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Research Article

Formulation & Evaluation of Ciprofloxacin Solid Dispersion Controlled Release Floating Capsules for Solubility Improvement

Gaurav Subhash Katore[1]*, S. J. Bidkar[2], G. Y. Dama[3]

*[1]*Sharadchandra Pawar College of Pharmacy, Dumberwadi, Pune, India*
[2]Assistant Professor, Department of Pharmaceutics, Sharadchandra Pawar College of Pharmacy, Dumberwadi, Pune, India
[3]Principal, Department of Pharmacognosy, Sharadchandra Pawar College of Pharmacy, Dumberwadi, Pune, India

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ABSTRACT

Solid dispersions in water soluble carriers have attracted considerable interests as a mean of improving the dissolution rate & hence possibly bioavailability range of hydrophobic drugs. The poor solubility of ciprofloxacin leads to poor dissolution & hence variation in bioavailability. The purpose of present investigation was formulation & evaluation of controlled release floating capsule of ciprofloxacin with improved solubility & dissolution rate. In present study solid dispersion using various carriers like mannitol & lactose in different ratios were prepared by solvent evaporation method. The prepared solid dispersions were characterized for drug content, solubility & dissolution rate. The dissolution rate substantially improved for ciprofloxacin from its solid dispersions compared with pure drug. Dissolution rate increased with increase in carrier content. The dissolution rate was increased 3 folds with solid dispersions containing 1:4 of drug: lactose. The granules of ciprofloxacin solid dispersion containing 1:4 of drug: lactose ratio was prepared by wet granulation method using polymer such as ethyl cellulose & HPMC. The prepared granules were evaluated to preformulation studies such as angle of repose (18.41-24.22), bulk density, tapped density, compressibility index (11.31-12.75) & hausner's ratio. All the parameters shows that the granules having good flow properties. These granules had converted into the capsule forms. Then the formulated capsules were taken to the evaluation studies such as weight variation, release study, buoyancy & floating duration (more than 6 hrs.). We can conclude that all the parameters were within the acceptable limits.

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Introduction

Oral ingestion is the most convenient & commonly employed route of drug delivery due to its ease of administration, high patient compliance, cost effectiveness, least sterility constraints & flexibility in the design of dosage form. Poorly water soluble drugs often administration [1]. Low aqueous solubility is the major problem encountered with formulation development of new chemical entities as well as generic development. The poor solubility & low dissolution rate of poorly water soluble drugs in the aqueous gastrointestinal fluids often cause insufficient bioavailability. Especially for class II (low solubility & high permeability) substances according to the BCS, the bioavailability may be enhanced by increasing the solubility & dissolution rate of the drug in the gastrointestinal fluids. As for BCS class II drugs rate limiting step is drug release from the dosage form & solubility in the gastric fluids & not the absorption, so increasing the solubility

***Corresponding Author: Gorja Ashok,** Department of Pharmaceutical Analysis & QA, Faculty of Pharmacy, Gland Institute of Pharmaceutical Sciences, Kothapet, Medak, Telangana, India.

in turn increases the bioavailability for BCS class II drugs[3]. A drug with poor bioavailability is the one with

1. Slow dissolution rate & poor bioavailability in biological fluids.
2. Poor permeation through biomembrane with inadequate partition coefficient.
3. Poor stability of dissolved drug at physiological pH.
4. Extensive presystemic metabolism.

Few literature were comes up with improved solubility of some poorly water soluble drugs,

1. Enhancement of dissolution profile of meloxicam using solid dispersion with various polymers. Solid dispersion was prepared by melting & solvent evaporation method. Dissolution studies were performed for plain meloxicam, SD's & tablet formulations. Infrared spectroscopy & differential scanning calorimetry were performed to identify the physicochemical interaction between drug & carriers.
2. Solid dispersion of furosemide in SSG was prepared in ratios of 1:1 & 1(furosemide): 2 (SSG) by kneading method. Dissolution studies indicated that the solid dispersion formulated in 1:2 ratios showed a 5.40-folds increase in dissolution & also exhibited superior dissolution characteristics to commercial furosemide tablets.
3. Solid dispersions (SDs) of Aceclofenac were prepared using lactose, Mannitol & urea to increase its aqueous solubility. Aceclofenac solid diversions were prepared in 9:1, 7:3 & 4:1 ratios of the drug to polymer (by weight). In Vitro release profiles of all SDs (F-1 to F-9) were comparatively evaluated & also studied against pure Aceclofenac. Faster dissolution was exhibited by solid dispersion containing 9:1 ratio of drug: lactose. The increase in dissolution rate of the drug may be due to increase in wettebility, hydrophilic nature of the carrier & due to reduction in drug crystallinity.

Preparation of solid dispersion

Solid dispersion is one of the most commonly used techniques to improve solubility of water insoluble drugs which in turn improves the bioavailability. Ciprofloxacin solid dispersions were prepared by using carriers (i. e. Mannitol & Lactose) in proportions VIZ. 1:1, 1:2 & 1:4 (drug: carrier) by solvent evaporation method. The drug & carrier was dissolved in dichloromethane & triturated in dry mortar until the solvent evaporated & a clear film of drug & carrier was obtained. The resultant solid dispersion was scrapped out with a spatula. Dispersions were pulverized in mortar & pestle & passed through a sieve no. 80. Then the prepared formulations were stored in desiccators until further use [7].

Solid dispersion solubility study

The objective of the present study is to increase its dissolution profile by the solid dispersion technique. When a drug administrated orally it should have less rapid absorption for achieving consistent & complete therapeutic response. For better therapeutic response the drug should be sufficiently & systemically bioavailable [1, 2, 3, 4].

Material & methods

Ciprofloxacin was obtained as a gift sample from Cipla Pvt. Ltd. (Goa, India). Mannitol, Lactose, Dichloromethane, Hydrochloric acid, Cetyl alcohol, Ethyl cellulose, HPMC, Sodium Bicarbonate, starch & Talc were procured from Pallav Chemicals, Mumbai. All materials used were of analytical grade.

Method estimation

Stock solution was prepared by dissolving 100 mg of accurately weighed ciprofloxacin in 100 ml of dichloromethane to get 1mg/ml solution. Further 10 ml of this solution was pipetted into 100 ml volumetric flask & made up to 100 ml with 0.1 N HCL to get 100 µg/ml solution. Further 10 ml of this solution was pipetted into 100 ml of volumetric flask & made up to 100 ml with 0.1 N HCL to get 10 µg/ml solutions. From this 0.1, 0.2, 0.3, 0.4, 0.5 ml solutions were pipetted out into a series of 10 ml volumetric flask & were made up to 10 ml with 0.1 N HCL to get 1, 2, 3, 4 & 5 µg/ml solutions of ciprofloxacin respectively. The absorbance of resulting solution was at 277 nm [5] against the blank.

Preliminary solubility study

Solubility measurements of ciprofloxacin were performed according to published method [6]. An excess amount of ciprofloxacin were added to 10 ml of aqueous solution of water soluble carriers like Mannitol & lactose in the various ratios such as 1:1, 1:2 & 1:4 in screw capped bottles. Samples were shaken in an orbital shaker for the 24 hrs at room temperature. Subsequently, the suspensions were filtered through a Whatman filter paper grade no. 1. Filtered solution diluted properly with distilled water. The diluted solution analyzed for the ciprofloxacin in UV 277 nm.

Table no. 1 Formulation plan of ciprofloxacin solid dispersion

Sr. No.	Formulation	Composition	Drug: Polymer Ratio
1	SDM1	Ciprofloxacin: Mannitol	1:1
2	SDM2	Ciprofloxacin: Mannitol	1:2
3	SDM4	Ciprofloxacin: Mannitol	1:4
4	SDL1	Ciprofloxacin: Lactose	1:1
5	SDL2	Ciprofloxacin: Lactose	1:2
6	SDL4	Ciprofloxacin: Lactose	1:4

Solubility measurements of ciprofloxacin were performed according to published method [10]. Solid dispersion equivalent to 100 mg of ciprofloxacin were shaken with 10 ml distilled water in stoppered conical flask in an orbital shaker for 24 hrs at room temperature. Subsequently, the solutions were filtered through a Whatman filter paper no.1. Filtered solution was diluted properly with distilled water. The diluted solution was analyzed for the ciprofloxacin on UV spectrophotometer at 277 nm.

Evaluation of solid dispersion

Drug content

Solid dispersion equivalent to 10 mg of ciprofloxacin were weighed accurately & dissolved in the 10 ml of dichloromethane. The solution was filtered, diluted suitably & drug content was analyzed at 277 nm by UV spectrophotometer. The actual drug content was calculated using the following equation as follows;

$$\%\ \text{Drug content (DC)} = \frac{M_{act}}{M_t} \times 100$$

Mact= Actual amount of drug in solid dispersion

Mt= Theoretical amount of drug in sold dispersion

Determination of flow properties

Bulk density & tapped density

Accurately weighed amount of solid dispersions were transferred to 100 ml of graduated cylinder to measure the apparent volume of bulk volume (V_b). The measuring cylinder was tapped for a fixed period of time & tapped volume (V_t) occupied in the cylinder was measured. The bulk density & tapped/true density were calculated in grams /milliliter by the following formula:

$$\text{Bulk density (BD)} = \text{Mass/Volume} = M/Vb$$

$$\text{Tapped density (TD)} = \frac{\text{Mass}}{\text{Tapped Volume}} = M/Vt$$

Carr's Index (CI) & Hausner's ratio (HR)

Carr's index & Hausner's ratio are calculated by using following formulae [11, 12].

$$CI = [\frac{(\text{Tapped density} - \text{Bulk density})}{\text{Tapped density}}] \times 100$$

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{bulk density}}$$

Angle of repose

A funnel was fixed in the stand in such a way that the top of the funnel was at the height of 6 cm from the surface. The solid dispersions were passed from the funnel was at height of 6 cm from the surface. The height & radius of the heap were measured & the angle of repose was calculated using the equation [13].

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

h = Height of heap

r = Radius of the heap

In Vitro release study

In vitro dissolution studies [14] were performed for prepared solid dispersion. The following conditions were maintained for the dissolution process:

Compressibility index & hausner's ratio

1. Equipment: dissolution test apparatus
2. Apparatus: Paddle type
3. Temperature: 37±0.5° C
4. RPM: 50
5. Dissolution medium: 0.1 N HCL
6. Volume of medium: 900 ml
7. Sampling intervals: 5, 10, 15, 20, 30 45, 60, 90 minutes
8. Sample volume: 5 ml withdrawn & replaced with 5 ml of 0.1 N HCL

Preparation of granules

Ciprofloxacin solid dispersions, Ethyl cellulose, HPMC, Cetyl alcohol & sodium bicarbonate were weighed by electronic balance & mixed well in m mortar. Required amount of starch was taken in a beaker. Small amount of water was taken init & stirred well until thick paste was formed without limps. Excess water was boiled in a separate beaker for 15 minutes 7 then add to the paste while stirring to form a mucilage. The mucilage was slowly added to the powder mix to form a damp mass that breaks with a snap when pressed between thumb & index finger. The damp mass was passed through the sieve & the granules were collected on dry tray. The granules were dried in hot air overate 60 °C for 2 hrs. Then the dried granules were passed through sieve. The granules were filled in empty gelatin capsules shell by hand filling capsules machine. The compositions of different ratios of floating capsules with different carriers are given in following tables [8, 9].

Evaluation of granules flow characteristics [15, 16, 17]

Bulk density

A known quantity of granules was poured into the measuring cylinder carefully level the granules without compacting, if necessary & read the unsettled apparent volume (V), to the nearest graduated unit. Calculate the bulk density, in gm per ml, by the formula m/v.

Tapped density

A known quantity of granules were taken in a measuring cylinder & tapped on mechanical tapping apparatus for 5 minutes. The initial 7 final volumes were noted.

$$\text{Tapped density} = \frac{\text{Volume of grannules}}{\text{Final volume afater tapping}}$$

Angle of repose

The frictional forces in a loose powder or granules can be measured by angle of repose. This is maximum angle possible between the surface of pile of powder or granules & the horizontal plane. The value of angle of repose are calculated by using the following formula,

$$\tan\theta = \frac{h}{r}$$

$$\theta = \tan^{-1}\frac{h}{r}$$

Where, θ = angle of repose, h = Height of heap & r = Radius of heap

The compressibility index 7 closely related hausner's ratio has become the simple, fast & popular method of predicting granules flow characteristics. The compressibility index & hausner's ratio were determined both the bulk density & tapped density of granules.

$$\text{Compressibility index} = \frac{\text{TD} - \text{BD}}{\text{TD}} \times 100$$

$$\text{Hausner}'\text{s ratio} = \frac{\text{TD}}{\text{BD}}$$

Composition of solid dispersion capsules

Table no. 2 composition of ciprofloxacin solid dispersion controlled release floating capsules

Ingredients	F1	F2	F3	F4	F5	F6
Solid dispersion equivalent to ciprofloxacin	100	100	100	100	100	100
Cetyl alcohol	q. s…	q. s…	q. s…	q. s…	q. s…	q. s…
Ethyl cellulose	125	100	75	50	25	-
HPMC	-	25	50	75	100	125
Starch	15	15	15	15	15	15
Sodium bicarbonate	25	25	25	25	25	25
Talc	2.5	2.5	2.5	2.5	2.5	2.5

Evaluation of capsules

Weight variation [9, 15]

Twenty capsules were randomly selected & individually weighed. The average weight of capsules were calculated & compared with individual weight.

Determination of In-Vitro dissolution study [18]

Dissolution study was carried out in USP- II type dissolution apparatus (paddle type). Dissolution study was performed at 50 rpm in 900 ml 0.1 N HCL 5ml of sample was withdrawn at predetermined intervals & the volume of dissolution medium was maintained by adding same volume of dissolution medium. Absorbance of these solutions was measured using UV visible spectrophotometer.

Floating capacity [8, 19]

Floating characteristics of the prepared formulations were determined by using USP- II paddle type apparatus at a paddle speed of 50 rpm in 900 ml of a 0.1 N HCL solution (pH= 1.2) at 37 ± 0.5°C for 12 hrs. The time between introduction of capsule & its buoyancy on the simulated gastric fluid (floating time) & the time during which the dosage form remains buoyant (floating duration) were measured.

Result & discussion

Method of estimation

Ciprofloxacin was estimated by UV spectrophotometer method by measuring the absorbance at 277 nm. The method was validated for linearity, accuracy, precision & interference. The method obeyed Beers law in the concentration range of 1-5 µg/ml (R^2=0.997).

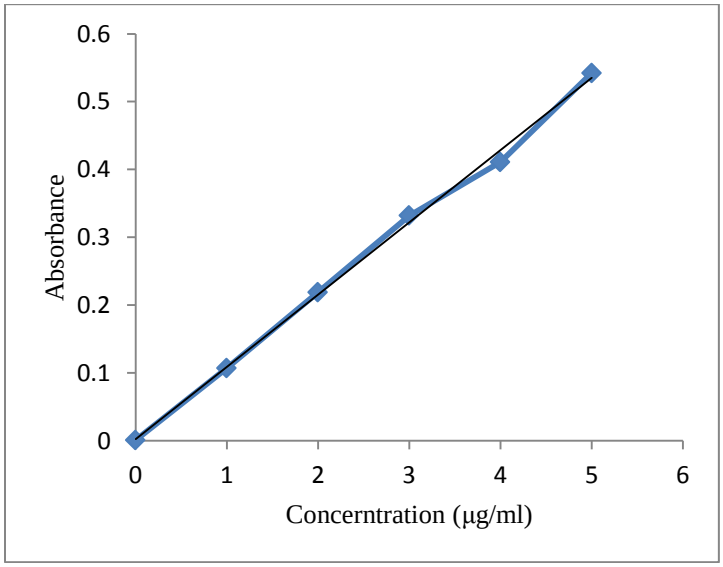

Figure no. 1 Calibration curve of ciprofloxacin in 0.1 N HCL

Preliminary solubility study

Table no. 3 Preliminary solubility studies of drug

Sr. no.	Drug: carrier	Solubility (µg/ml)
1	Pure drug	4.7
2	Ciprofloxacin + Mannitol	9.57
3	Ciprofloxacin + Mannitol	11.41
4	Ciprofloxacin + Mannitol	14.53
5	Ciprofloxacin + Lactose	20.51
6	Ciprofloxacin + Lactose	27.23
7	Ciprofloxacin + Lactose	31.89

In case of solid dispersions initially preliminary solubility analysis were carried out to select the appropriate water soluble carriers for the preparation of solid dispersion in which pure drug solubility found to be 4.7 mcg/ml.From this Mannitol and Lactose in the ratio of 1:1, 1:2, 1:4 was selected for the preparation of the solid dispersion. Complete composition of six formulations showed. The preliminary solubility study of ciprofloxacin was carried out for pure form as well as for drug: carrier mixture forms as shown in table no. 8.1. The solubility of pure ciprofloxacin was found to be 4.7 mg/ml. The preliminary solubility for drug: mannitol ratios 1:1, 1:2, 1:4 was observed 9.57 mg/ml, 11.41 mg/ml and 14.53 mg/ml respectively. On another hand, drug: lactose ratios 1:1, 1:2, 1:4 respectively showed 20.51 mg/ml, 27.23 mg/ml, 31.89 mg/ml preliminary solubility. The drug: lactose ratio 1:4 showed higher solubility as compared to drug: mannitol ratio 1:4 as showed in figure no. 2.

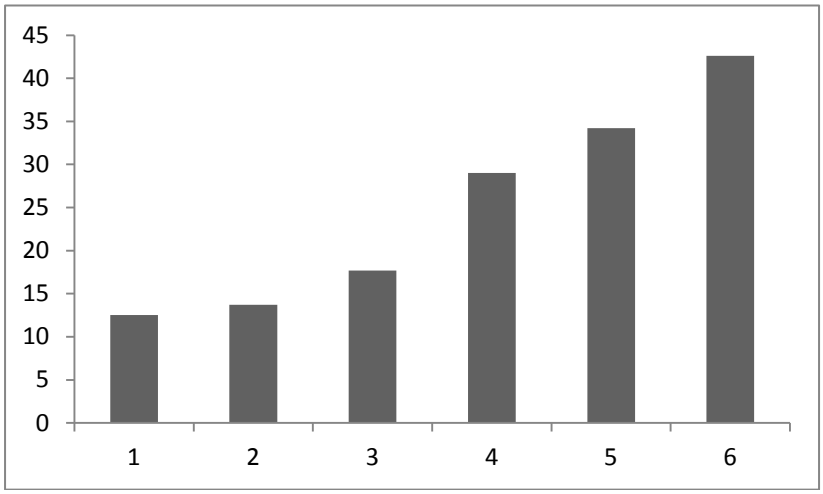

Figure no. 2 Preliminary solubility studies of ciprofloxacin (On X axis: 1. PD; 2. Ciprofloxacin + Mannitol (1:1); 3. Ciprofloxacin + Mannitol (1:2); 4. Ciprofloxacin + Mannitol (1:4); 5. Ciprofloxacin + Lactose (1:1); 6. Ciprofloxacin + Lactose (1:2); 7. Ciprofloxacin + Lactose (1:4)

Solid dispersion solubility study

Solid dispersions were prepared by solvent evaporation method with their respective carriers. All the SDs prepared was found to be fine and free flowing powders. After preparation of solid dispersion solubility analysis were carried out and compared with pure drug. The formulation with Lactose in the ratio of 1:4 (drug to carrier) which had increased the solubility almost 8 fold compared to that of pure drug. The solid dispersion solubility study of ciprofloxacin was carried out as showed in table no. 8.2.The solid dispersion solubility for SDM1, SDM2, SDM4, SDL1, SDL2, and SDL4 was found to be 12.52 mg/ml, 13.71 mg/ml, 17.67 mg/ml, 29.01 mg/ml, 34.23 mg/ml, and 42.61 mg/ml respectively. The SDL4 showed higher solubility as compared to SDM4 as showed in figure no. 3.

Table no. 4 solubility studies of ciprofloxacin solid dispersions

Sr. no.	Drug: carrier	Solubility (µg/ml)
1	SDM1	12.52
2	SDM2	13.71
3	SDM4	17.67
4	SDL1	29.01
5	SDL2	34.23
6	SDL4	42.61

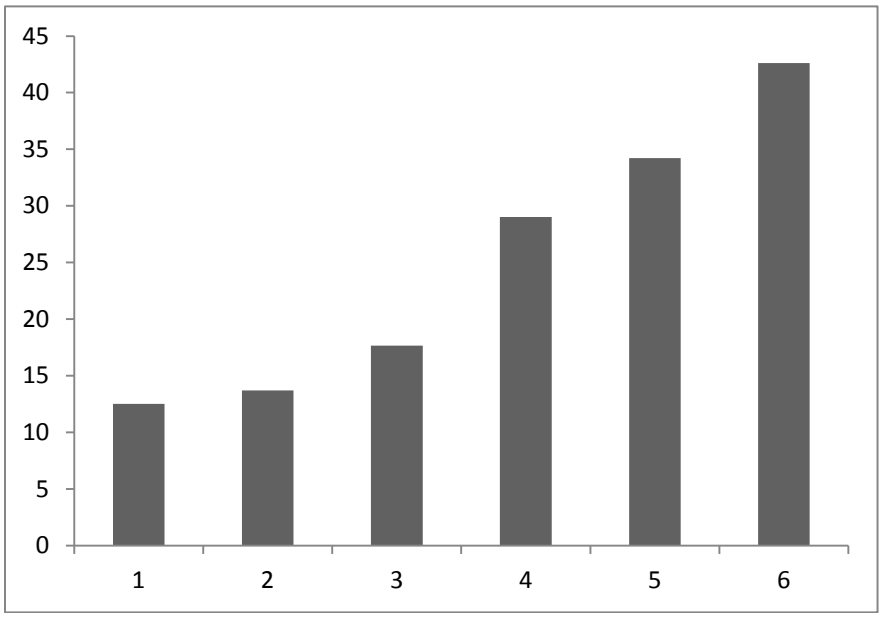

Figure no. 3 Solubility studies of ciprofloxacin solid dispersions (On X axis: 1.SDM1; 2.SDM2; 3.SDM4; 4.SDL1; 5.SDL2; 6.SDL4)

Micromeritic & morphological study of solid dispersions

Table no. 5 Drug content, Micromeritics properties, Solubility & Dissolution efficiency of ciprofloxacin & its solid dispersion

Sample	Drug content (%)	Carr's index	Hausner's ratio	Angle of repose (°)	Aqueous solubility (µg/ml)
Pure drug	100	38.37	1.62	45	4.7
SDM1	95.54	16.77	1.201	30.32	12.52
SDM2	93.02	16.62	1.199	29.72	13.71
SDM4	92.08	16.52	1.197	29.51	17.67
SDL1	96.89	16.19	1.193	29.68	29.01
SDL2	94.02	14.33	1.167	29.24	34.23
SDL4	92.72	13.98	1.162	28.59	42.61

Flowability of ciprofloxacin (pure drug) & its solid dispersion was assessed by determination of Carr's index (CI), Hausner's ratio & angle of repose. Micromeritic behavior of the untreated ciprofloxacin powder & all prepared solid dispersions are listed. Table no. 5 shows that the flowability represented in terms of Carr's index, Hausner's ratio & angle of repose was much improved compared to those of original powders (untreated ciprofloxacin). In case of pure ciprofloxacin powder could not pass through the funnel during the angle of repose experiment. The poor flow of ciprofloxacin could be due to the irregular shape & high fitness of the powder, which posed hurdles in the uniform flow from the funnel. These results are significantly different from those of untreated ciprofloxacin. Actual drug content of al 6 formulations are shown in table no. 5. The drug content of prepared SD's was found to be in range of 92.08 to 96.89 %.

In Vitro dissolution study of solid dispersion

Table no.6 Cumulative % drug release of ciprofloxacin solid dispersion

Time (Min)	PD	SDM1	SDM2	SDM4	SDL1	SDL2	SDL4
5	2.77	18.96	27.53	38.53	51.56	63.68	77.63
10	4.94	39.65	46.23	51.56	62.50	75.12	82.41
15	9.80	52.89	61.28	69.87	71.23	84.39	87.35
20	14.54	69.14	76.96	73.20	80.23	87.22	92.96
30	22.60	80.61	82.52	84.37	88.91	93.76	97.07
45	30.20	84.23	87.85	89.23	91.52	96.78	98.68
60	36.56	87.85	91.23	92.56	97.05	97.21	---
90	42.21	90.84	93.96	96.97	95.03	---	---

The dissolution rate study was carried out for pure ciprofloxacin as well as for ciprofloxacin solid dispersions. The cumulative % drug release has showed in table no. 6.The % drug release of pure form was found to be 42.21 % at 90 minutes. The SDM4 showed 98.97 % drug release at 90 minutes as showed in figure no. 4. The SDL4 showed 99.68 % drug release at 45 minutes as showed in figure no. 5. On another hand, the SDL4 showed 99.68 % drug release at 45 minutes, which is higher than % drug release of SDM4.

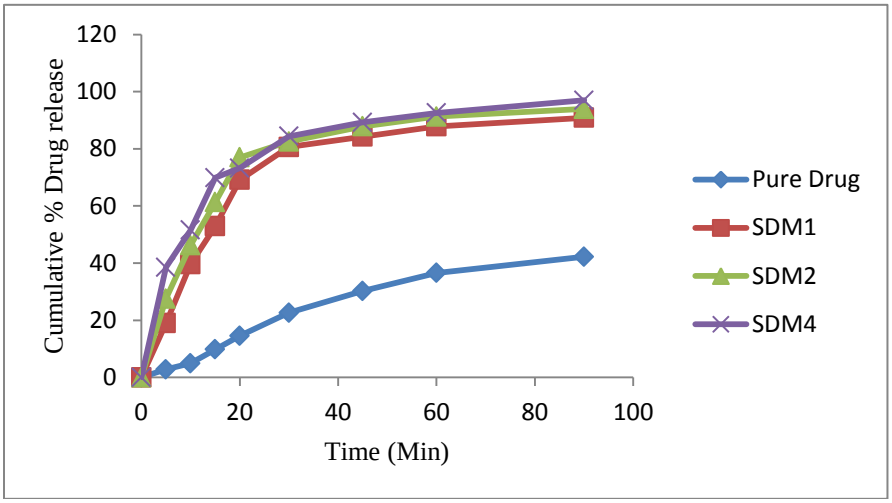

Figure no.4 Cumulative % drug dissolved Vs time plots of ciprofloxacin solid dispersion containing mannitol

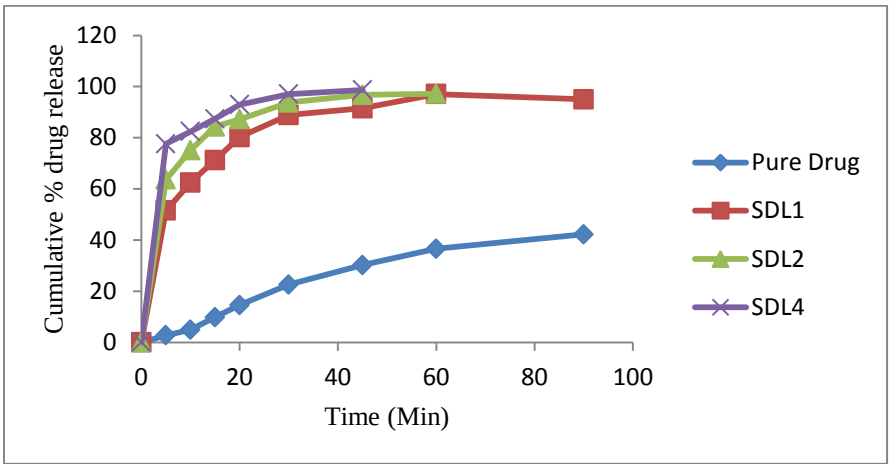

Figure no.5 Cumulative % drug dissolved Vs time plots of ciprofloxacin solid dispersion containing lactose

Evaluation of solid dispersion granules

Micromeritic & morphological study of solid dispersion granules

In the present investigation, ciprofloxacin controlled release floating capsules were prepared by using polymers such as ethyl cellulose (EC) & HPMC. A total number of 6 formulations were prepared by wet granulation method. Angle of repose for F1-F6 is between 18.41° to 24.22°, bulk density is in between 0.442-0.450, compressibility index is in between 11.235-12.751 & Hausner's ratio is in between 1.126-1.146 are within the acceptable limits (Table no.7). The above values of pre compression parameters show the prepared granules having good flow property. From the preformulation studies for drug excipients compatibility, it was observed that no physical incompatibility existed between the drug & excipients. The weight variation was within ±5 %, it was within the acceptable limit.

Table no. 7 Evaluation of ciprofloxacin + Lactose solid dispersion granules (Ratio = 1:4)

Formulation	Angle of repose	Bulk density	Tapped density	Compressibility index (%)	Hausner's ratio
F1	18.41	0.392	0.442	11.312	1.127
F2	23.19	0.395	0.445	11.235	1.126
F3	17.35	0.390	0.447	12.751	1.146
F4	20.22	0.393	0.444	11.486	1.129
F5	22.30	0.395	0.449	11.026	1.136
F6	24.22	0.395	0.450	11.555	1.130

Table no. 8 Evaluation of ciprofloxacin + Lactose solid dispersion capsules (Ratio = 1:4)

Formulation	Buoyancy lag time (Sec)	Floating duration (hrs)
F1	27	>6
F2	48	>6

F3	51	>6
F4	36	>6
F5	45	>6
F6	58	>6

The floating duration was greater than 6 hrs in F1-F6 (Table no. 8). The formulation F6 showed higher buoyancy lag time as well as floating duration than others as showed in table no. 8.

In Vitro dissolution study of formulated capsules

In-vitro drug release showed (Figure no. 6) that the variation of release pattern of different batches (F1-F6) of the ciprofloxacin in 6 hrs study period. In-Vitro dissolution study was carried out for ciprofloxacin solid dispersion controlled release floating capsules. The % drug release has showed in table no. 9. The F6 showed 53.86 % drug release at 360 minutes, which is higher than % drug release of others. Formulation F6 showed higher solubility profile.

Table no. 9 In Vitro dissolution study of ciprofloxacin + Lactose solid dispersion capsules (Ratio = 1:4)

Time (Min)	F1	F2	F3	F4	F5	F6
60	21.01	22.86	24.56	27.86	29.32	31.58
120	22.56	24.86	28.96	30.45	32.56	36.34
180	24.81	27.61	31.56	35.68	37.96	43.08
240	26.56	29.76	35.07	39.05	42.63	46.89
300	28.82	31.45	36.89	41.56	46.03	49.89
360	29.98	34.89	39.91	45.63	49.05	53.86

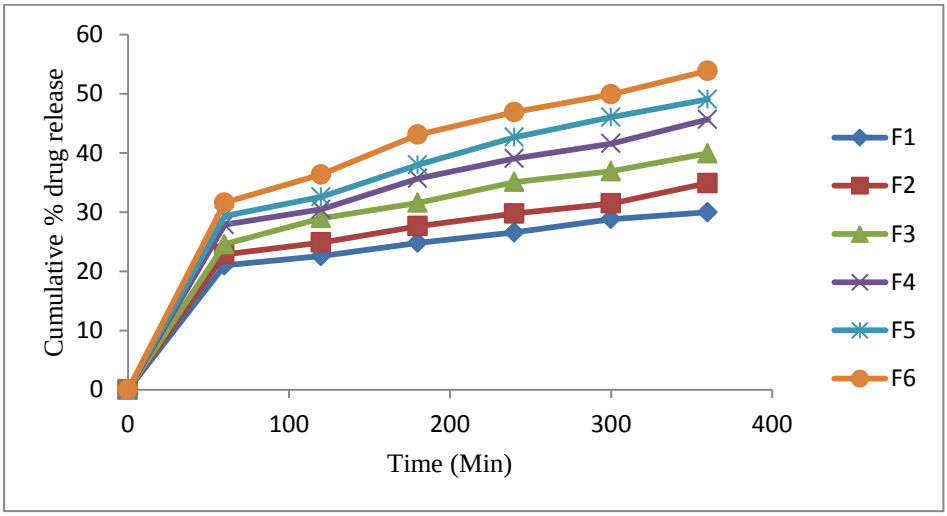

Figure no. 6 In Vitro dissolution study of formulated capsules

Conclusion

Solid dispersions prepared by hydrophilic polymers like mannitol & lactose using the solvent evaporation technique was effective in improving drug dissolution. These solid dispersions were analyzed for solubility & in vitro dissolution profile. Dissolution of drug increase with an increase in carrier content. Solid dispersions prepared with lactose had shown enhanced solubility with improved dissolution rate. Controlled release floating capsules of ciprofloxacin & different carriers can enhance the gastric residence time as well as bioavailability & better patient compliance can be achieved.

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