

FORMULATION, DEVELOPMENT, EVALUATION AND CHARACTERIZATION OF BILAYER TABLETS OF AN ANTI-BACTERIAL DRUG

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ABSTRACT

Several pharmaceutical companies are currently developing bi-layer tablets for a variety of reasons like patent extension, therapeutic efficacy, marketing etc. This technology has been used to reduce capital investment. Modified tablet presses have been used to develop bilayer tablets in order to overcome problems associated with tablets like layer separation, insufficient hardness, inaccurate individual layer weight control, cross contamination between the layers, reduce yield etc. When high production output is required a modified tablet press is used. Bilayer tablets are widely used in anti-bacterial therapy to deliver an immediate-release dose for a rapid therapeutic effect, combined with a sustained-release layer to maintain consistent therapeutic levels and reduce dosing frequency. Common antibiotic combinations formulated in this manner include Cefixime with Ofloxacin, Amoxicillin with Lansoprazole, or Ciprofloxacin alone utilizing a bilayer floating drug delivery system.

Keywords: Cefotaxime, Bilayer, Tablet, Sustained release, Novel drug delivery system.

INTRODUCTION

Since many decades treatment of acute and chronic disorders have been done with the help of conventional drug delivery systems like tablets, capsules, solutions, suspensions, creams, ointments, suppositories, liquids and injectables. These types of conventional therapy are most widely used and it is available commonly on prescription as well as over the counter. The conventional therapy is regarded as prompt release therapy. In order to maintain and achieve drug concentration within effective therapeutic range the conventional therapy has to be administered several times in a day and slight delay causes fluctuation in drug concentration which leads to poor patient compliance as well as poor aesthetic value. In order to avoid fluctuation or disadvantages of conventional therapy several new techniques have been developed to improve patient compliance which is capable of controlling rate of drug delivery to the site of action ¹.

Oral route is one of the best and most widely used routes for administering drug to site of action. Tablets and capsules are the most widely used conventional therapy for the patients because they can be easily administered without any problem ². Bilayer tablet is suitable for sequential release of two drugs in

combination, separate two incompatible substances and also for sustained release tablets in which one layer is immediate release which act as loading dose and second layer is sustained release which act as maintenance dose³⁻⁵. Bilayer tablet is the most recent form of tablet which comprises of combination of immediate release tablets and sustained release tablets. It is a type of once a day oral dosage form which acts immediately upon administration and provides the action for prolonged period of 12-24hrs. Bilayer tablets can be an excellent technique to avoid all types of incompatibilities between drugs, API and excipients etc.

Various techniques for bilayer tablet: OROS® push pull technology

This system consist of mainly two or three layer among which the one or more layer are essential of the drug and other layer are consist of push layer (Fig.1). The drug layer mainly consists of drug along with two or more different agents. So this drug layer comprises of drug which is in poorly soluble form. There is further addition of suspending agent and osmotic agent. A semi permeable membrane surrounds the tablet core⁶.

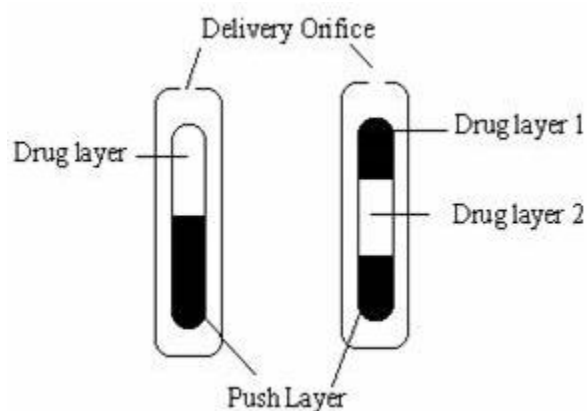


Fig. 1: Bilayer and trilayer OROS Push pull technology

L-OROStm technology

This system used for the solubility issue Alza developed the L-OROS system where a lipid soft gel Product containing drug in a dissolved state is initially manufactured and then coated with a barrier membrane, then osmotic push layer and then a semipermeable membrane, drilled with an exit orifice (Fig.2).

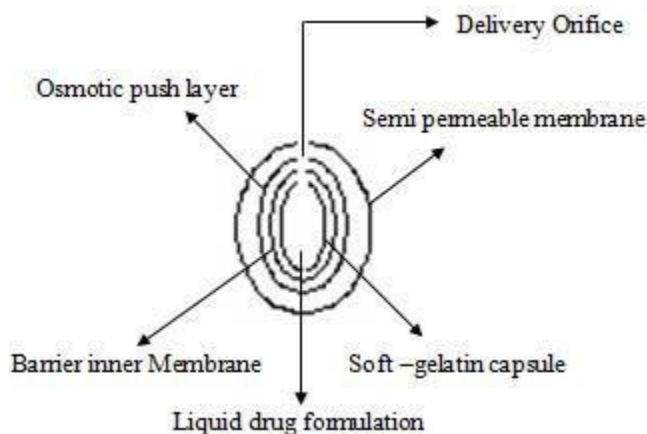


Fig. 2: L – OROS tm technology.

EN SO TROL technology

Solubility enhancement of an order of magnitude or to create optimized dosage form Shire laboratory use an integrated approach to drug delivery focusing on identification and incorporation of the identified enhancer into controlled release technologies ⁷⁻⁸..

Dissolution Studies

Bilayer tablets were subjected to *in vitro* drug release studies in simulated gastric and intestinal fluids to assess their ability in providing the desired controlled drug delivery. Drug release studies were carried out using USP dissolution test apparatus I at 100 rpm, 37±0.5°C, and pH 1.2 buffer (900 ml) (i.e. 0.1 N HCl) for 2 hours, since the average gastric emptying time is about 2 hours. The dissolution medium was replaced with pH 6.8 phosphate buffer (900ml) and experiment continued for another 10 hours. At different time intervals, 5ml of the samples were withdrawn and replaced with 5ml of drug-free dissolution medium. The samples withdrawn were analyzed by UV spectrophotometer using multi component mode of analysis

PREFORMULATION STUDY

Preformulation is a phase of research and development process where the new drug substances are characterized for their physical, chemical and mechanical properties in order to develop stable, safe and effective dosage form. Preformulation may include organoleptic properties, melting point, solubility, identification of drug by chemical and spectrophotometrically method.

Solubility Study

The drug sample was qualitatively tested for its solubility in various polar, semi polar and non polar solvents. Solubility of the drug was determined by taking about 10 mg of drug sample in a test tube containing 2.0 mL of solvent and shaking for 10 min at room temperature and observed for its solubility¹².

Table :1 Solubility of Cefotaxime

S. No.	Solvent used	Observation
1	Distilled Water	+++ -
2	0.1 N Hydrochloric acid	+++ -
3	Ethanol	+++ -
4	Methanol	+++ -
5	Chloroform	+ - - -
6	0.1 N NaOH	+ - - -

++++ = freely soluble; +++ - = Soluble; ++ - - = sparingly soluble; + - - = Slightly Soluble; - = Insoluble

Table:-2 Determination of moisture content

S. No.	Drug	KF Factor	Amount of KF Reagent consumed	Moisture content
1	Cefotaxime	0.385	0.125ml	0.0481

Determination of $\lambda_{\max}$ of Cefotaxime

The $\lambda_{\max}$ of Cefotaxime was determined by analyzing the drug solution in double beam ultraviolet spectrophotometer. Accurately weighed 10 mg of drug was dissolved in 10 ml of 0.1 N HCl in 10 ml of volumetric flask. The resulted solution was 1000 μ g/ml of strength and from this solution 1 ml solution was pipette out and transfer into 10 ml capacity of volumetric flask and volume was made upto 10 mL with 0.1 N HCl. This solution was scan at wavelength 400-200 nm on UV spectrophotometer. The higher absorption peak was obtained at 260 nm which was the $\lambda_{\max}$ of drug.

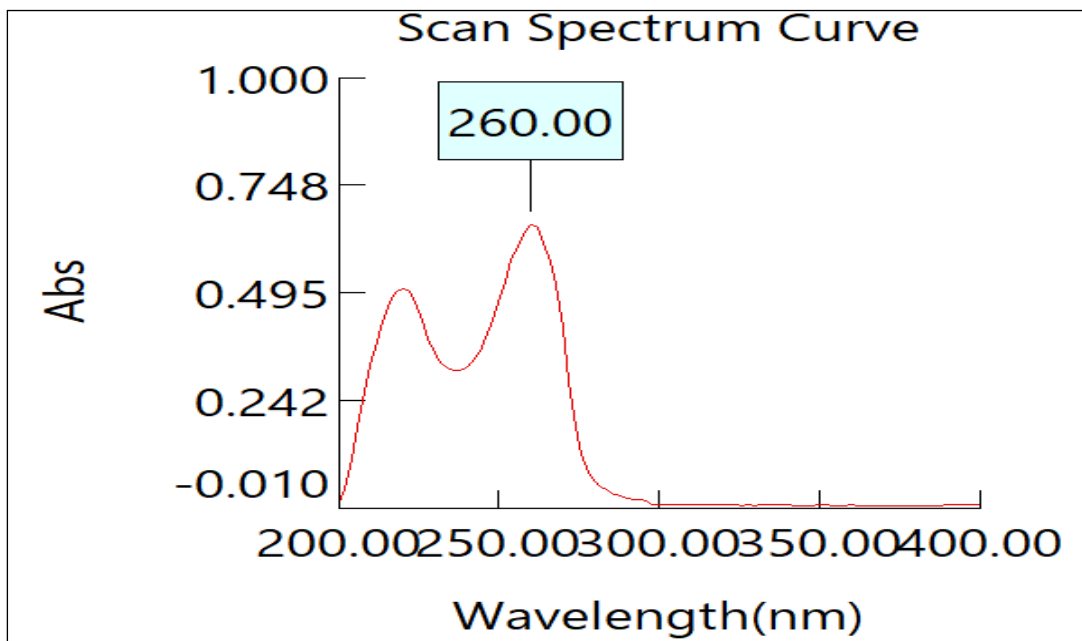


Figure 3: $\lambda_{\max}$ scan graph of Cefotaxime in 0.1 N HCl

Preparation of calibration curve of Cefotaxime

Previously prepared stock solution (1000 $\mu\text{g/mL}$ of strength) of Cefotaxime was use to prepare suitable dilution into concentration range of 10-50 $\mu\text{g/mL}$. 0.1, 0.2, 0.3, 0.4 and 0.5 mL of solution was taken in different volumetric flask having 10 mL of capacity and dilute upto 10 mL with 0.1 N HCl to obtained 10, 20, 30, 40 and 50 $\mu\text{g/mL}$ of solution. The absorbance of this solution was taken at 260nm using UV-spectrophotometer (Labindia-3000 Plus). Graph between absorbance and concentration was plotted followed linearly regressed on Microsoft excel ¹³.

Table:-3 Calibration curve of Cefotaxime

S. No.	Concentration ($\mu\text{g/mL}$)	Absorbance
1	10	0.180
2	20	0.402
3	30	0.623
4	40	0.816
5	50	1.011

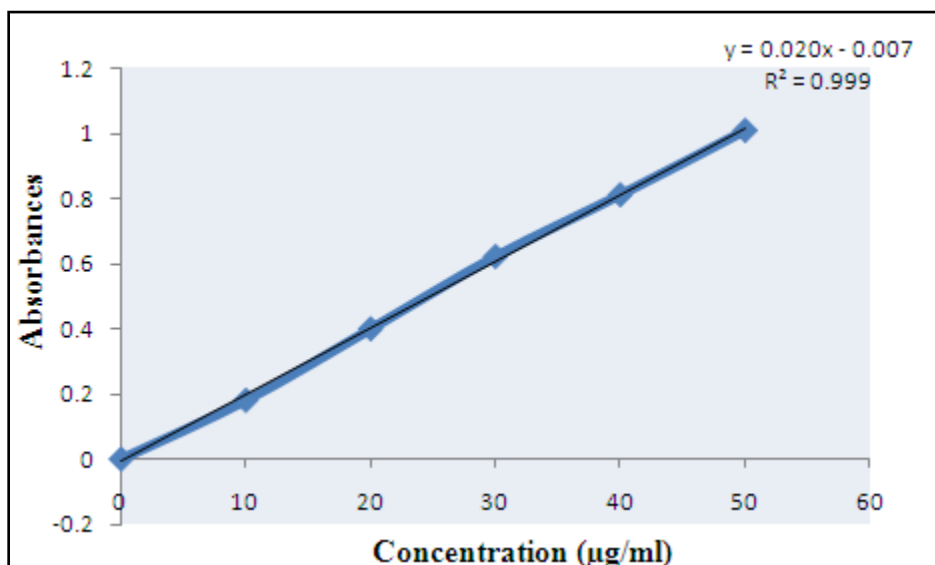


Figure: 4 Calibration curve of Cefotaxime in 0.1 N HCl at 260nm

Table 4: Static Data for Linearity

S. No.	Parameter	Remark
1	Linearity Range	10-50 µg/ml
2	Regression Equation	0.020x-0.007
3	Correlation Coefficient	0.999

Formulation Development

Preparation of Instant Layer of Cefotaxime (Phase-1)

All the required ingredients were passed through 40 mesh to get uniform size particles and weighed accurately. Drug, super disintegrants except lubricant were mixed in the increasing order of their weights in a mortar. To this mixture talc and magnesium stearate were added. The final mixture was shaken manually for 5- 10 min in a plastic bag. This powder was passed through the hopper of 10 station rotary tableting machine and punched into tablets using 8 mm s/c. Each tablets weighing 150mg, were obtained. Composition of tablets is mentioned ¹⁵.

Composition of Cefotaxime Fast Dissolving Tablets (Instant Layer)

Table :-5 Composition of Cefotaxime Fast Dissolving Tablets F1-F9

Ingredients(mg)	Formulation code								
	IF1	IF 2	IF 3	IF 4	IF 5	IF 6	IF 7	IF 8	IF 9
Cefotaxime	100	100	100	100	100	100	100	100	100
Sodium Starch glycolate	10	20	30	-	-	-	-	-	-
Croscarmellose sodium	-	-	-	10	20	30	-	-	-
Crospovidone	-	-	-	-	-	-	10	20	30
Microcrystalline cellulose	29	19	9	29	19	9	29	19	9
Talc	5	5	5	5	5	5	5	5	5
Magnesium stearate	6	6	6	6	6	6	6	6	6
Total weight	150	150	150	150	150	150	150	150	150

Method for Preparation of Cefotaxime Floating Gastroretentive tablet

Direct compression was followed to manufacture the gas generating floating tablets of Cefotaxime. Nine different formulations (F1, F2, F3, F4, F5, F6, F7, F8, & F9) were prepared by direct compression. All the polymers selected, drug and excipients were passed through sieve no. 40 before using into formulation. The amount and ratio of drug and polymers were weighed as per given in table No. 6 and all the formulation were used for further evaluations parameters ¹⁶.

Table 6: Various formulations of Cefotaxime floating gastro retentive tablets

Excipients(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Cefotaxime	150	150	150	150	150	150	150	150	150
HPMC K 4	50	80	110	-	-	-	25	40	55
HPMC K 15	-	-	-	50	80	110	25	40	55
PVP K30	10	10	10	10	10	10	10	10	10

Citric acid	5	5	5	5	5	5	5	5	5
NaHCO₃	10	10	10	10	10	10	10	10	10
Mg(C₁₈H₃₅O₂)₂	5	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5	5
Lactose	65	35	5	65	35	5	65	35	5
Total Weight	300	300	300	300	300	300	300	300	300

Evaluation of Precompression Parameter

Bulk density: Both loose bulk density (LBD) and tapped bulk density (TBD) were determined. Accurately weighed amount of granules taken in a 50 ml capacity measuring cylinder was tapped for 100 times on a plane hard wooden surface and estimated the LBD and TBD, calculated by using following formulas.

$$\text{LBD (Loose Bulk Density)} = \frac{\text{Mass of Powder}}{\text{Volume of Packing}}$$

$$\text{TBD (Tapped Bulk Density)} = \frac{\text{Mass of Powder}}{\text{Tapped Volume of Packing}}$$

Carr's Compressibility index: Percent compressibility of powder mix was determined by Carr's compressibility index, calculated by using following formula:-

$$\text{Carr's Index \%} = \frac{\text{TBD} - \text{LBD}}{\text{TBD}} \times 100$$

Table 7: Grading of the powders for their flow properties according to Carr's Index

S. No.	Carr's index	Flow
1.	5 – 15	Excellent
2.	12 – 16	Good
3.	*18 – 21	Fair to passable
4.	*23 – 35	Poor

5.	33 – 38	Very poor
6.	>40	Very very poor

***Adding glidant e.g. Talc should improve the flow properties**

Hausners ratio: It is determined by comparing tapped density to the bulk density by using following equation:-

$$\text{Housner's ratio} = \frac{\text{Tapped bulk density}}{\text{loose Bulk density}}$$

Hausner's ratio value <1.25 shows better flow properties

Evaluation of post compression Parameter

Shape and colour of tablets:

Uncoated tablets were examined under a lens for the shape of the tablet and colour was observed by keeping the tablets in light.

Thickness test

Three tablets were picked from each formulation randomly and thickness was measured individually. It is expressed in mm and standard deviation was also calculated. The tablet thickness was measured using dial-caliper (Mitutoyo, Japan).

Weight variation test

Twenty tablets were selected randomly from each formulation and average weight was determined. The tablets were weighed individually and compared with average weight. The U.S Pharmacopoeia allows a little variation in the weight of a tablet. The following percentage deviation in weight variation is allowed ¹⁸.

Table 8: Percentage deviation in weight variation

S. no.	Average weight of a tablet	Percentage deviation
1.	130 mg or less	10
2.	More than 130 mg and less than 324 mg	7.5
3.	324 mg or more	5

In all the formulations the tablets weight is more than 130 mg and less than 324 mg, hence 7.5% maximum difference allowed.

Hardness test

The hardness of tablet was measured by Pfizer hardness tester and results were expressed in Kg/cm².

Friability test

For this, 20 tablets were taken from each formulation and the friability was determined using Roche friabilator. The equipment was run for 4min at 25 revolutions per minute. The tablets were taken out, dedusted and reweighed and % friability was calculated¹⁹. The friability was determined as the mass loss in percent according to Equation:-

$$\% \text{Friability} = (\text{Loss in weight} / \text{Initial weight}) \times 100$$

The test complies if tablets not lose more than 1% of their weight

Uniformity of drug content:

The test is mandatory for tablets with 10mg or less weight of active ingredient. Ten randomly selected tablets from each formulation (F1 to F9) were finely powdered and Drug equivalent to 10 mg of drug dissolved in 10 ml 0.1 N HCl (simulated gastric fluid of pH 1.2 without enzymes) sonicate it for 20 minutes, till the entire drug leached out from complex, then the solution was filtered through whatman filter paper No. 41. From this Solution take 1 ml and Diluted up to 100 ml with 0.1 N HCl and the drug content was determined spectrophotometrically at 260nm for Cefotaxime²⁰.

Evaluation of Bilayer tablets

All the tablets were evaluated for following different parameters which includes;

General Appearance

Five tablets from different batches were randomly selected and organoleptic properties such as color, odor, taste, shape, were evaluated. Appearance was judged visually. Very good (+++), good (++), fair (+) poor (-), very poor (- -).

Thickness and diameter

Thickness and diameter of tablets were determined using Vernier caliper. Five tablets from each batch were used, and an average value was calculated.

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 100mg of drug was transferred to 100ml standard flask. The powder was dissolved in 50 ml of 0.1 N HCl and made up to volume with of 0.1 N HCl. The sample was mixed thoroughly and filtered through a 0.45 μ m membrane filter. The filtered solution was diluted suitably and reacts with dye and analyzed for drug content by UV spectrophotometer at a λ_{max} of 260nm using of 0.1 N HCl as blank.

Hardness

For each formulation, the hardness of five tablets was determined using the Monsanto hardness tester (Cadmach).

Friability

The friability of a sample of 10 tablets was measured using a Friability tester (Electro Lab). Ten tablets were weighed, rotated at 25 rpm for 4 minutes. Tablets were reweighed after removal of fines (dedusted) and the percentage of weight loss was calculated ²¹.

Uniformity of weight

Twenty tablets were randomly selected from each batch individually weighed, the average weight and standard deviation of 20 tablets was calculated.

***In vitro* buoyancy studies:**

In vitro buoyancy was determined by floating lag time as per the method described below. The tablets were placed separately in a 100 ml glass beaker containing simulated gastric fluid (SGF), pH 1.2 as per USP. The time required for the tablet to rise to the surface and float was determined as floating lag time ²²⁻²³.

Dissolution rate studies

In vitro drug release of the sample was carried out using USP- type II dissolution apparatus (Paddle type). The dissolution medium, 900 ml 0.1N HCl was placed into the dissolution flask maintaining the temperature of $37 \pm 0.50^\circ\text{C}$ and rpm of 75. One Cefotaxime tablet was placed in each basket of dissolution apparatus. The apparatus was allowed to run for 10 hours. Sample measuring 5 ml were withdrawn after every 1 hour up to 10 hours using 10ml pipette. The fresh dissolution medium (37°C) was replaced every time with the same quantity of the sample. From this take 0.5 ml and dilute up to 10 ml with 0.1 N HCl and take the absorbance at 260nm using spectroscopy ²⁴.

RESULTS AND DISCUSSION:

The granules of different formulations were evaluated with respect to angle of repose, bulk density, tapped density, compressibility index, moisture content and drug content. Other parameters for granules were found to be in the acceptable range. All the blends/ granules have shown good compression properties. Drug content was found to be uniform among different batches and was more than 95%. The compressed tablets were evaluated for weight variation, thickness, hardness, friability, disintegration time (for Cefotaxime IR tablets) and content. The weight of tablets from all the formulation batches was found within acceptable range of weight variation ($\pm 5\%$) as per USP. The hardness of the tablets was found in the range of $5.1\text{-}5.4\text{ kg/cm}^2$. The disintegration time obtained for the cefixime trihydrate IR tablets was less than 1 min which was well below the limit of disintegration time of uncoated IR tablets as per the USP (i.e. not more than 15 min). A dissolution study shows the release of Cefotaxime. The

Bilayer control floating layer Cefotaxime shows release up to 12 Hours Approx 98.96±0.12 percent of Drug release.

Results of pre-compressional parameters

Table 9: Results of pre-compressional parameters of Cefotaxime

Formulation code	Parameters				Hausner's Ratio
	Loose density(gm/ml)	Bulk Tapped density(gm/ml)	bulk Carr's Index (%)		
IF1	0.412	0.518	20.463		1.257
IF2	0.415	0.519	20.039		1.251
IF3	0.421	0.521	19.194		1.238
IF4	0.419	0.519	19.268		1.239
IF5	0.416	0.523	20.459		1.257
IF6	0.418	0.525	20.381		1.256
IF7	0.419	0.519	19.268		1.239
IF8	0.415	0.523	20.650		1.260
IF9	0.417	0.525	20.571		1.259

Table 10: Results of post-compressional parameters of all formulations

Thickness (mm)	Hardness (kg/cm ²)	Weight variation(mg)	Friability (%)	Drug content (%)	Disintegration Time (sec.) (n=3) Mean ± SD
3.85	5.2	305	0.658	98.85	85
3.82	5.3	302	0.785	98.99	62
3.78	5.4	310	0.658	98.65	36
3.65	5.2	306	0.852	97.89	112
3.79	5.4	308	0.658	98.45	95
3.56	5.2	304	0.458	99.56	85
3.65	5.3	306	0.658	98.89	120
3.74	5.1	305	0.741	98.78	114
3.58	5.2	306	0.954	99.12	95

Table 11: Post-Compressional Parameters of Optimized Formulation

Formulation	Hardness* test (kg/cm ²)	Friability* (%)	Weight Variation*	Thickness*
1.	5.8	0.568	pass	4.2

*Average of three determination (n=3)

Table 12: Results of Drug content analysis

Formulation	Cefotaxime (% Label Claim)
In-house Bilayer floating tablet	99.25±0.45

Dissolution rate studies of Floating layer:

Table 13: Results of Dissolution rate studies of Floating layer

Time (Hour)	% Drug Release of Bilayer tablets
0.5	38.56±0.56
1	39.98±0.45
1.5	46.85±0.56
2	54.56±0.47
4	62.36±0.65
6	74.65±0.78
8	83.36±0.68
10	93.25±0.85
12	98.96±0.12

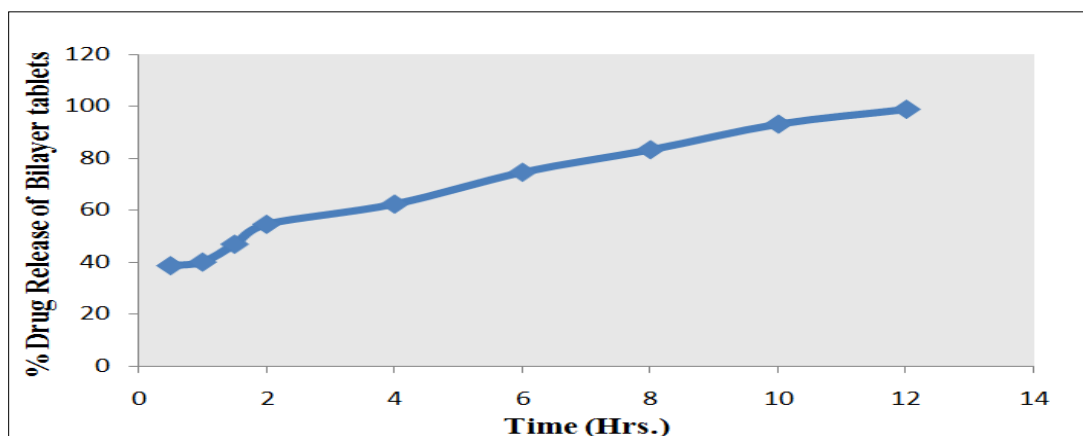


Figure 5: Graph of Release of Bilayer tablets

CONCLUSION

This study discusses the preparation of floating tablets of Cefotaxime Bi-layer tablets provide one of the important design approaches where incompatible drugs, with different indication, and same drug with different release rate can be incorporated in a single unit. Based on the results it can be concluded that, optimized tablets were stable with insignificant change in the floating lag time, floating time, drug content and in vitro drug release characteristics

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