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Research Article

Formulation and evaluation of fast dissolving tablet of Ciprofloxacin

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Ciprofloxacin,
Crospovidone,
Orodispersible.

Abstract

Difficulties of swallowing and first-pass metabolism are of the major limitations of oral medicaments resulting in patient non-compliance and poor oral bioavailability. These drawbacks can be avoided by the administration of alternative dosage forms e.g. mouth dissolving tablets (MDTs) that dissolve upon contact with saliva and consequently allowing systemic drug absorption via buccal mucosa. This study aimed to prepare MDTs Ofloxacin containing superdisintegrants and effervescent agents. MDTs were prepared using different excipients where powdered blends were evaluated to investigate their flow properties followed by physical characterization of the directly compressed tablets. Formula (F6) containing 20mg crospovidone and effervescent base as a disintegration-aiding agent achieved the best results according to the standard specifications.

1. Introduction

The main problem with the common oral dosage forms is that they have to be swallowed along with water and many patients find it difficult to swallow tablets, especially in elderly and pediatrics, because of the physiological changes associated with these groups. Due to this dysphagic condition, they do not comply with prescription, which results in patient non-compliance. Thus FDTs are beneficial to patients who find it difficult to swallow tablets, moreover some of the drugs which are soluble in saliva are absorbed from the mouth, and pharynx and esophagus as the saliva passes down into stomach, which enhances bioavailability by avoiding first pass metabolism. [1-6]

Difficulty in swallowing (Dysphasia) is common among all age groups, especially in elderly, and is also seen in swallowing of conventional tablets and capsules. Geriatric and pediatric patients and travelling patients who may not have ready access to water are most in need of easy swallowing dosage forms. Another study shows that an estimated 50% of the population suffers from this problem. These studies show an urgent need for a new dosage form that can improve patient compliance. Solid dosage forms that can be dissolved or suspended with water in the mouth for easy swallowing are highly desirable for the pediatric and geriatric population, as well as other patients who prefer the convenience of readily administered dosage forms. In order to allow fast disintegrating tablets to dissolve in the mouth, they are made of either very porous or soft moulded matrices or compressed into tablets with very low compression force. Fast disintegrating drug delivery (FDDTs,) can be achieved by various conventional methods like direct compression, wet granulation, moulding, spray drying, freeze drying, and sublimation. The oral fast-disintegrating tablets are also known as-fast dissolve, rapid dissolve, rapid melt and quick disintegrating tablet. However, the function and concept of all these dosage forms are similar. By definition, a solid dosage form that dissolves or disintegrates quickly in the oral cavity, resulting in solution or suspension without the need for the administration of water is known as an oral fast dispersing dosage form. Recently, the European Pharmacopeia adopted the term orodispersible tablet for a tablet that disperses or disintegrates in less than 3 minutes in the mouth before swallowing. Such a tablet disintegrates into smaller granules or melts in the mouth from a hard solid to a gel-like structure, allowing easy swallowing by patients.

There are several synonyms in use of FDTs like orodisperse, orally disintegrating tablets, quick dissolving tablets, fast melt tablets, rapid disintegrating tablets. The tablets are disperse in oral cavity hence called orodisperse, dissolves in mouth within a matter of seconds hence called quick dissolving and rapid disintegrating tablets. These tablets releases the medicament in the mouth for absorption through local oromucosal tissue and through pregastric (oral cavity, pharynx, and esophagus), gastric (stomach), and post gastric (small and large intestine) segments of gastro intestinal tract. [7-10]

2. Materials and Methods

2.1 Manufacture of Ciprofloxacin tablets: [11-25]

2.1.1 Direct compression technique:

Ciprofloxacin tablets were manufactured for six batches F1 to F6 using different ratios of superdisintegrants mentioned in the Table keeping the total weight (500mg) of the tablet constant in all the formulations.

Ciprofloxacin tablets were prepared by direct compression technique as per the formula given in the Table. The superdisintegrants such as croscarmellose sodium, crospovidone and sodium starch glycolate were used in different proportions. All the ingredients were passed through sieve #40 and were subjected for drying to remove moisture content at 40 to 45^{0}C. Weighed amount drug and excipients except magnesium stearate and talc were mixed properly by geometric addition method for 20 minutes manually.Talc and magnesium stearate were then passed through sieve #80, mixed and blended well with the initial mixture. The mixed blend of drug and the excipients was compressed on Karnavati 10 station rotary punching machine using 8 mm diameter round punches.

Table 3: Formulation of Ciprofloxacin Fast Dissolving Tablets Prepared by Direct Compression Method (1 Tablet)

Ingredients	Formulation Code & Quantities (mgs)					
	F1	F2	F3	F4	F5	F6
Ciprofloxacin	250	250	250	250	250	250
Sodium starch glycolate (%)	25	20	-	-	-	-
Crosscarmellose sodium (%)	-	-	25	20	-	-
Crospovidone (%)	-	-	-	-	25	20
Lactose	90	95	90	95	90	95
Mannitol	70	70	70	70	70	70
Aerosil	30	30	30	30	30	30
Magnesium stearate	15	15	15	15	15	15
Talc	20	20	20	20	20	20
Total weight	500	500	500	500	500	500

2.2 Experimental Data:

2.2.1 Preformulation Studies:

The following Preformulation studies were performed for Ciprofloxacin and excipients;

1. Determination of melting point of Ciprofloxacin
2. Drug- excipients compatibility studies.

Determination of melting point:

Melting point was determined by taking small amount of Ciprofloxacin in a capillary tube closed at one end. The capillary tube was placed in an electrically operated melting point apparatus and the temperature at which the drug melts was recorded. This was performed thrice and average value was calculated.

Drug-excipients compatibility studies:

Excipients were integral components of almost all pharmaceutical dosage forms. The successful formulation of a stable and effective solid dosage forms depends on the selection of excipients, which are added to facilitate administration of the drug and protect it from degradation.

2.2.2 FT-IR Studies:

In the preparation of tablet formulations, drug and polymer may interact as they are in close contact with each other, which could lead to the instability of drug. Preformulation studies regarding the drug-polymer interaction are therefore very critical in selecting appropriate polymers. FT-IR spectroscopy was employed to ascertain the compatibility between Ciprofloxacin and selected polymers. The pure drug, drug-polymers combinations and formulations were subjected to FT-IR studies. Potassium bromide, pure drug, and the polymers were heated to 105^{0}C for one hour to remove the moisture content if present in a hot air oven. Then in presence of IR lamp, potassium bromide was mixed with drug and /or polymer in 1:1 ratio. Grinding in smooth mortar can effect mixing. The mixtures were then placed in the sample holder

of the instrument and the spectra were taken. The spectra were run from 4000 cm-1 to1000 cm-1 wave number. FT-IR spectrum of Ciprofloxacin was compared with FT-IR spectrum of Ciprofloxacin with polymer. The pure drug and the drug with excipients were scanned separately. Disappearance of Ciprofloxacin peaks or shifting of peak in any of the spectra was studied.

2.2.3 Preparation of Ciprofloxacin standard stock solution (100µg/ml) in Phosphate Buffer ph 6.8 solution:

A standard stock solution of Ciprofloxacin was prepared by dissolving accurately weighed 10 mg of Ciprofloxacin in Phosphate Buffer ph 6.8 solution in a 100 ml volumetric flask and the volume was made up to 100 ml by using Phosphate Buffer ph 6.8 solution to obtain a stock solution of 100µg/ml.

2.2.4 Calibration curve of Ciprofloxacin in Phosphate Buffer ph 6.8 solution:

An accurately weighed 10 mg of Ciprofloxacin was dissolved in 100 ml of Phosphate Buffer ph 6.8 to get a concentration of 100 µg/ml.

From this stock solution, aliquots with suitable dilutions were made in order to get concentration in between the Beer's range of 2-20 µg/ml. The dilutions of 2 µg/ml, 4µg/ml, 6µg/ml, 8µg/ml and 10µg/ml were prepared. The absorbance was measured at 276 nm using UV visible spectrophotometer. The standard curve was obtained by plotting absorbance V/s concentration in µg /ml.

3. Results

3.1 Evaluation of Tablets: [26-38]

3.1.1 Pre-compression parameters:

Melting Point:

The melting point of Ciprofloxacin was determined by capillary tube method and it was found to be 311^{0}C -318^{0}C.

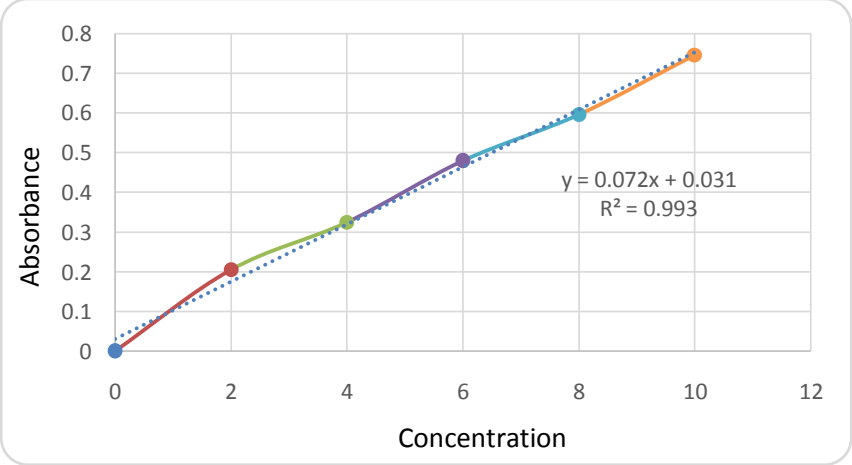

Figure 1: Standard Calibration Curve of Ciprofloxacin.

3.1.2 Drug- excipients Compatibility Studies:

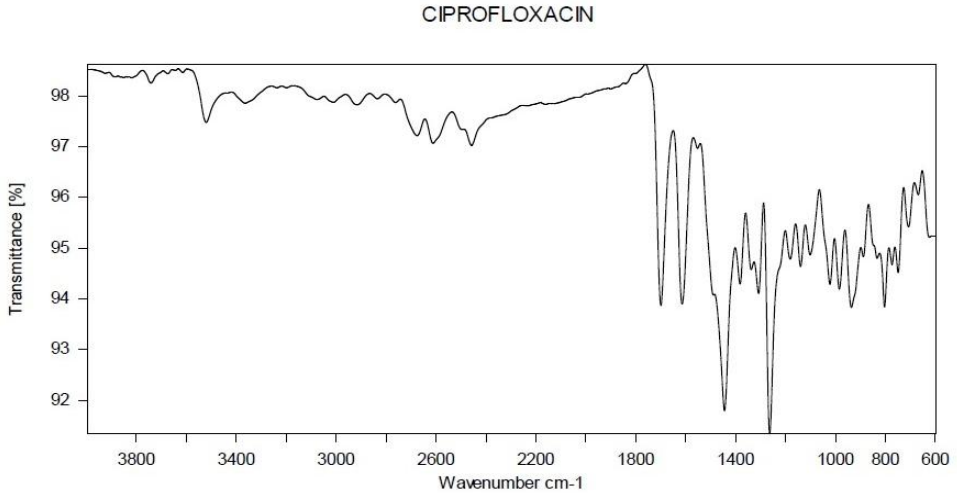

Figure 2: IR spectra of Ciprofloxacin

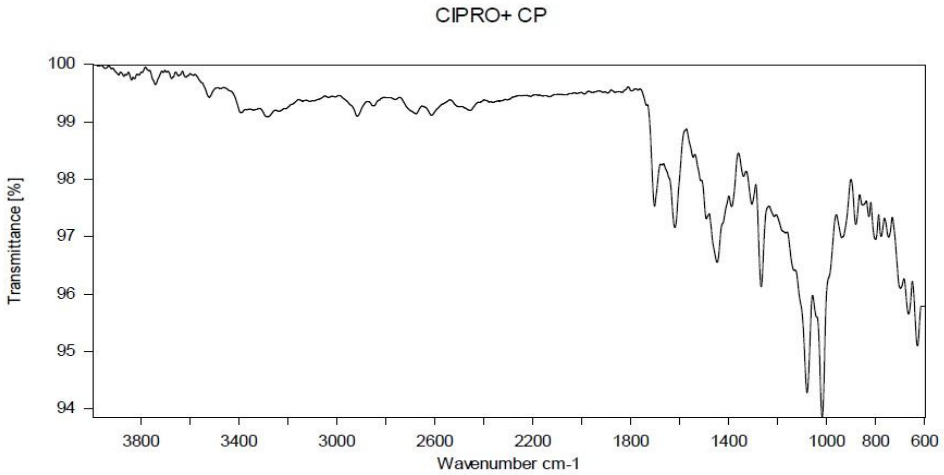

Figure 3: IR spectra of Ciprofloxacin + Crospovidone

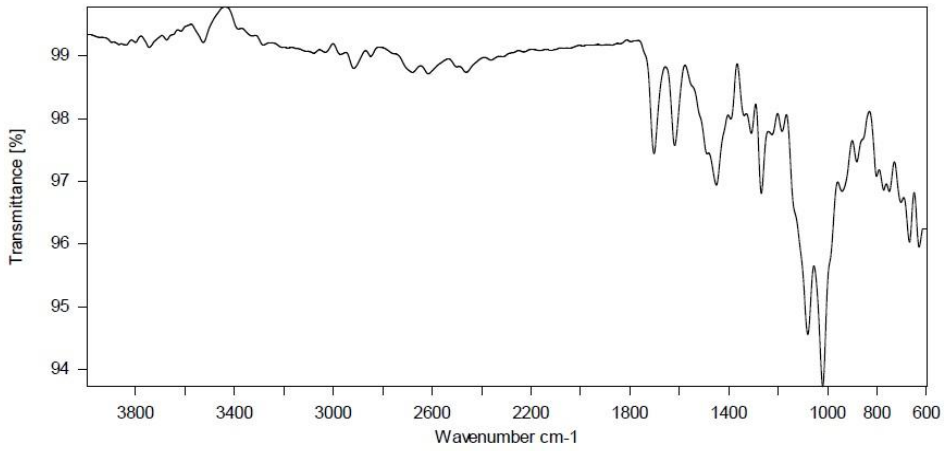

Figure 4: IR spectra of Ciprofloxacin + Croscarmellose sodium

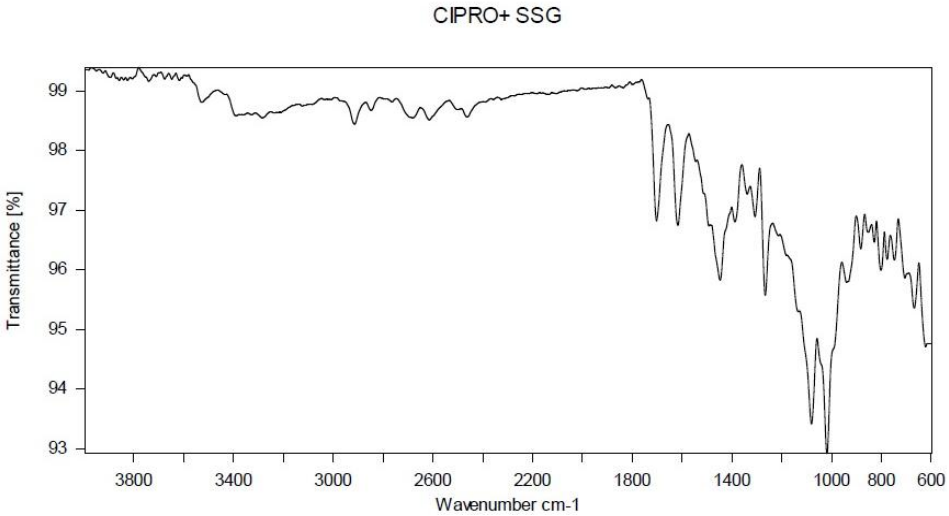

Figure 5: IR spectra of Ciprofloxacin + Sodium Starch Glycolate

3.1.3 Angle of repose (θ):

Table shows the results obtained for angle of reposes of all the formulations. The values were found to be in the range of 26.55 to 29.63 All formulations showed the angle of repose within 30^0. It indicates that all formulations showed good flow properties.

Table 4: Angle of Repose, Loose Bulk Density, Tapped Bulk Density, Carr's Compressibility Index

Formulation Code	Angle of Repose(θ) (degree)	Loose Bulk Density(gm/cm^3)	Tapped Bulk Density (gm/cm$^{3)}$	Compressibility (Index %)	Hausner's ratio
F1	26.56	0.47	0.46	15.18	1.17
F2	26.69	0.46	0.48	14.03	1.16
F3	27.56	0.45	0.47	13.90	1.14
F4	26.55	0.43	0.50	14.28	1.16
F5	29.01	0.48	0.56	15.73	1.17
F6	29.63	0.49	0.58	15.97	1.18

3.1.4 Bulk density:

Both loose bulk density LBD and tapped bulk density results are shown in table 4 the loose bulk density and tapped bulk density for all the formulations varied from 0.43gm/cm^3 to 0.49gm/cm^3 and 0.46gm/cm^3 to 0.58gm/cm^3 respectively. The values obtained lies within the acceptable range and not large differences found between loose bulk density and tapped density. This result helps in calculating the % compressibility of the powder.

3.1.5 Percentage compressibility:

The percent compressibility of powder mixture was determined by Carr's compressibility index. The table Shows result obtained for percentage compressibility. The percent compressibility for all the nine formulations lies within the range of 13.90 to 15.97 %. All formulations are showing good compressibility.

3.1.6 Hausner's ratio:

Hausner ratio of the powder was determined from the loose bulk density and tapped bulk density. Hausner ratio of all the formulation lies within the acceptable range. The Hausner's ratio of all the formulations is in the range of 1.14 to 1.18.

3.2 Post-compression parameters:

All the formulations were subjected for Organoleptic, physical and chemical evaluations. Shape, thickness, hardness, friability, weight variation, in vitro disintegration time, wetting time, water absorption ratio, drug content, in vitro dissolution studies were carried out. All the formulations were passed the parameter.

3.2.1 Shape and Color of Tablets:

Randomly picked tablets from each formulation batch examined under lens for shape and in presence of light for color. The tablet shows round shape, white in color. All ingredients used were white in color. There was no change in color and odor of the tablets in all the formulations. It indicates that all the excipients used were compatible with the drug and did not cause any chemical reaction that affects the properties of formulation.

3.2.2 Thickness Test:

The thickness of the tablets was measured by using Vernier caliper by picking the tablets randomly. The mean values are shown in table. The values are almost uniform in all formulations. Thickness was found in the range from 4.2±0.06 mm to 4.2±0.14mm respectively. Uniformity in the values indicates that formulations were compressed without sticking to the dies and punches.

3.2.3 Hardness test:

The results of hardness are given in table 5 Hardness test was performed by Monsanto hardness tester. Hardness was maintained to be within 3.1±0.10 kg/cm^2 to 3.2±0.20kg/cm^2. The lower standard deviation values indicated that the hardness of all the formulations were almost uniform and posses good mechanical strength with sufficient hardness.

3.2.4 Friability:

The results are tabulated in table was found well within the approved range (<1%) in all the formulation. Friability was in between 0.204% to 0.466%. Results revealed that the tablets possess good mechanical strength.

3.2.5 Weight variation test:

The percent weight variation for all the formulation is tabulated in Table. All the tablets passed weight variation test as the % variation was within the pharmacopoeia limit of ±10%. It was found to be from 500±1 mg to 501±2 mg. The weight of all the tablets was found to be uniform. This is due good flow property and compressibility of all the formulations.

3.2.6 Drug content uniformity:

The content uniformity was performed for all nine formulations and results are shown in table. Three trials from each formulation were analyzed spectrophotometrically. The mean value and standard deviation of all the formulations

were calculated. The drug content of the tablets was found between 95.96 % to 97.35 % of Ciprofloxacin. The results indicated that in all the formulations the drug content was uniform.

3.2.7 Wetting time:

Wetting is closely related to inner structure of tablets and the hydrophobicity of excipients. The record of the wetting time was shown in table 6. The wetting time in all the formulation was very fast. This may be due to ability of swelling and also capacity of absorption of water. Croscarmellose sodium, Crospovidone, Sodium starch glycolate absorbs water in all the formulations and shows fast wetting time. Apart from all the superdisintegrants formulations containing Crospovidone shows fast wetting time.

Table 5: Uniformity of Thickness, Hardness and Friability

Formulation Code	Uniformity of Thickness (n=3) (mm)	Hardness (n=3) (Kg/cm^2)	Friability% (n=10)
F1	4.2±0.06	3.1±0.10	0.306
F2	4.2±0.08	3.2±0.13	0.466
F3	4.2±0.14	3.2±0.12	0.256
F4	4.2±0.12	3.2±0.16	0.305
F5	4.2±0.06	3.2±0.20	0.204
F6	4.2±0.07	3.2±0.09	0.265

Table 6: Uniformity of Weight and Drug Content

Formulation Code	Uniformity of Weight (n=10) (mg)	Drug Content (n=3) (%)
F1	500±1	96.85
F2	501±2	98.00
F3	500±3	96.23
F4	501±2	95.96
F5	500±4	97.35
F6	500±5	98.83

Table 7: Wetting Time, Water Absorption Ratio

Formulation Code	Wetting Time (n=3) Mean ±SD	Water Absorption Ratio (n=3) Mean ±SD
F1	25±0.35	90.74±0.016
F2	26±0.23	86.67±0.013
F3	24±0.35	85.64±0.010
F4	21±0.32	87.31±0.035
F5	25±1.30	90.74±0.052
F6	27±1.23	93.67±0.036

Table 8: *In vitro* Disintegration Time, *In vitro* Dispersion Time

Formulation Code	*In vitro* Disintegration Time (Sec)	*In vitro* Dispersion Time (Sec)
F1	17±0.37	21±1.09
F2	16±1.46	23±1.20
F3	20±0.99	20±.55
F4	21±0.58	23±1.35
F5	18±1.19	22±1.52
F6	15±0.53	21±0.15

***3.2.8 In vitro* dissolution studies:**

In vitro dissolution study was performed by using dissolution test apparatus (electro lab) at 50 rpm. Phosphate buffer pH 6.8 of 900 ml was used as dissolution medium which maintained at 37 ± 0.5^0C. Aliquot of dissolution medium (5 ml) was withdrawn at specific time interval (3 min) and was filtered. The amount of drug dissolved was determined by UV spectrophotometer (Shimadzu 1800, Japan) by measuring the absorbance of the sample at 276 nm. Three trials for each batch were performed and average percentage drug release with standard deviation was calculated and recorded.

Table 9: *In vitro* Dissolution Profile of all the Formulations

Formulation code	After 3 min % Release	After 6min % Release	After 9 min % Release	After 12 min % Release	After 15 min % Release
	0.00	0.00	0.00	0.00	0.00
F1	21.68	44.56	52.63	76.86	84.47
F2	19.93	27.49	43.65	67.23	79.44
F3	23.68	32.63	39.58	56.82	78.31
F4	29.78	43.38	51.25	62.93	74.11
F5	16.62	29.28	56.90	76.63	88.10
F6	23.72	47.63	57.51	77.69	89.68

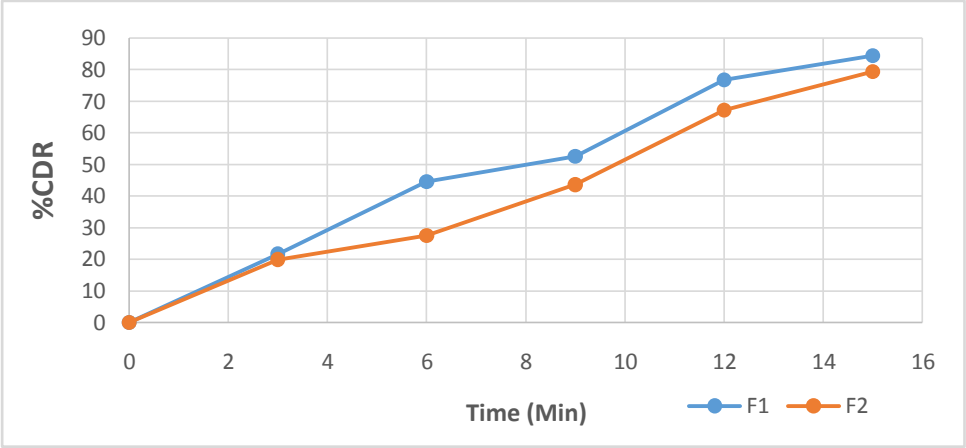

Fig. 6 *In-vitro* Drug release profile of batch F1 & F2

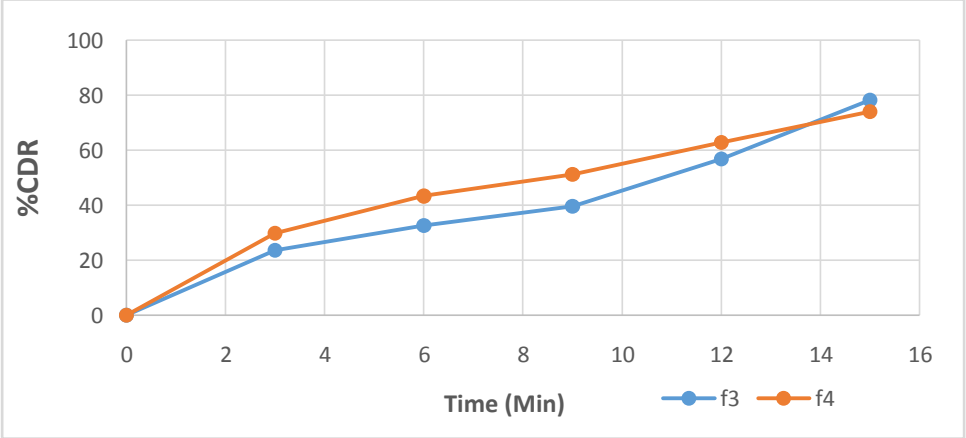

Fig. 7 *In-vitro* Drug release profile of batch F3 & F4

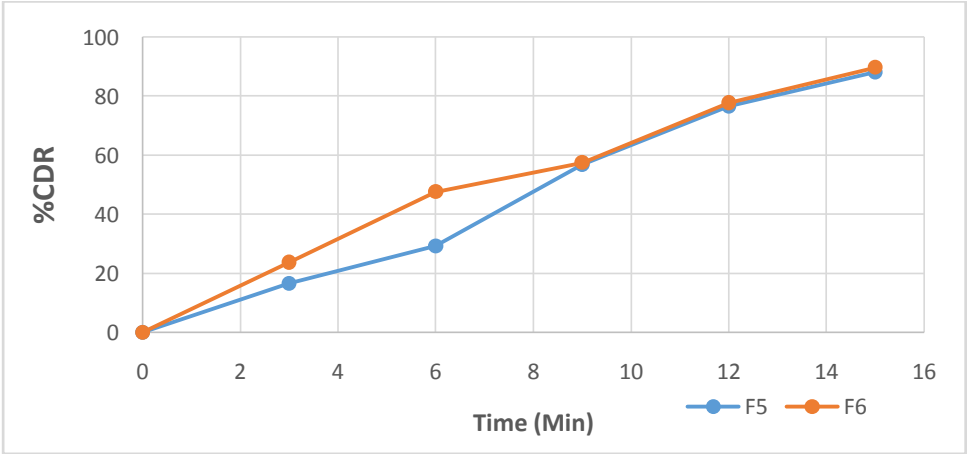

Fig. 8 *In-vitro* Drug release profile of batch F5 & F6

4. Conclusion

- Preformulation studies of Ciprofloxacin were performed, the FT-IR analysis revealed that the superdisintegrants and excipients used were compatible with Ciprofloxacin
- Fast dissolving tablets Ciprofloxacin can be prepared by direct compression technique using superdisintegrants, namely crospovidone, sodium starch glycolate and croscarmellose sodium.
- Amongst all the formulations, formulation containing crospovidone as superdisintgrants is fulfilling all the parameters satisfactorily. It has shown excellent in vitro disintegration, in vitro dispersion time compared to other superdisintegrants.
- Apart from all the formulations of F6 formulation showed maximum drug release (89.68%) at the end of 15 sec.

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