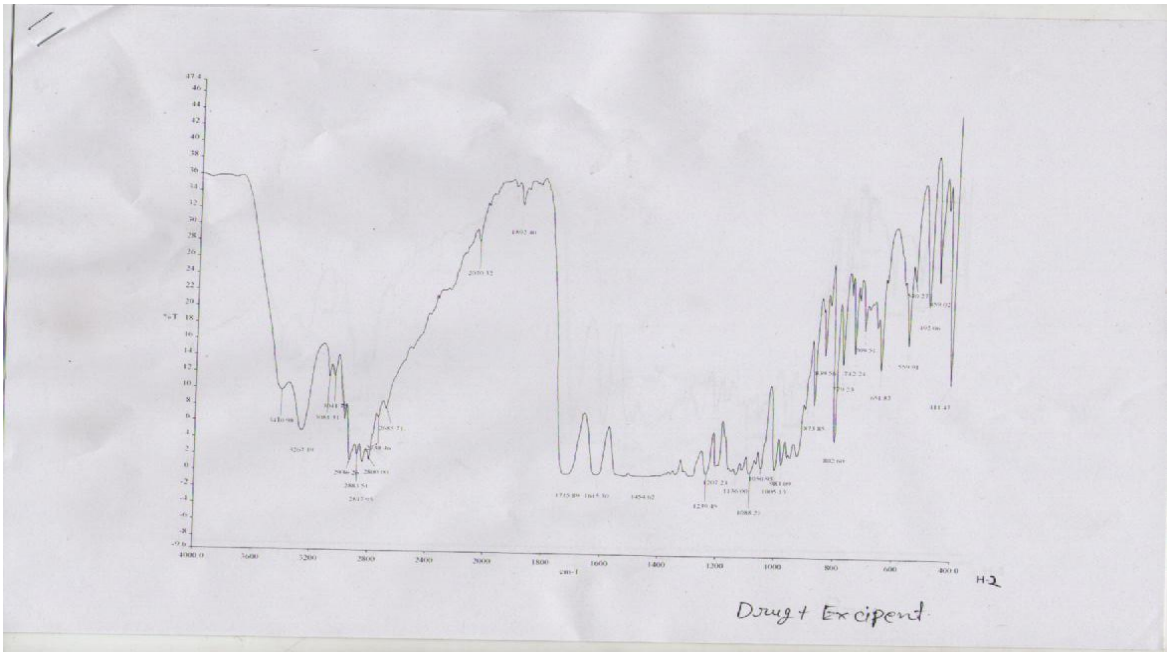

Figure no. 4: IR spectrum of Levofloxacin + Excipients.

IR spectra of the pure drugs were recorded using IR spectrophotometer by KBr pellet of the samples method. The resultant spectrum was found same when compared. The physicochemical compatibility of the drug and the excipients was established through infrared spectroscopy; IR spectrum showed no predominant drug interaction was detected between drug and polymer along with excipients.

Evaluation of levofloxacin granules

Table no. 7: Pre-compression Evaluation of levofloxacin floating tablet.

Formulation	Angle of repose (Ɵ)	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Carr's Compressibility Index (%)	Hausner's Ratio
F1	26.54	0.33±0.12	0.33±0.018	13.55± 0.18	1.18± 0.05
F2	27.63	0.35±0.25	0.35±0.028	12.93± 0.82	1.14 ±0.01
F3	26.25	0.33±0.15	0.33±0.028	13.44± 1.33	1.15± 0.01
F4	29.47	0.32±0.11	0.33±0.024	12.70± 1.60	1.14±0.02
F5	28.36	0.35±0.16	0.32±0.026	13.74± 0.84	1.15± 0.014
F6	30.25	0.33±0.14	0.32±0.029	12.15± 0.14	1.16± 0.054

 # All the values are expressed as mean ± SD= standard deviation (n=3)

Post compression evaluation of levofloxacin floating tablet

Table no.8: Post compression evaluation of Levofloxacin floating tablet.

Formulation	Weight variation (mg)	Thickness (mm)	Diameter (cm)	Hardness (Kg/cm^2)	Friability (%)	Drug content (%)	Buoyancy lag time (minutes)	Total Floating Time (hr)
F1	396.5 ± 0.34	3.5 ± 0.12	1.4 ± 0.59	5.1 ± 0.02	0.35 ± 0.07	98.5 ± 0.64	15.6 ± 0.75	8.26 ± 0.03
F2	392.2 ± 0.24	3.2 ± 0.07	1.2 ± 0.05	5.3 ± 0.11	0.46 ± 0.05	98.4 ± 3.36	13.2 ± 1.53	8.75 ± 0.05
F3	398.3 ± 0.45	3.6 ± 0.08	1.6 ± 0.02	4.8 ± 0.19	0.41 ± 0.07	98.32 ± 3.36	15.4 ± 3.36	9.05 ± 0.06
F4	396.2 ± 0.48	3.8 ± 0.20	1.3 ± 0.09	5.2 ± 0.15	0.38 ± 0.02	99.23 ± 2.36	14.6 ± 1.70	8.05 ± 0.06
F5	391.3 ± 0.55	3.6 ± 0.10	1.4 ± 0.08	5.3 ± 0.20	0.39 ± 0.09	98.83 ± 3.09	16.3 ± 3.36	10.50 ± 0.06
F6	389.4 ± 0.32	3.4 ± 0.15	1.3 ± 0.06	4.9 ± 0.25	0.37 ± 0.08	99.21 ± 2.40	15.5 ± 2.36	9.19 ± 0.02

***All the values are expressed as mean ± SD= standard deviation (n=3).**

***In -vitro* dissolution studies**

Table.no.9: *In -vitro* dissolution studies data.

Time (hrs)	% of Drug Release					
	F1	F2	F3	F4	F5	F6
0	0	0	**0**	0	0	0
1	5.45	4.27	**8.36**	6.72	3.79	7.18
2	12.13	7.23	**16.41**	12.50	9.51	15.41
3	19.32	17.05	**24.76**	19.95	21.59	23.13
4	25.57	24.20	**33.18**	27.03	28.11	32.91
6	41.39	35.77	**51.57**	44.57	38.13	55.39
8	58.57	48.15	**65.95**	56.64	49.66	64.29
10	69.85	65.82	**83.63**	67.21	66.32	79.75
12	88.53	81.09	**95.74**	83.12	82.42	92.33

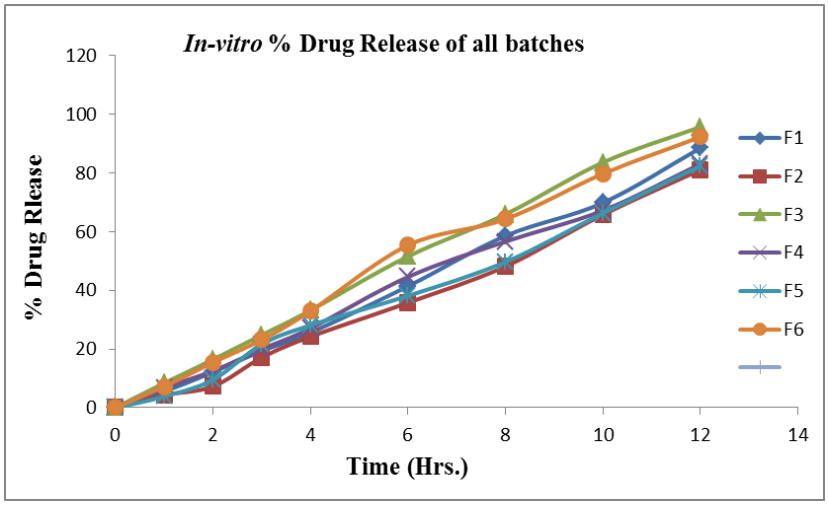

Figure no. 5: in-vitro drug release of all prepared batches (F1-F6).

Table no. 10: *In-Vitro* drug release profile of Levofloxacin foating tablet.

Formulation code	Linearity equation	Regression coefficient R^2
F1	y = 7.401x - 2.185	R^2 = 0.997
F2	y = 6.828x - 3.391	R^2 = 0.993
F3	**y = 8.137x + 0.586**	**R^2 = 0.998**
F4	y = 6.953x - 0.235	R^2 = 0.997
F5	y = 6.821x - 1.582	R^2 = 0.993
F6	y = 7.905x + 0.746	R^2 = 0.992

Drug Release Kinetic modeling

Table no. 11: *in-vitro* drug release data of optimized micro floating tablet batch (F-3).

Time (hr.)	S.R.T.	Log T.	Abs. (After 10times dilution)	Conc. (µg/ml) (After 10times dilution	Amt. in 5ml (mg)	Amt. in 900ml (mg)	Correction factor	% C.R	Log % C.R	% Drug remaining	Log% drug remaining
0	0	0	0	0	0	0	0	0	0	100	2
1	1	0	0.243	2.322	0.116	20.90	-	8.36	0.922	91.64	1.962
2	1.141	0.301	0.449	4.56	0.228	41.03	0.116	16.41	1.215	83.59	1.922
3	1.732	0.477	0.664	6.91	0.345	62.19	0.228	24.76	1.394	75.24	1.876
4	2	0.602	0.881	9.26	0.463	83.29	0.345	33.18	1.521	66.82	1.825
6	2.449	0.777	1.352	14.38	0.719	129.38	0.463	51.57	1.712	48.43	1.685
8	2.828	0.903	1.714	18.32	0.916	164.88	0.719	65.95	1.819	34.05	1.532
10	3.162	1.000	2.176	23.33	1.166	209.99	0.916	83.63	1.922	16.37	1.214
12	3.464	1.079	2.476	26.59	1.329	239.35	1.166	95.74	1.981	4.26	0.629

Zero order models

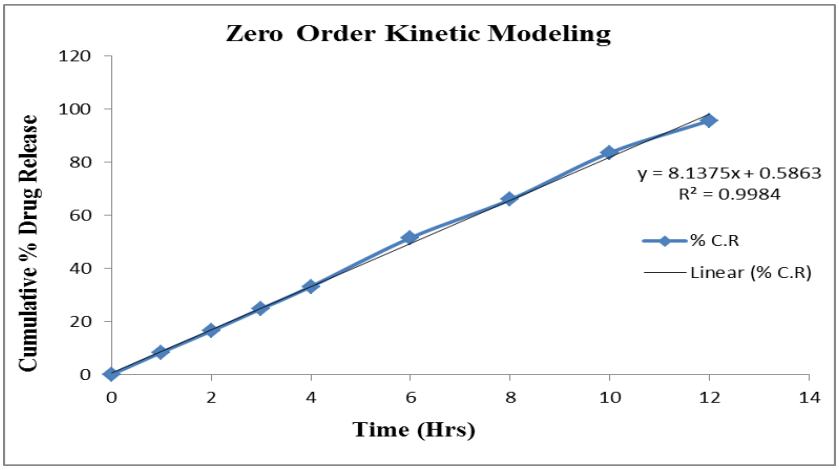

Figure no. 6: zero order kinetic models for batch F-3.

First Order Model

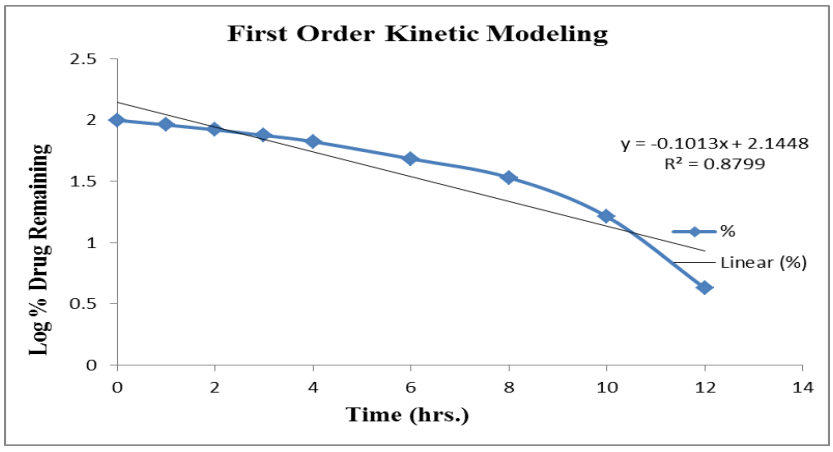

Figure no.7: First order kinetic models for batch F-3.

Higuchi Kinetic Model

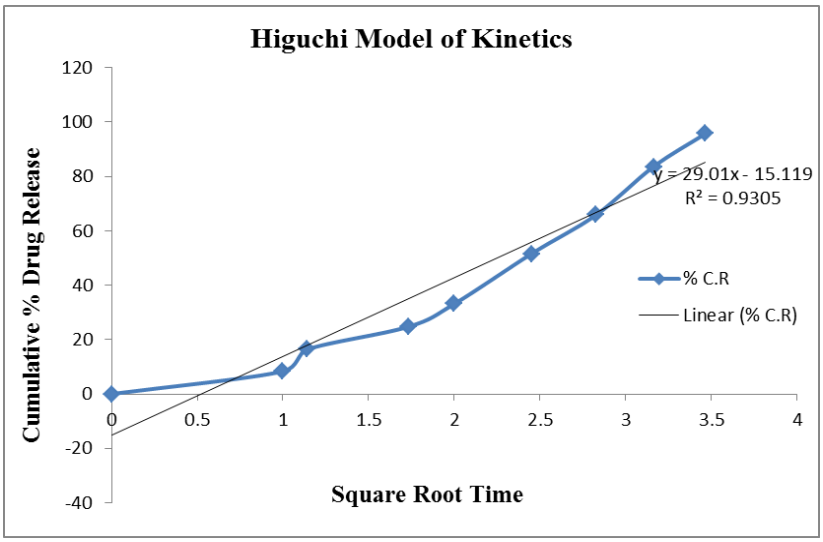

Figure no. 8: Higuchi kinetic models for batch F-3

Korsmeyer-Peppas Model

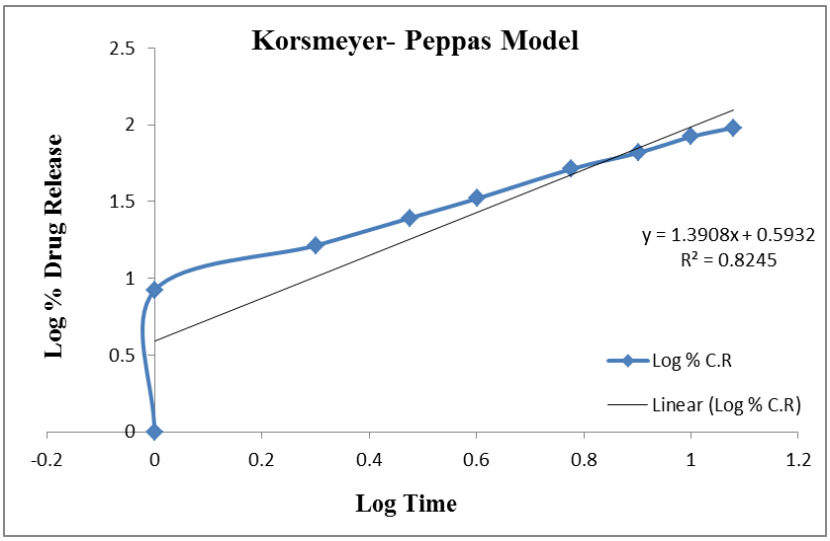

Figure no. 9: Korsmeyer- Peppas kinetic models for batch F-3.

Table no. 12: *in-vitro* curve fits for various release systems for optimized gel F-3.

Model	Equation	R^2
Zero order	y = 8.137x + 0.586	**R² = 0.998**
First order	y = -0.101x + 2.144	R² = 0.879
Higuchi	y = 29.01x - 15.11	R² = 0.930
Korsmeyer –Peppas	y = 1.390x + 0.593	R² = 0.824

Stability Studies

Stability study of batch F3 was performed for 45 day and the formulation was kept in threr different temperature conditions.

Table no. 13: Stability studies of optimized floating tablet batch –F3.

S. no.	Parameter	4 °C	27 °C	45 °C
1	Drug content (%)	95.50±2.36	95.15±0.63	94.70±0.61
2	Buoyancy lag time (minutes)	15.3 ± 1.70	14.8±0.18	14.4±0.25
3	Duration of buoyancy(Hours)	9.00±0.06	8.95±0.45	8.84±0.42

DISCUSSION

Preformulation study

Preformulation studies realized that that the Levofloxacin pure drug is yellowish odorless, bitter crystalline powder, sparingly soluble in water and ethyl acetate, soluble in 0.1 N NaOHand 0.1N HCl and freely soluble in methanol, having melting point 218°C. Partition coefficient was obtained as 0.887. λ_{max} of levofloxacin was determined at 290 nm. Calibration curve was prepared in 0.1N HCl as solvent between concentration range 2-10 µg/ml, linearity equation was y = 0.092x + 0.029 and regression R^2 value was found at 0.995. Drug-excipient interaction study also performed by FT-IR showed no predominant drug interaction was detected between drug and polymer spectrum.

Pre-compression Evaluation of Levofloxacin floating granules

The bulk density was found in the range of 0.32-0.35gm/cm^3. It is within the acceptable limit. The tapped density was found in the range 0.33-0.36gm/cm^3. The angle of repose of all the formulation was within 30^0. The result showed that the granules of all formulation showed good flow properties. The result of the Hausner ratio of all the formulation is in between 1.14-1.18. If the Hausner ratio lies between 1.12-1.18, it shows good flow behavior of the granules. The result indicates good flow property.

Post-compression Evaluation of Levofloxacin floating tablet

The tablets of all the formulation were subjected to many in-processes such as hardness, thickness, friability, drug content (%) and weight variation. The hardness value found between 4.8-5.3 Kg/cm^2. The friability values were approximately 0.35-0.46%. All the formulation showed the thickness in the range of 3.2-3.8 mm, diameter between 1.2-1.6 cm and buoyancy lag time in between 13 to 16.3 minutes and duration of buoyancy was 8 to 10 hours.

In -vitro dissolution studies

The *In -vitro* dissolution studies were performed to evaluate the dissolution character of levofloxacin floating tablet. The dissolution study of all formulations was found as the

percentage drug release were F1- 88.53%, F2- 81.09%, F3- 95.74%, F4-83.12%, F5-82.12%, F6- 92.33 %, in 12 hrs. From all the formulation F3 showed excellent drug release with 95.74% release and F6 also showed good drug release with 92.33% but value of regression coefficient (R^2) of batch F3 is highest compared to other formulation. Hence F3 was considered as optimized formulation and subjected for kinetic modeling and stability studies.

Drug release kinetic

From the data of drug release kinetic modeling of F3 formulation batch, it was found that formulations F3 follow Zero Order release and diffusion mechanism with continuous drug release.

Stability studies

The data for stability studies were carried out for the formulation F3 at 4±2^{0}C, 27± 2 ^{0}C and 45 ±2 ^{0}C for 45 days and it revealed that no considerable difference in drug content.

CONCLUSION

Floating tablet Formulations of levofloxacin were prepared by simple blending and punching with carbopol, HPMC K4M, sodium bicarbonate, citric acid and talk for oral application. levofloxacin is an antibiotic drug having higher protein binding, hepatic metabolism low oral bioavailability and lower half life. The drug requires a drug delivery system that provides a solution of these problems and improves bioavailability. Prepared floating batches were characterized for compatibility study, pre compression and post compression evaluation, % drug content, *in-vitro* drug release. Due to selection of appropriate polymer ratio this drug delivery systems showed good sustained release that provides the levofloxacin for 12 hrs to the body continuously. Major advantages of the system include ease of preparation, high % drug release and long duration over 12 hours. From this study, it was concluded that floating tablet batch F3 offers better sustained release in continuous manner that helpful to maintain bioavailability for long duration and reduces frequency of dose, also reduces dose.

CONFLICTS OF INTEREST

There are no conflicts of interests.

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