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Formulation and Evaluation of Floating Tablet of Cefadroxil

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ABSTRACT

The purpose of this study was to formulate floating tablet of cefadroxil using hydoxy propyl methyl cellulose K 100 M, Carbopol 934 P, gas generating agent sodium bicarbonate and citric acid. The present investigation concerns the development and evaluation of floating tablets of cefadroxil which, after oral administration, are designed to prolong the gastric residence time. The granules were prepared by wet granulation method and evaluated for their granules property. In these formulations PVP-K30 was used as granulating agent by dissolving it in isopropyl alcohol. PVP-K30 used in all formulations, which is responsible for preparing good tablets. Tablets were compressed by using hand operated single punch tablet machine and evaluated with different parameters like diameter, thickness, average weight, hardness, friability, drug content, *in vitro* drug release study and swelling characteristics etc. All the formulations batches from F1 to F10 were evaluated for thickness measured by Vernier caliper, thickness were in the range of 5.8±0.06 to 6.2±0.01 mm. The hardness of tablets were in the range of 4.3 to 6.4 kg/cm^2 measured by Monsanto hardness tester. The friability was in the range of 0.77 to 0.99 %. The values of average weight were in the limit. Drug content was in the range of 97.01 to 99.69 indicating good content uniformity in the prepared formulation. Floating lag time were in the range of 78 to 175 Sec. The result of *in vitro* drug release studies showed the optimized formulation (F10) could sustain drug release (95%) for 8 hours and remain buoyant for 8 hours. Floating lag time and total floating time of formulation F10 was 110 sec and 480 min respectively. Swelling index of tablets is also determined at a time interval of 1 hour to 5 hour. Swellings of all the batches were performed and they are in the accepted range

Keywords: Cefadroxil, floating drug delivery system, hydroxy propyl methyl cellulose, carbopol, sustained release.

1. INTRODUCTION

For gaining a prolonged and predictable drug delivery profiles in the gastro intestinal tract is to control the gastric residence time, using a gastro retentive dosage forms that will provides as with new and important therapeutic options.The design of oral controlled drug delivery system primarily is aimed at achieving more predictable and increased availability of drugs. However, the development process is pre included by several physiological difficulties, such as inability to restrain and locate the controlled drug delivery systems within the desired regions of gastrointestinal tract due to the variable gastric emptying and motility. The FDDS also called as Hydro dynamically balanced system or gastro retentive system.It can be anticipated that, depending upon the physiological state of the subject and design of pharmaceutical formulation the emptying process can last from a few minutes to 12 hours. This variability may lead to unperiodic table time to peak plasma levels and bioavailability.[1]

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Formulating low- density dosage form that remains brought above gastric fluid. Formulating high density dosage form that is retained at the bottom of the stomach, imparting bio adhesion to the stomach mucosa, modifying of the GI tract by concomitant administration of drugs, expanding the dosage form by swelling or unfolding to a large size which limits empting of the dosage through the pyloric sphincter.[2] Increase in retention time of dosage form may also be due to mucoadhesion by mechanism of charged based attraction by ion exchange region. Morphological parameters size and shape major influence on gastric and emptying and ultimately GRT of dosage form. The oral dosage form swells within 30 min in shape having two orthogonal Axes of different length and shorter axis being long enough to achieve a length at least 1.2 cm, retained in stomach for prolonged period of time.[3]

Cefadroxil is a first-generation cephalosporin antibacterial drug that is the para-hydroxy derivative of cefalexin, and is used similarly in the treatment of mild to moderate susceptible infections such as the bacterium *Streptococcus pyogens*, causing the disease popularly called strep throat or *Streptococcal tonsillitis*, urinary tract infection, reproductive tract infection and skin infection. Cefadroxil is almost completely absorbed from the gastrointestinal tract; it is well absorbed on oral administration; food does not interfere with its absorption. Binding rates of Cefadroxil were 28.1%. Over 90% of the drug is excreted unchanged in the urine within 24 hours.[4] Hydroxy Propyl Methyl Cellulose (HPMCK100M) Empirical Formula is $C_8H_{15}O_6$-($C_{10}H_{18}O$) n-$C_8H_{15}O_5$**.** Molecular Weight is Approximately 86. Soluble in cold water, forming a viscous colloidal solution; insoluble in alcohol, ether and chloroform, but soluble in mixtures of methyl alcohol and methylene chloride. Certain grades are soluble in aqueous acetone, mixture s of methylene chloride and isopropyl alcohol and other organic solvents. It is very stable in dry condition solution are stable at P^H 3.0-11.0 aqueous solutions are liable to be affected by microorganisms. When used as a viscosity –increasing agents in ophthalmic solutions, an anti-microbial agent, such as benzalkonium chloride, should be incorporated. Store in a tight container, in a cool place. [5]

2. MATERIALS AND METHODS

Cefadroxil was received as a gift samplefrom Schon Pharmaceuticals (Orchid chemicals), Indore (M.P.). Hydroxy propyl methyl cellulose K 100 M, Carbopol, Microcrystalline cellulose, Sodium bicarbonate, Citric acid, Poly vinyl pyrrollidone K 30, Magnesium stearate and talc purchased from central drug house, Delhi. All chemicals of analytical grades were required.

2.1 Preformulation Studies (Test for identification of Cefadroxil)

The preformulation studies were carried out in term of test of identification (physical appearance, melting point, IR spectra, solubility profile and quantitative estimation of drug.[6]

2.1.1 Physical appearance

The sample of cefadroxil was analyzed for its nature and colour.[6]

2.1.2 Melting point

The melting point was determined by capillary method using melting point apparatus. Here; the capillary tube was filled by pressing the open end gently into the pure drug sample by tapping the bottom of capillary of a hard surface. So that the drug pack down into the bottom of the tube. When the drug packed into bottom of the tube, it was placed into the slot behind the eyepiece of the apparatus. Make sure the unit was plugged in and set to zero, and then turn it on.[7]

2.1.3 Solubility Studies

Drug (5 mg) was suspended successively in 5 ml of different solvent at room temperature in a tightly closed 10 ml volumetric flask and shaken for about 5-10 min. [6]

2.1.4 Determination of absorbance maxima (λ_{max}) and preparation of standard curve

The identification of drug was done by UV spectroscopy by scanning the drug in the range of 200-400nm. Scanning was done in 0.1 N HCl.[5]

2.1.5 FTIR-Spectroscopy

Determination by infra red absorption spectroscopy, the spectrum was compared with reference spectrum of Cefadroxil. The FT-IR spectra for pure drug was obtained by powder diffuse reflectance on a FT-IR spectro photometer in the wave range of 900-4000 cm^{-1} [8]

2.1.6 Drug and excipient interaction studies

Drug excipient interaction was determined by infrared absorption spectroscopy, the spectrum of pure drug and polymer was compared and interaction studied. The FT-IR spectra for pure drug was obtained by powder diffuse reflectance on a FT-IR spectrophotometer in the wave no. region of 900-4000 cm^{-1} FTIR-Spectra of Cefadroxil and HPMC Polymer and FTIR-Spectra of Cefadroxil and other excipient were also determined. [8]

2.2 Method of tablet preparation

Floating tablet containing Cefadroxil drug were prepared by wet granulation technique using different concentration of polymer with sodium bicarbonate and citric acid . All the ingredients were mixed thoroughly except magnesium stearate and talc. Granules were prepared manually with a solution of polyvinyl pyrrolidone (PVP K30) as binder in sufficient isopropyl alcohol. The wet mass was passed through a 16 mesh sieve no. and the wet granules produced were dried in hot air oven for 30 min. at 50^{o}C. The dried granules mixed with magnesium stearate as lubricant, talc as glidant and compressed using hand operated single punch tablet machine (Table No. 1).

2.3 Evaluation of granules

2.3.1 Angle of Repose (θ)

The granules were allowed to flow through the funnel fixed to a stand at definite height (H). The angle of repose was then calculated by measuring the height and radius of the heap of granules formed. [9]

$$\tan\theta = \frac{H}{R}$$

2.3.2 Bulk density

For determining bulk density, a quantity of 5gm of granules blends from each formulation, which is previously shaken to break any agglomerate forms introduced into 25 ml graduated cylindrical flask. After that initial volume is noted .Then the bulk density was calculated by using the formula. [9]

$D_b = M / V_b$

2.3.3 Tapped density

For determining tapped density, a quantity of 5gm of powder blends from each formulation. Which is previously shaken to break any agglomerate forms, introduced into 25 ml graduated cylindrical flask? After that tapping was done 50 times and volume is noted .Then the tapped density was calculated by using the formula. [10]

$$D_t = M / V_t$$

2.3.4 Carr's index

The Carr's index were calculated using following equation [11]

$$CI = \frac{D_t - D_b}{D_t} \times 100$$

2.4 Evaluation of tablets

2.4.1 Shape of tablets

Directly compressed tablets were examined under the magnifying lens for the shape of the tablets.[9]

2.4.2 Tablets dimensions

Thickness was measured using a vernier caliper. Three tablets of each formulation were picked randomly and thickness was measured individually.[11]

2.4.3 Hardness test

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in Kg/cm^2. Three tablets were randomly picked and hardness of the tablets was determined.[9]

2.4.4 Friability test

20 tablets were accurately weighed and placed in friability test apparatus, then revolved it at 25 rpm for 4 minutes. After dedusting, the friability was calculated by using the following formula. [10]

$$\%\ Friability = \frac{Initial\ Weight - Final\ Weight}{Initial Weight} \times 100$$

2.4.5 Weight variation test

Twenty tablets were selected randomly from each batch and weighed individually to check for weight variation. As per total weight of tablet max. ±5% deviation is allowed. [11]

2.4.6 Content uniformity test

Tablets containing 250 mg of drug is dissolved in 100 ml 0.1 N HCl taken in volumetric flask. The solution was filtered, 1 ml of filtrate was taken in 50 ml of volumetric flask and diluted up to mark with 0.1 N HCl and analyzed spectrophotometrically at 265 nm. The concentration of Cefadroxil in mg/ml was obtained by using standard curve of the drug. Claimed drug content was 250 mg per tablet. Drug studies were carried out in triplicate for each formulation batch. [12]

2.4.7 In-vitro dissolution studies

In-vitro release studies were carried out using USP XX dissolution test apparatus, 900 ml of 0.1 N HCl (pH 1.2) was filled in dissolution vessel and the temperature of the medium was set at

37°C±0.1°C. For the study ring/mesh assembly was used. The tablet was put inside the ring assembly and placed inside the dissolution vessel. The speed was set at 50 rpm. Samples were withdrawn at predetermined time intervals and same volume of fresh medium was replaced. The samples were analyzed against 0.1 N HCl as a blank at λ_{max} 265 nm using UV spectrophotometer. [13]

2.4.8 Swelling Index (Water Uptake %)

The swelling index of tablets was determined in 0.1 N HCl (pH 1.2) at room temperature. The swollen weight of the tablets was determined at predefined time intervals over a period of 5 hours. The swelling index (SI) was calculated and expressed as % by the following equation: [14]

$$WU\ \% = \frac{W_t - W_0}{W_0} \times 100$$

2.4.9 Buoyancy floating test

The time between introduction of dosage form and its buoyancy on the simulated gastric fluid and the time during which the dosage form remain buoyant were measured. The time taken for dosage form to emerge on surface of medium called Floating Lag time (FLT) or Buoyancy Lag Time (BLT) and total duration of time by which dosage form remain buoyant is called Total Floating Time (TFT). [12]

3. RESULTS AND DISCUSSION

The sample of cefadroxil was white or almost white powder, odour pungent. The reported melting point value for cefadroxil is 197 °C. The observed melting point ranged between 194°C -198°C. Solubility studies of Cefadroxil were determined in various aqueous and non- aqueous solvents. The drug is insoluble in ether, chloroform and ethanol while slightly soluble in distilled water and soluble in 0.1 N HCl.

The absorption maximum of the standard solution was scanned between 200-400 nm regions by *SHIMAZDU* UV Spectrophotometer. The absorption maximum was found to be 265 nm **(Fig. No. 1)**. Calibration curve of cefadroxil was prepared in 0.1 N HCl at 265 nm **(Fig. No. 2).**

IR spectrum of cefadroxil drug indicated that characteristics peaks belonging to measure functional groups in the wave region of 900-4000 cm^{-1} The peak of cefadroxil sample drug were observed in the range of 2750-3250 cm^{-1} **(Fig. No. 3)** and compared with the IR of standard drug **(Fig. No. 4).**

IR spectrum cefadroxil and HPMC K 100 M indicated that characteristics pekas belonging to measure functional groups. The major IR peaks observed in HPMC K 100 M. 2978 (C-H), 1755 (C=O), 1609(C=N), 1555(N-H), 1396 (O-H) **(Fig. No. 5).** IR spectrum of cefadroxil & excipients **(Fig. No. 6).**

Precompression studies of granules has also performed (Bulk density, Tapped density, Angle of repose, Carr`s index). The bulk density of granules was found to be between 0.294 to 0.357 $gm/cm^3$ and the tapped density of granules was found to be between 0.357 to 0.454 $gm/cm^3$. The angle of repose determined were in the range of 23.26 to 25.85. Carr`s index were calculated 12.94 to 26.92 **(Table 2)**

All the formulation batches from F1 to F10 was evaluated for thickness measured by Vernier caliper, thickness were in the range of 5.8±0.06 to 6.2±0.01 mm. The hardness of tablets were in the range of 4.3 to 6.4 kg/cm^2 measured by Monsanto hardness tester. The friability was in the range of 0.77 to 0.99 %. The values of average weight were in the limit. Drug content was in the range of 97.01 to 99.69. indicating good content uniformity in the prepared formulation. Floating lag time were in the range of 78 to 175 Sec. result shown in **(Table 3)**

The drug release profile of formulation containing different amount of polymer and binder. In the batch F1 concentration of polymer HPMC K 100 M and citric acid is 50 mg and 7.5 mg, this batch shows drug release up to 5 hours which is less. In the batch F2, HPMC K 100 M and citric acid is 62.5 mg and 7.5 mg, this batch shows drug release up to 6 hours. Now in the batch F3 concentration of polymer HPMC K 100 M is higher 75 mg and citric acid is 7.5 mg, this batch shows drug release up to 8 hours.

After that in batch F4, F5 and F6 concentration of polymer and citric acid both are increases which are 50 mg, 62.5 mg, 75 mg and 8 mg, 10 mg, 12 mg respectively, due to which drug release of these 3 batches (F4, F5 and F6) is 7 hrs, 6 hrs, and 8 hrs respectively. In batch F7, F8 and F9 concentration of HPMC 50 mg. 62.5 mg and 75 mg while Carbopol is 50 mg in all the 3 batches. This batch shows drug release up to 5 hrs, 6 hrs and 8 hrs. After preparing all this batches we prepared a common batch which is called an ideal batch F10. In this batch the concentration of polymers HPMC K 100 M and Carbopol is 75 mg and 50 mg respectively, and the amount of citric acid is 12 mg, this batch shows drug release in 8 hours. This batch shows good result from the above batches. **(Table 4) & (Fig. No.7).**

In these formulations PVP-K30 was used as binding agent by dissolving it in isopropyl alcohol. PVP-K30 used in all formulations, which is responsible for preparing good tablets.

Table 1: Composition of floating tablet formulations (F1- F10) of Cefadroxil

S.No.	Ingredients (in mg/tab.)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1.	Cefadroxil	250	250	250	250	250	250	250	250	250	250
2.	HPMC K100M	50	62.5	75	50	62.5	75	50	62.5	75	75
3.	Carbopol	-	-	-	-	-	-	50	50	50	50
4.	Sodium bicarbonate	75	75	75	75	75	75	75	75	75	75
5.	Citric acid	7.5	7.5	7.5	08	10	12	7.5	7.5	7.5	12
6.	MCC	25	25	25	25	25	25	25	25	25	25
7.	PVPK30	20	20	20	20	20	20	20	20	20	20
8.	Mag. stearate	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
9.	Talc	05	05	05	05	05	05	05	05	05	05
10.	Total wt. of tablets (in mg)	440	452.5	465	440.5	455	470	490	502	515	519.5

Table 2: Evaluation parameters of granules of different formulations (F1-F10)

S.No.	**Formulation code**	**Angle of repose (θ)**	**Bulk density (gm/cm^3)**	**Tapped density (gm/cm^3)**	**Carr`s index (%)**
1.	F1	23.65	0.333	0.454	26.65
2.	F2	24.97	0.294	0.357	17.64
3.	F3	24.66	0.318	0.384	17.18
4.	F4	23.98	0.357	0.426	16.19
5.	F5	25.85	0.322	0.397	18.89
6.	F6	25.66	0.298	0.396	24.74
7.	F7	23.99	0.338	0.450	24.89
8.	F8	23.26	0.312	0.420	25.71
9.	F9	25.61	0.343	0.394	12.94
10.	F10	24.58	0.304	0.416	26.92

Table 3: Evaluation of physical parameters of Cefadroxil floating tablets

S. No.	Formulation code	Weight Variation(in mg)	Hardness(Kg/cm^2)	Friability (%)	Thickness (mm)	Floating lag time (in sec.)	Drug content uniformity (%)
1.	F1	440	5.6	0.90	6.0±0.01	175	98.02
2.	F2	452.5	4.5	0.99	5.9±0.02	102	97.01
3.	F3	465	6.4	0.86	6.1±0.03	115	99.53
4.	F4	440.5	5.1	0.79	6.2±0.01	95	98.01
5.	F5	455	4.3	0.87	6.0±0.02	136	97.04
6.	F6	470	5.1	0.85	5.9±0.04	90	98.40
7.	F7	490	4.3	0.81	6.0±0.01	100	97.11
8.	F8	502	6.4	0.79	5.9±0.04	78	99.55
9.	F9	515	5.1	0.77	5.8±0.06	140	99.01
10.	F10	519.5	4.3	0.86	6.1±0.03	110	99.69

Table 4: *In vitro* drug release study from different formulations (F1-F10)

S.No.	Time (in hrs)	% Drug Release									
		F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1.	0	0	0	0	0	0	0	0	0	0	0
2.	1	41.49	39.61	30.91	30.64	40.56	32.41	38.71	26.16	28.81	26.11
3.	2	54.91	50.41	39.62	42.38	51.32	40.51	51.36	39.65	36.94	36.91
4.	3	68.42	62.18	47.78	54.91	63.98	48.62	63.91	52.28	47.74	46.8
5.	4	81.91	74.78	54.92	66.61	74.79	56.78	74.78	63.95	58.54	55.81
6.	5	94.56	84.61	65.79	78.38	86.41	67.52	87.32	76.55	68.42	67.52
7.	6	-	96.38	77.48	90.91	98.15	75.62	-	90.91	80.15	74.61
8.	7	-	-	89.16	98.12	-	87.32	-	-	87.32	82.89
9.	8	-	-	98.14	-	-	97.25	-	-	98.15	95.48
FLT (sec.)		175	102	115	95	136	90	100	78	140	110
TFT (hrs)		5	6	8	7	6	8	5	6	8	8

Table 5: Swelling index of different formulations

Time (hrs)	Water uptake (%)									
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**
1	32	33	31	40	35	29	36	48	30	42
2	39	38	38	51	42	36	46	59	41	51
3	41	43	44	62	49	48	56	65	46	67
4	49	49	52	73	57	59	64	78	54	76
5	56	65	68	90	68	62	77	82	60	91

In these formulations HPMC K 100 M and Carbopol are also used in the formulation batches in different proportions, which are responsible for the delayed release or sustained release of tablets. In all the batches effervescent agent sodium bicarbonate is also used. Concentration of sodium bicarbonate is used which help to determine Floating lag time (FLT) and Total floating time (TFT) of tablets. From the determination it was found that FLT and TFT of the batch F10 is good. Floating lag time and Total floating time of formulation F10 was 110 sec and 480 min respectively. **(Table 4)** Swelling index of tablets is also determined at a time interval of 1 hour to 5 hour. Swellings index of all the batches were found in the acceptable range. **(Table 5) & (Fig. No. 8).**

4. CONCLUSION

This research work concluded that preparation and evaluation of floating tablet of cefadroxil. The floating drug delivery system was a promising approach to achieve in vitro buoyancy. The addition of polymer HPMC K 100 M, Carbopol 934P and gas generating agent sodium bicarbonate was essential to achieve in vitro buoyancy. Addition of citric acid , to achieve in vitro buoyancy under the elevated P^H of the stomach, caused an enhancement of drug release. This type of polymer affects the drug release rate and the mechanism. Polymer swelling is crucial in determining the drug release rate and it is also important for floatation. A lesser FLT and a prolonged floating duration could be achieved by varying the amount of effervescence and using different polymer combinations. The invitro drug release obtained for tablets (F10) made with combinations of HPMC K 100 M and Carbopol 934P showed FLT of 110 sec and a prolonged floating duration (8 hours) which was controlled release characteristics (95%) for 8 hours. Formulation F10 can be used for the better result as the formulation showed sufficient release for prolonged period.

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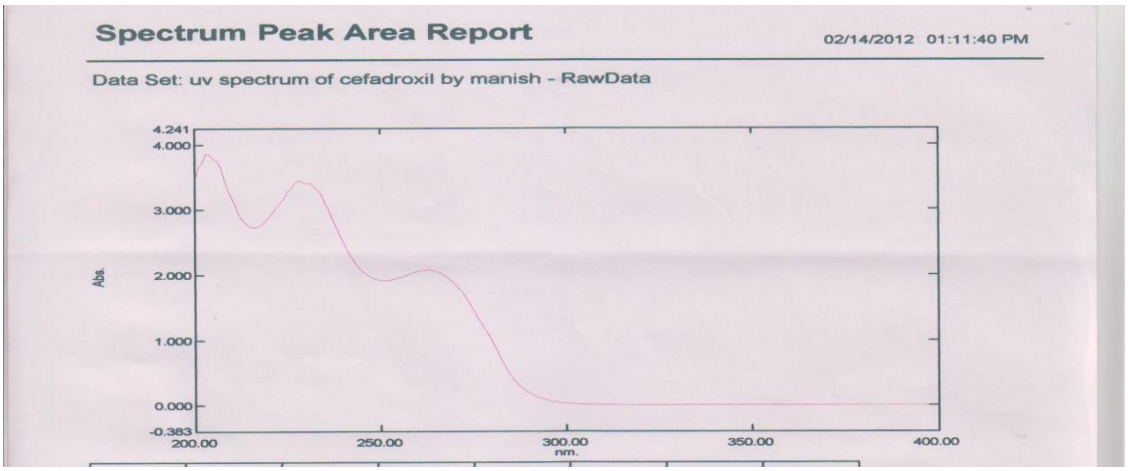

Fig. No. 1: Determination of absorption maxima (λ_{max})

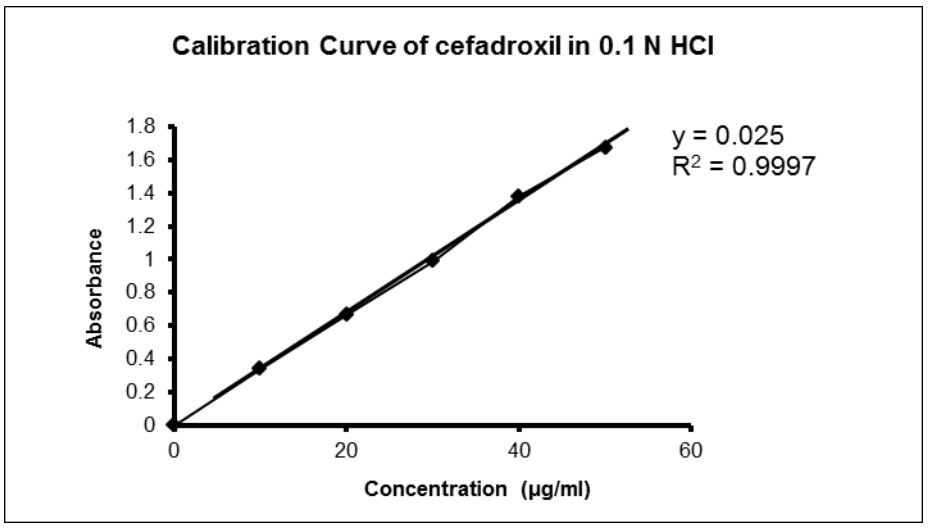

Fig. No. 2: Preparation of Standard curve of cefadroxil in 0.1 N HCl at λ_{max} 265 nm

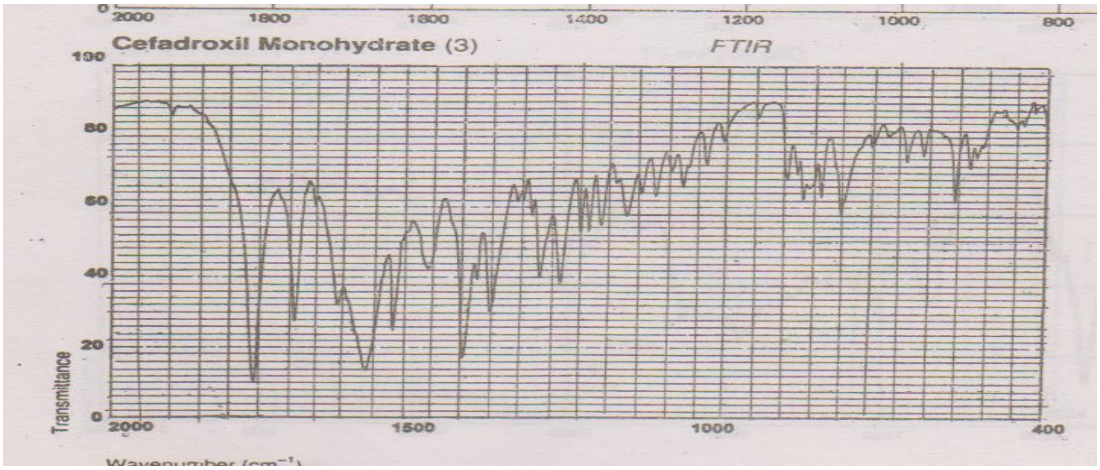

Fig. No. 3: FT-IR Spectrum of Cefadroxil (Standard)

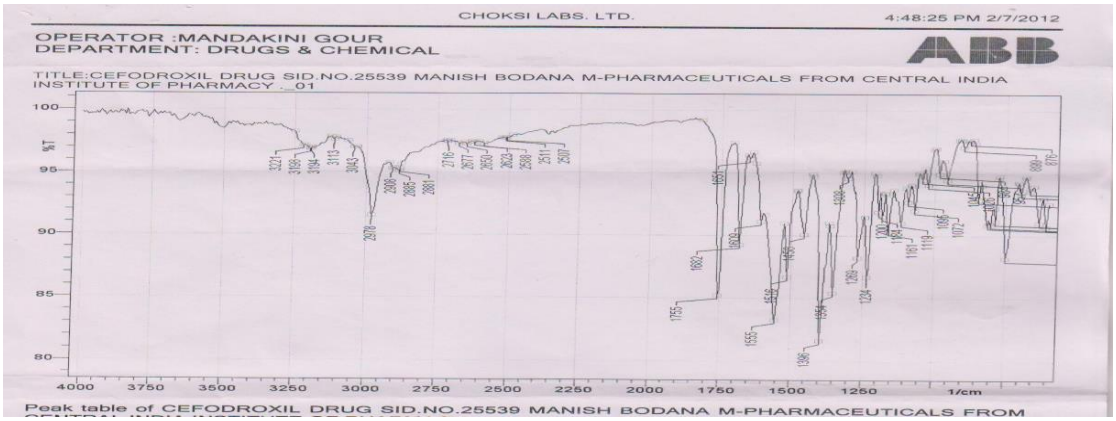

Fig. No. 4: FT-IR Spectrum of Cefadroxil (Sample)

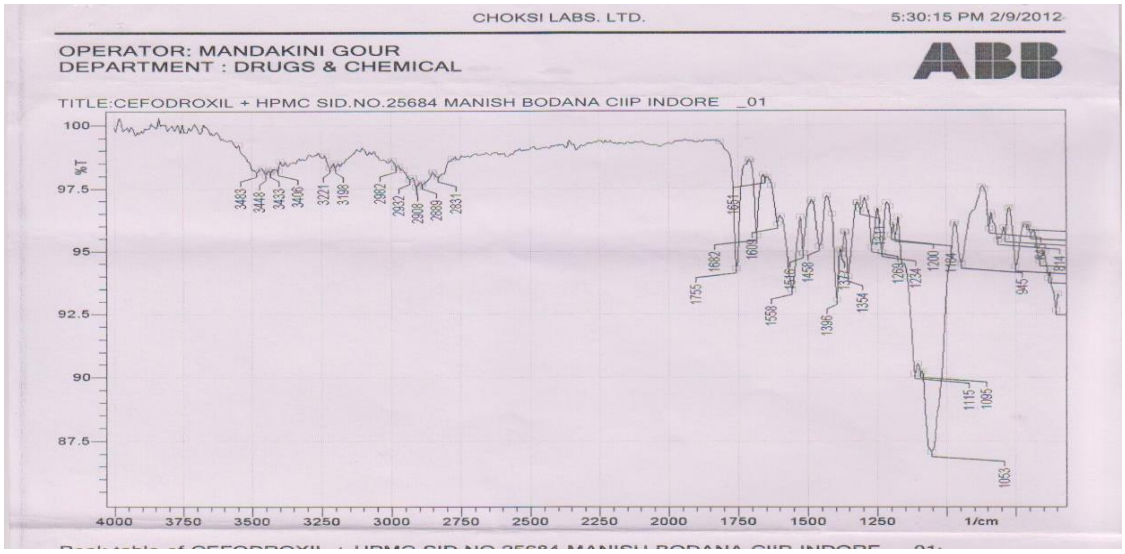

Fig. No. 5: FT-IR Spectra of Cefadroxil and HPMC

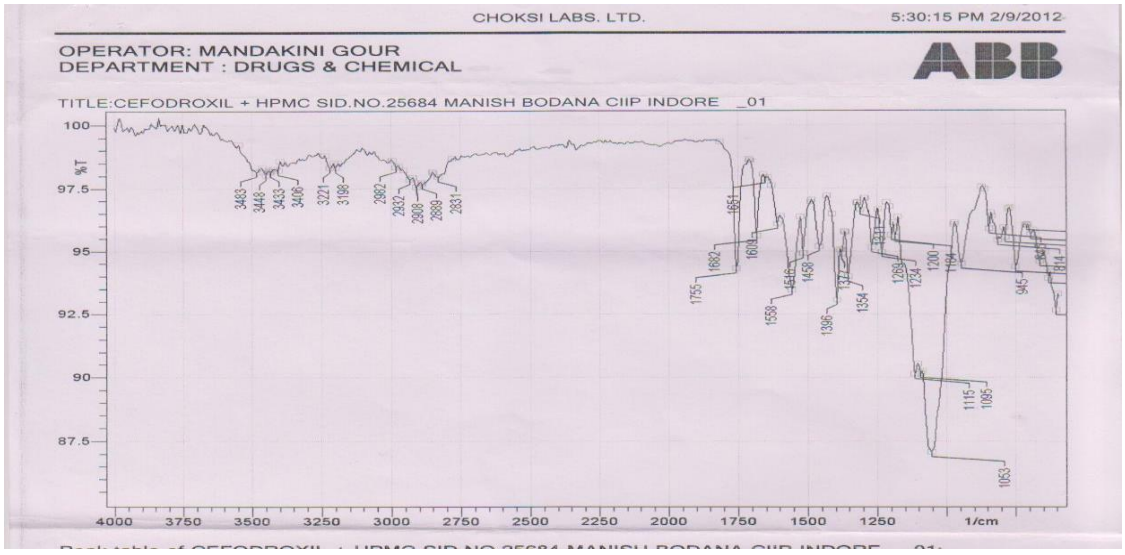

Fig. No. 6: FT-IR spectra of Cefadroxil and Excipients

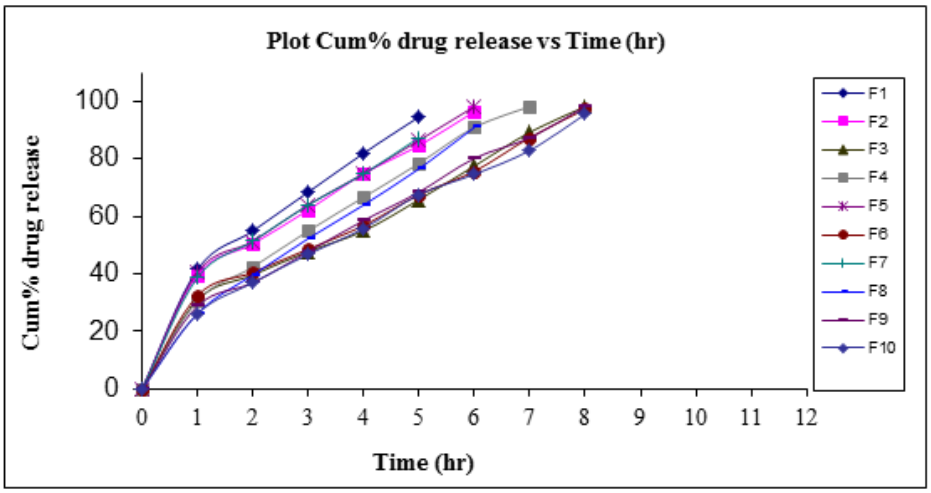

Fig. No. 7: Comparison of in-vitro dissolution profiles of F1 to F10

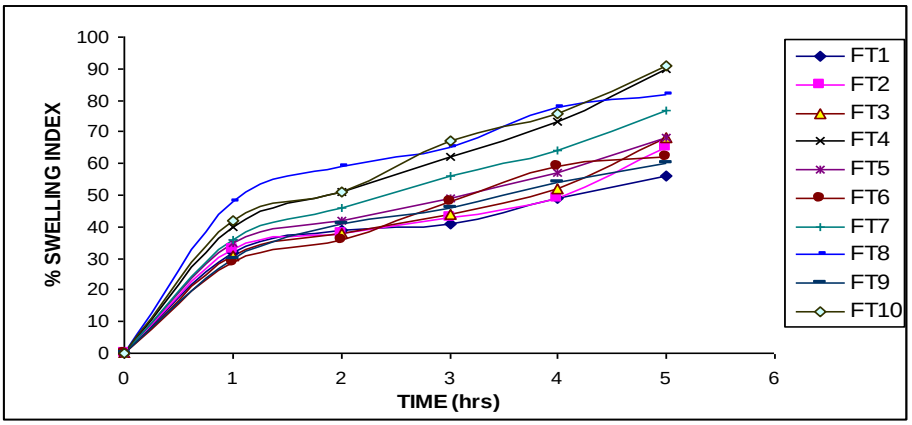

Fig. No. 8: Swelling index for tablets of batch F1 to F10