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FORMULATION AND EVALUATION OF CEFUROXIME AXETIL ORODISPENSIBLE TABLETS

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Abstract:

The Study was undertaken with an aim to formulate oro-dispersible tablets of cefuroxime axetil by using superdisintegrants like crospovidone, sodium starch glycolate and Ac-di-sol .

Different formulations were prepared varying the superdisintegrant concentration. Preformulation study of the tablet blend was carried out, the tablet blends showed good flowing properties directing for the further course of formulation. The tablets were prepared by direct compression method.Tablets were evaluated for postformulation studies like hardness, weight variation, friability, wetting time, in vitro disintegration time and in vitro dissolution, stability studies.The hardness was found to be in the range of 3.0 -4.0 kg/cm^2.Weight variation was found to be in the range of 240 – 254 mg. Friability was NMT 0.5% meeting the USP limits.Weight variation and hardness of cefuroxime axetil tablets were within range.

Wetting time was in the range of 30 to 39.3, as wetting time increases disintegration time of tablet decreases. Wetting time of F9 with superdisintegrants Ac-di-sol shows lower values hence higher disintegration time. Formulations containing of Ac-di-sol showed somewhat lower wetting time than other batches hence showed satisfactory disintegration time.

Disintegration time of tablets was evaluated and was found to be in the range of 29±1 to 41±1.52. Lower disintegration time was for F9 formulations containing Ac-di-sol as superdisintegrant. Formulations containing of Ac-di-sol in higher quantity showed good disintegration time. Formulations containing of sodium starch glycolate showed higher disintegration time compared with other formulations. The formulations were stable at both the temperatures maintained for stability studies and were found to be maintaining the same dissolution velocity.

Key words: *cefuroxime axetil, crospovidone , sodium starch glycolate , Ac-di-sol*

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INTRODUCTION:

Recent advances in novel drug delivery systems (NDDS) aim to enhance safety and efficacy of drug molecules by formulating a convenient dosage form for administration and to achieve better patient compliance [1]. One such approach was oral dispersible tablets which has gained acceptance and popularity in the recent time. Oro-dispersible tablet provides a convenient means of administrating drugs, particularly to pediatrics and geriatric patients, more importantly they can be taken without water for oral drug administration.

Several pharmaceutical industries prepared oro-dispersible tablets by direct compression technique by selecting suitable superdisintegrants. Direct compression technique offers important advantages such as increased output, reduced cost, less machinery and improved drug stability when compared to the wet granulation method [2].

Cefuroxime axetil is a second generation oral cephalosporin antibiotic. This antibiotic treats only bacterial infections [3]. It will not work for viral infections (e.g., common cold, flu). Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness. To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefuroxime axetil and other antibacterial drugs, cefuroxime axetil should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria [4].

The present research work has been carried out with an aim to formulate Cefuroxime axetil orally disintegrating tablets with superdisintegrants like crospovidone, croscaramellose sodium and sodium starch glycolate in different concentrations.

MATERIALS AND METHOD:

CHEMICALS REQUIRED:

Cefuroxime axetil, Mannitol, Microcrystalline cellulose, crospovidone, Magnesium stearate, Sodium starch glycolate, Ac-di-sol.

APPARATUS REQUIRED:

Balance, sieves, tapped density tester, mixer granulator, mechanical stirrer, dryer, compression meachine, vernier calipers, hardness tester, disintegration apparatus, stability chambers, phmeter and dissolution

Pre-formulation studies:

A) Organoleptic evaluation

Organoleptic characters of drug was observed and recorded by using descriptive terminology.

B) Analytical Evaluation

Preformulation Studies [5,6]

Preformulation involves the application of biopharmaceutical principles to the physicochemical parameters of a drug with the goal of designing an optimum drug delivery system. Preformulation testing is defined as investigation of physical and chemical properties of drug substances alone and when combined with excipients prior formulation.

The tablet blend was tested for angle of repose, bulk density, tapped density, Carr's index, hausner's ratio.

Angle of repose [7]

The frictional force in a loose powder can be measured by the angle of repose. Angle of Repose is the maximum angle between the surface of a pile of powder and horizontal plane. It is usually determined by fixed funnel method and is the measure of the flow ability of powder/granules. A funnel with 10 mm inner diameter of stem was fixed at a height of 2 cm. over the platform.

About 10 gm of sample was slowly passed along the wall of the funnel till the tip of the pile formed and touches the steam of the funnel. A rough circle was drawn around the pile base and the radius of the powder cone was measured.

Angle of repose was calculated from the average radius using the following formula.

$$\theta = \mathrm{Tan}^{-1}\,(h/r)$$

Where,

θ = Angle of repose, h = Height of the pile, r = Average radius of the powder cone

Flow properties corresponding to Angle of repose

Table 1: Angle of repose range

Angle of repose	Type of flow
<25	Excellent
25 – 30	Good
30 – 40	Passable
> 40	Very Poor

Higher the angle of repose the rougher and more irregular is the surface of the particles.

Bulk and Tapped Density [8]

An accurately weighed quantity of the granules (w) that was previously passed through # 40 was carefully poured into the graduated cylinder and the volume (vo) was measured.The graduated measuring cylinder was tapped for 100 times and after that, the volume (vf) was measured and continued the operation till the two consecutive readings were equal. Bulk density and tapped density determines the floating capacity of the formulation. The bulk density and tapped density were calculated using the formulas below

Bulk density = w/v_o

Tapped density=w/v_f

Where w - Weight of powder

v_o - Initial volume. ,v_f - Final volume.

Percentage compressibility [9]

Compressibility is the ability of powder to decrease in volume under pressure. Compressibility is a measure that is obtained from density determinations. It is also one of the simple methods to evaluate flow property of powder by comparing the bulk density and tapped density. A useful empirical guide is given by the Carr's compressibility or compressibility index.

Compressibility measures gives idea about flow property of the granules as per Carr's index which is as follows.

Table 2: Compressibility Index range

% Compressibility	Flow description
5 – 15	Excellent
12 – 16	Good
18 – 21	Fair
23 – 35	Poor
35 – 38	Very poor
< 40	Extremely poor

Hausner's ratio [10]

It provides an indication of the degree of densification which could result from vibration of the feed hopper.

Table 3: Hausner's ratio range

Hausner's ratio	Type of flow
<1.25	Good flow
1.25 – 1.5	Moderate
>1.5	Poor flow

Characterization [11]

FTIR

FTIR spectroscopy was found to be the most reliable technique for predicting the possible interaction between the drug and the polymer and excipients used for formulation. The IR spectra of physical mixtures were studied using KBr disc method.

The IR absorption spectra of the pure drug and with different excipients were taken in the range of 4000-400 cm-1 using KBr disc method. Triturate 1-2 mg of the substance to be examined with 300-400 mg, specified quantity; of finely powered and dried potassium bromide .These quantities are usually sufficient to give a disc of 10-15mm diameter and spectrum of suitable intensity by a hydraulic press. The Infrared spectrum of cefuroxime axetil was recorded by using FTIR spectroscopy and observed for characteristic peaks of drug.

Post formulation Studies

1.Thickness [12]

Thickness was determined for 20 pre-weighed tablets of each batch using a digital vernier scale (Mitutoyo - Digimatic) and the average thickness was determined in mm**.** The tablet thickness should be controlled within a ± 5% variation of a standard.

2.Weight Variation [13]

20 tablets were selected randomly from a batch and were individually weighed and then the average weight was calculated. The tablets meet the USP specifications if not more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limits.

Table 4: Limits for Weight variation

Dosage form	Average weight of tablet (mg)	% deviation
Uncoated and film coated tablets	80 mg or less	10
	More than 80 mg but not less than 250 mg	7.5
	250 mg or more	5

3. Hardness Test

The crushing load which is the force required to break the tablet in the radial direction was measured using Electrolab hardness tester. The hardness of 10 tablets was noted and the average hardness was calculated. It is given in kp or kg/cm^2.

4. Friability

If the tablet weight is ≥ 650 mg 10 tablets were taken and initial weight was noted. For tablets of weight less than 650 mg the number of tablets equivalent to a weight of 6.5 g were taken. The tablets were rotated in the Roche Friabilator for 100 revolutions at 25 rpm. The tablets were dedusted and reweighed. The percentage friability should be not more than 1% w/w according to IP and 0.5% w/w according to USP of the tablets were being tested.

The percentage friability is expressed as the loss of weight and is calculated by the formula:

% Friability = $[(W_0—W_f) / W_0] \times 100$

W_0 = Initial weight of tablets, W_f = Final weight of tablets

5. Disintegration Time [14]

The disintegration test is carried out in an apparatus containing a basket rack assembly with six glass tubes of 7.75 cm in length and 2.15 mm in diameter, the bottom of which consists of a #10 mesh sieve. The basket is raised and lowered 28-32 times per minute in a medium of 900 ml which is maintained at 37 ± 2^0C. Six tablets were placed in each of the tubes and the time required for complete passage of tablet fragments through the mesh (#10) was considered as the disintegration time of the tablet. The disintegration time that patients can experience for oral disintegrating tablets ranges from 5 to 30 sec.

6. Dissolution Studies [15]
The dissolution test was carried out in USP Apparatus Type II (paddle). The samples were drawn at 5, 10, 15, 20, 25 and 30. Fresh volume of the medium was replaced with the withdrawn volume to maintain the sink conditions. Samples withdrawn were analyzed for the percentage of drug released.

Preparation of Dissolution Medium [16]:
a. **Preparation of 0.1N HCl / pH 1.2 buffers:**
Place 85ml of 0.2M HCl dissolved in 1000ml of water.
b. **Preparation of pH 6.8 buffer**:
Place 22.4 ml of 0.2M NaOH in 1000ml of distilled water.

Preparation of standard curve:
Standard calibration curve of cefuroxime axetil in 0.1 N HCl were prepared. First dissolve 100mg of pure drug in 100ml 0.1 N HCl buffer this is primary stock solution. From the above primary stock solution pipette out 10ml of solution and again make up to 100ml this is secondary stock solution. From this secondary stock solution different concentrations of cefuroxime axetil (2, 6, 10, 14, 18, 22, 26, 30µg/mL) in 0.1 N HCl buffer were prepared & absorbance of these solutions measured at 281 nm by spectrophotometrically (Shimazdu-1700, UV/Visible spectrophotometer, Shimadzu Corp, Kyoto, Japan) using 0.1 N HCl as reference solution.

7. Wetting Time [17]
A piece of tissue paper folded double was placed in clean and dry petri plates containing 6 mL of water. The tablet was placed on the paper and the time for complete wetting of the tablet was measured in seconds.

8. Stability Studies [18,19]
The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors, such as temperature, humidity etc.
Accelerated study: The product is subjected to accelerated stability studies at 40°C±2°C/75% ±5% RH for 6 months.

Table 5: Formulation of Cefuroxime axetil tablets

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Cefuroxime axetil	150	150	150	150	150	150	150	150	150
Mannitol	30	30	30	30	30	30	30	30	30
Microcrystalline cellulose	57.2	52.2	47.2	57.2	52.2	47.2	57.2	52.2	47.2
Cross povidone	5	10	15	--	--	--	--	--	--
Sodium starch glycollate	--	--	--	5	10	15	--	--	--
Crosscaramellose sodium(Ac-di-sol)	--	--	--	--	--	--	5	10	15
Aspartame	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6
Talc	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8
Magnesium stearate	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Flavor	QS	QS	QS	QS	QS	QS	QS	QS	QS
Total weight	250	250	250	250	250	250	250	250	250

RESULTS:

Analytical Method Development

Standard plot of cefuroxime axetil in 0.1N HCl

Table 6: Standard plot of cefuroxime axetil

Concentration	Absorbance at 281 nm
2	0.091
4	0.189
6	0.288
8	0.395
10	0.501

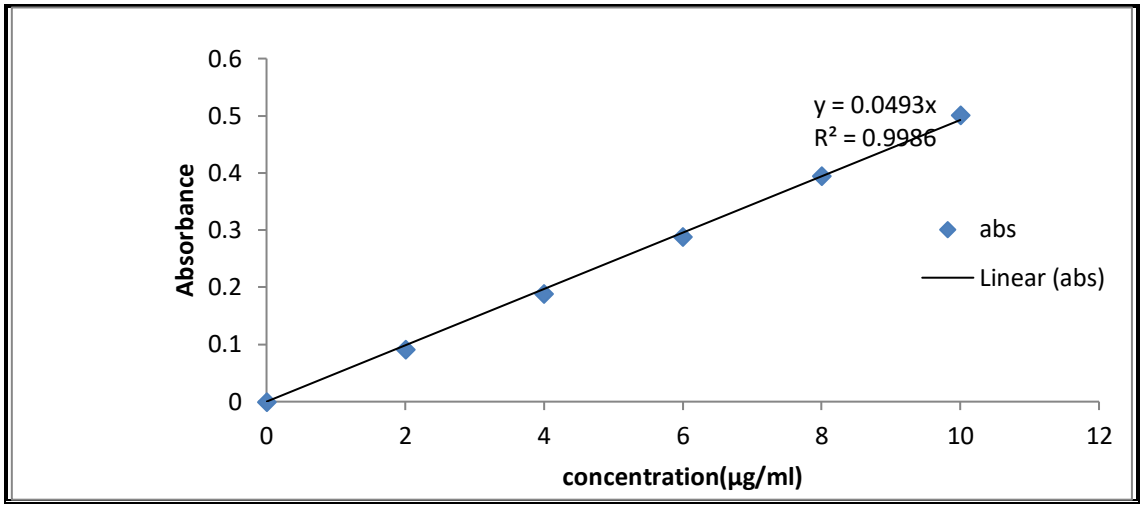

Fig.1: Standard plot in Cefuroxime axetil 0.1N HCl

Preformulation Studies of Cefuroxime Axetil Orally Disintegrating Tablets

Table 7: Preformulation studies of Tablet blend

All valueswere expressed as mean ± S.D; Number of trials (n) = 3

Formulation	Angle of repose (°)	Bulk density (gm/cm^2)	Tapped density (gm/cm^2)	Hausner's ratio	Compressibility index (%)
F1	24.55±1.052	0.633±0.007	0.721±0.009	1.136±0.22	12.23±1.033
F2	24.58±0.921	0.626±0.010	0.731±0.006	1.30±0.014	14.44±1.031
F3	23.92±1.435	0.635±0.007	0.727±0.011	1.14±0.021	14.29±1.123
F4	24.38±0.722	0.633±0.002	0.733±0.005	1.15±0.021	13.58±1.632
F5	22.96±1.495	0.633±0.006	0.728±0.012	1.14±0.014	12.98±1.102
F6	24.55±0.868	0.629±0.002	0.724±0.008	1.14±0.025	13.18±1.851
F7	23.82±0.769	0.637±0.003	0.728±0.013	1.15±0.020	14.38±1.125
F8	24.78±0.742	0.635±0.004	0.733±0.004	1.14±0.019	13.58±1.623
F9	23.96±1.495	0.637±0.005	0.729±0.014	1.14±0.015	12.98±1.105

Characterization of Cefuroxime Axetil: Fourier Transform Infrared spectroscopy

The IR absorption spectra of the pure drug was taken in the range of 4000-400 cm-1 using KBr disc method .The major peaks were reported for evaluation of purity.

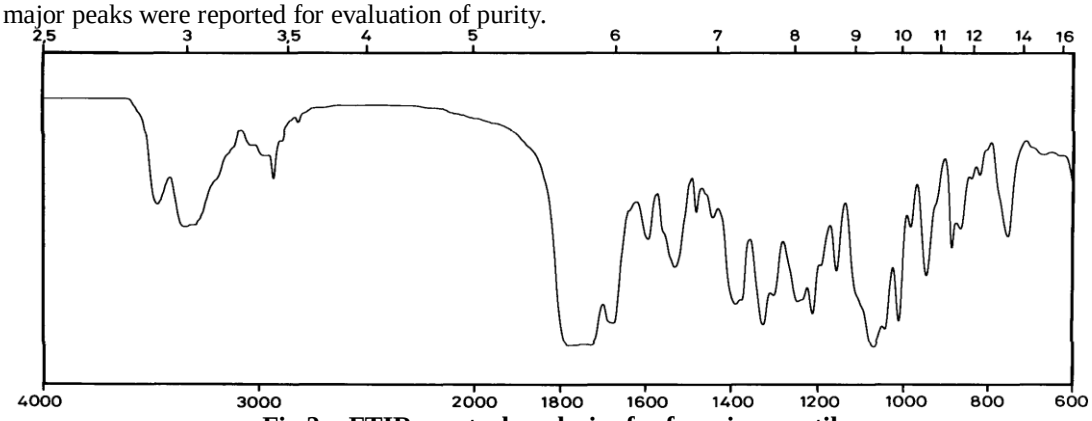

Fig.2: FTIR spectral analysis of cefuroxime axetil

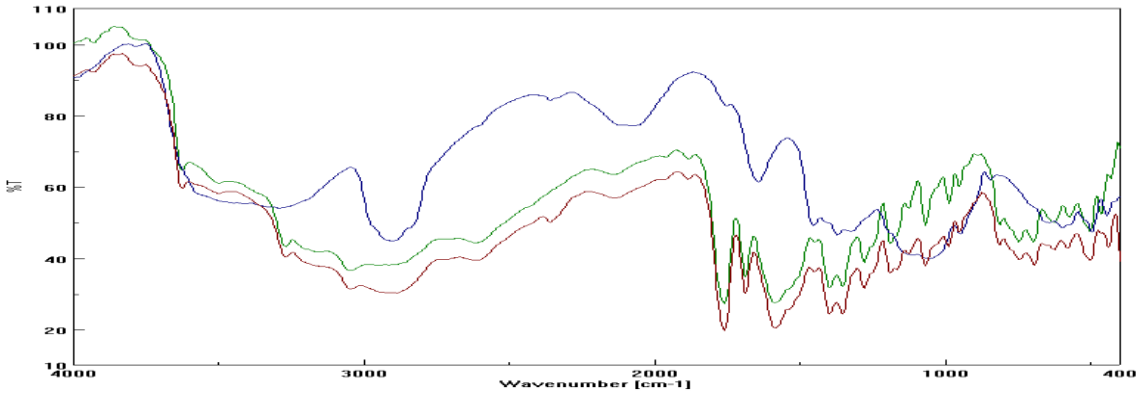

Fig.3: Overlay spectra of a) cefuroxime axetil (green), b) Ac-Di-Sol (brown) and c) Sodium starch glycolate(blue)

Post Compression Parameters

Table 8: Evaluation of cefuroxime axetil tablets

All valueswere expressed as mean ± S.D; Number of trials (n) = 3

Formulation Code	Weight Variation (mg)	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)
MRKT	240 ± 0.5	4.8±0.32	3.4 ±0.32	0.5 ± 0.11
F1	248.3±0.15	4.0±0.05	3.1± 0.85	0.25±0.21
F2	246.6±0.15	4.9±0.10	3.3±1.04	0.30±0.25
F3	242±0.2	4.1±0.10	3.1±0.86	0.27±0.02
F4	240±0.3	4.1±0.10	3±0.85	0.28±0.01
F5	248.3±0.5	4.2±0.05	3.2±0.74	0.29±0.16
F6	246.3±0.2	5.1±0.05	3.4±0.90	0.5 ± 0.11
F7	251.3±0.3	4.9±0.33	3.5 ±0.33	0.5 ± 0.10
F8	253.3±0.10	5.0±0.31	3.1 ±0.30	0.5 ± 0.21
F9	254.0±0.3	4.9±0.35	3.2 ±0.33	0.29 ± 0.23

Table 9: Evaluation of cefuroxime axetil tablets

Formulation code	Wetting Time(sec)	Disintegration Time(sec)	Content uniformity (%)
MRKT	35 ±0.5	38±0.5	101.10±0.1
F1	37±0.4	35±0.4	100.08±0.01
F2	31±0.5	32±0.5	99.38±0.23
F3	39±0.5	32±0.3	99.32±0.15
F4	34±0.3	41±0.2	100.82±0.4
F5	30±0.6	40±0.4	99.48±0.2
F6	28±0.5	39±0.4	99.58±0.6
F7	30±0.4	31±0.3	98.58±0.5
F8	29.1±0.3	30±0.2	99.58±0.3
F9	27±0.3	29±0.2	99.85±0.6

All valueswere expressed as mean ± S.D; Number of trials (n) = 3

Table 10: *In vitro* dissolution studies

Time (min)	MRKT	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0	0
5	39±0.2	32±0.4	29±0.2	36±0.2	30±0.3	36±0.6	36±0.1	32±0.1	35±0.4	38±0.2
10	60±0.3	40±0.3	40±0.1	45±0.4	42±0.4	49±0.5	51±0.2	45±0.2	51±0.3	59±0.4
15	79±03	49±0.3	45±0.2	52±0.3	48±0.5	53±0.2	59±0.2	53±0.2	56±0.3	76±0.2
20	90±0.2	72±0.2	70±0.4	78±0.4	74±0.2	76±0.2	78±0.4	68±0.4	78±0.4	89±0.2
25	99±0.4	82±0.5	80±0.6	84±0.2	85±0.2	88±0.3	92±0.2	90±0.2	92±0.2	98±0.4

Invitro drug release studies of formulations

All values are expressed as mean of ± S.D; Number of trials (n) = 3

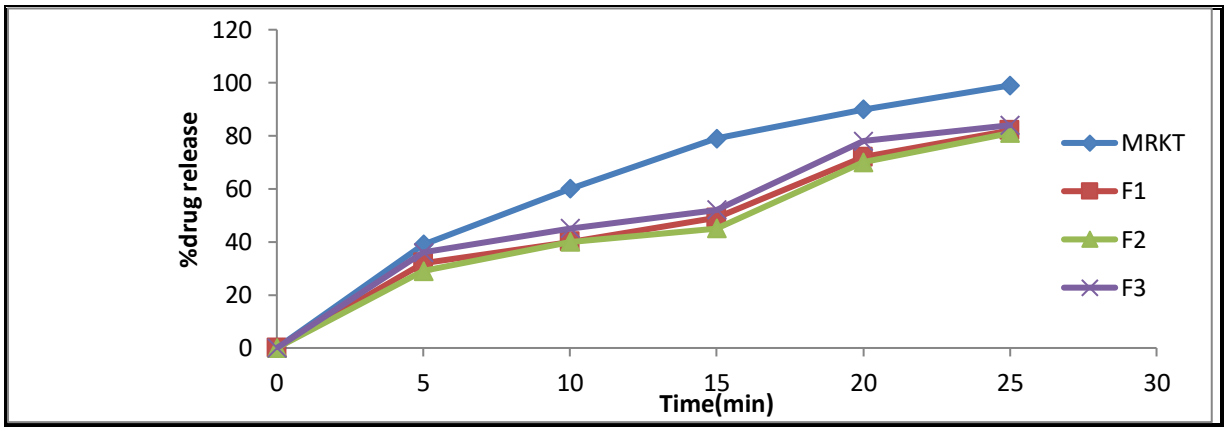

Fig.4: Plot for *in vitro* drug release for formulation F1-F3 and marketed tablet

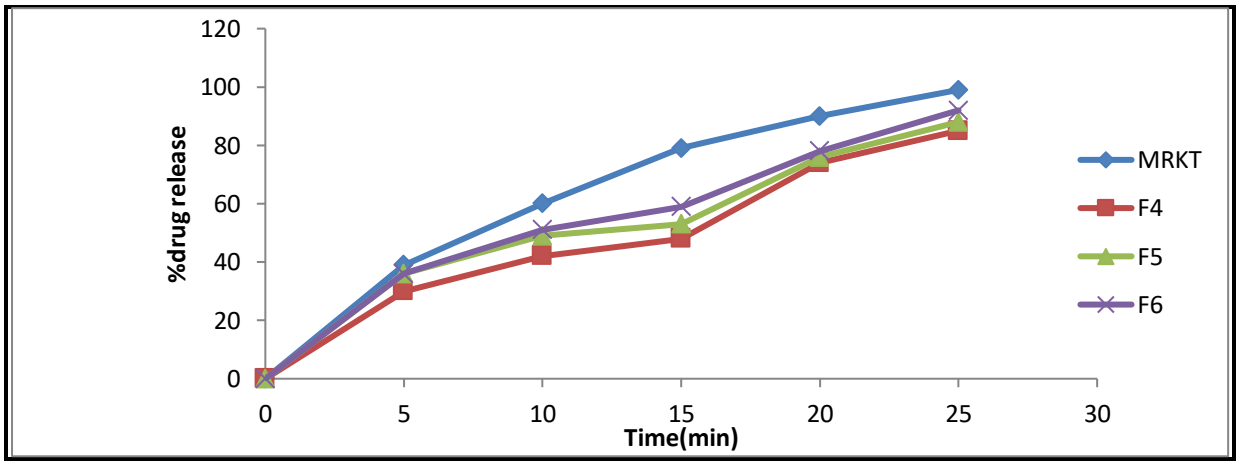

Fig.5: Plot for *in vitro* drug release for formulation F4-F6 and marketed tablet

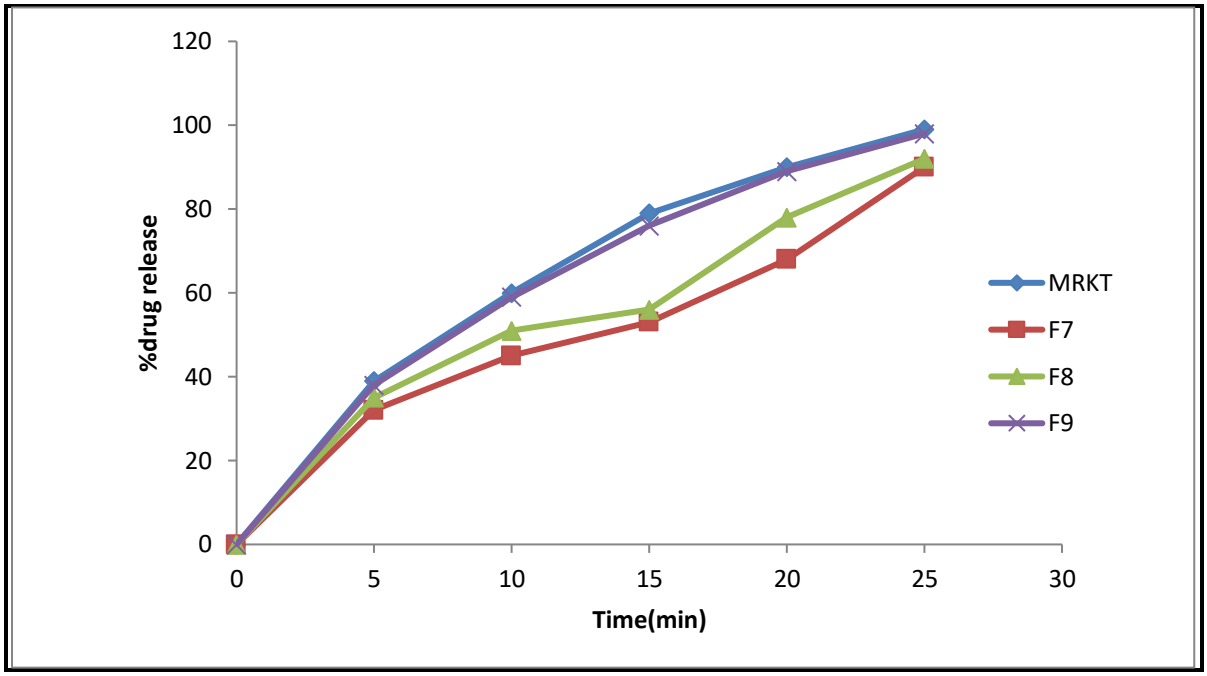

Fig.6: Plot for *in vitro* drug release for formulation F7-F9 and marketed tablet

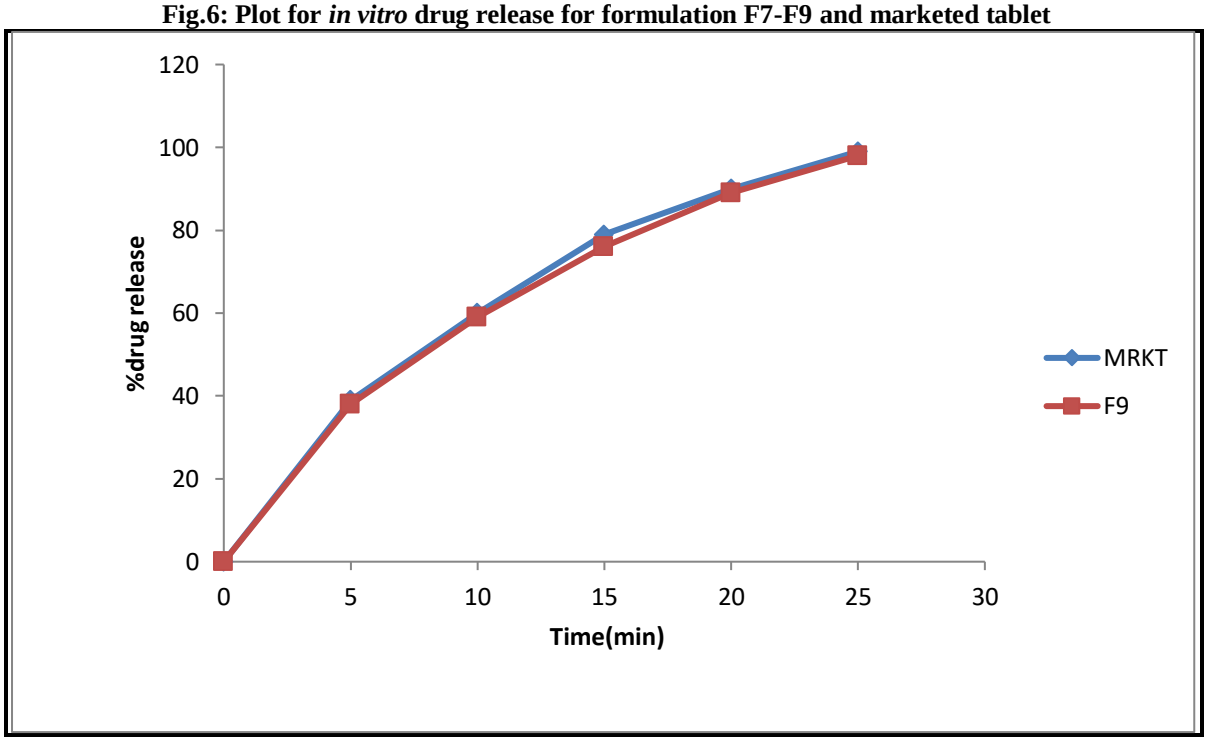

Fig.7: Plot for *in vitro* drug release for marketed and F9

DISCUSSION:

Evaluation of API

Organoleptic Evaluation

Cefuroxime axetil is White to off-white powder.,Taste: slightly bitter,Odour: Characteristic odour

Characterization

FTIR spectroscopic Analysis

The IR absorption spectra of the pure drug was taken in the range of 4000-400 cm-1 using KBr disc method .The major peaks were reported for evaluation of purity.

Major peaks were observed at 1714.7cm-1, 1609.53 cm-1, 1540.73cm-1 ,1428.33 cm-1 and 838.33cm-1 etc.

FT-IR spectrum for Cefuroxime axetil

Major peaks were observed at 1719.78 cm-1, 1610.24 cm-1, 1542.56 cm-1,1484.13 cm-1 and 866.88 cm-1 etc.

FT-IR spectrum for final blend:

Major peaks were observed at 1716.19cm-1, 1634.91 cm-1, 1569.86 cm-1,1481.2 cm-1 and 866.53 cm-1 etc.

From the above peaks of FTIR graphs it was observed that no peak changes in drug, inclusion complex and final blend.

Preformulation STUDIES

Bulk characteristics of cefuroxime granules

Angle of repose of granules are in the range of 22.96 ± 1.49 to 24.58 ± 0.92

Bulk density was in the range of 0.626±0.01 to 0.633±0.007

Tapped density was in the range of 0.721±0.009 to 0.733±0.005

Percentage compressibility was in the range of 12.23±1.633 to 14.44±1.031

Hausner's ratio was in the range of 1.136±0.021 to 1.30±0.014.

From the above results it was observed that F5 formulation having better bulk characteristics than compared to remaining formulations.

Evaluation of Oral Orodispersible Tablets of Cefuroxime Axetil

Cefuroxime axetilorodispersible tablets were compressed with 3.5 mm round shaped standard punch.

Weight variation was found to be in the range of 220– 240 mg. Thickness was found to be 3.0 – 3.6, hardness was found to be in the range 3 – 4 kg/cm^2 indicating good mechanical strength, friability was within the USP limits, drug content was found to be within 95- 105% which is acceptable limits, *in vitro* disintegration time of the tablet were evaluated and found to be between 29- 41 sec. Weight variation was in the range 220- 250 mg.

Dissolution test

The dissolution results show that there was an hike in the dissolution velocity of the tablets.

The maximum drug release was observed at 25 min which is acceptable and almost equal to the marketed sample. Formulation F9 having higher concentration of Ac-di-sol showed more drug release.

Statistical treatment of data

f_1 is the difference factor and f_2 is the similarity factor. The limits for f_1 are 0- 10 and for f_2 50- 100.

The f_1 value was found to be more than the limits indicating that the drug release of F6 formulation was different from that of the marketed formulation.

The f_2 value was found to be less than the limits indicating that the drug release of F9 formulation was not similar to the marketed formulation and the drug release is almost equal to the marketed formulation.

Discussion of results

Weight variation was in range of 24.3±1.6 to 254.3±1.5

Hardness was in range of 3.0±0.05 to 4.1±0.1.

Weight variation and hardness of cefuroxime axetil Tablets were within range.

Length and breadth of tablet was as per the punch dimension.

Percentage friability of tablet was evaluated in 100rpm and tablet passed the friability test.

Tablets from each batch showed uniformity of weight as per IP limits. Each sample was analyzed in triplicate (n = 3).

Content uniformity was done as per IP and the values were satisfactory.

Wetting time was in the range of 30 to 39.3 as wetting time increases disintegration time of tablet decreases. Wetting time of F9 withsuperdisintegrantsAc-di-sol shows lower values hence higher disintegration time. Formulations containing of Ac-di-sol showed somewhat lower wetting time than other batches hence showed satisfactory disintegration time..

Disintegration Time of tablets was evaluated and was found to be in the range of 29±1 to 41±1.52. Lower disintegration time was for F9 formulations containing Ac-di-sol as superdisintegrant. Formulations containing of Ac-di-sol in higher quantity showed good disintegration time. Formulations containing of sodium starch glycolate showed higher disintegration time compared with other formulations.

In vitro dissolution studies:

Superdisintegrants has a dominant role in disintegration as well as drug release form orodispersible tablet. Hence all the formulations showed better and satisfactory drug release profile.

Due to the swelling and wicking action of all the superdisintegrants the tablets showed better disintegration time which in turn showed good drug release from tablet formulations.

The Dissolution study of various batches from F1-F9 shows that cefuraxmineaxetil release from tablets containing Ac–di-sol at higher concentrations showed higher drug release. As concentration of Ac- di- sol decreased it showed lower drug release. The formulation F9 which contain Ac- di- sol showed 98% of drug release. The formulation F3 with crospovidone showed 84% of drug release.The formulation F6 with sodium starch glycolate showed 92% of drug release. Drug release was very much less for formulations which contain sodium starch glycolateand crospovidone when compared with formulations containing croscaramellose sodium.
The formulation F9 showed a comparative release profile as the marketed formulation. Hence it is selected as the best formulation.

Further we can say that as concentration of superdisintegrants increases it causes higher % of drug release.

CONCLUSION:

Of the three superdisintegrantsAc-di-sol showed better performance in terms of disintegration time when compared to crospovidoneand sodium starch glycolatein case of cefuroxime axetil.
It was concluded that the formulations containing Ac-di-sol as super disintegrants can be proved to be ideal formulation considering all the evaluation parameters mainly wetting time, *in vitro* disintegration time and *in vitro* dissolution studies.
Superdisintegrants has a dominant role in disintegration as well as drug release form oro-dispersible tablet. Hence all the formulations showed better and satisfactory drug release profile.
Due to the swelling and wicking action of all the superdisintegrants the tablets showed better disintegration time which in turn showed good drug release from tablet formulations.
The Dissolution study of various batches from F1-F9 shows that cefuraxmineaxetil release from tablets containing Ac–di-sol at higher concentrations showed higher drug release. As concentration of Ac- di- sol decreased it showed lower drug release. The formulation F9 which contain Ac- di- sol showed 98% of drug release. The formulation F3 with crospovidone showed 84% of drug release.The formulation F6 with sodium starch glycolate showed 92% of drug release.
Drug release was very much less for formulations which contain sodium starch glycolate and crospovidone when compared with formulations containing croscaramellose sodium.
The formulation F9 containing Ac-di-sol showed a comparative release profile as the marketed formulation. Hence it is selected as the best formulation.

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