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FORMULATION AND EVALUATION OF FEXOFENADINE IMMEDIATE RELEASE TABLETS

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ABSTRACT

This work, deals with formulation and evaluation of Fexofenadine immediate release tablets. Fexofenadine is an over-the-counter second-generation antihistamine used in the treatment of various allergic symptoms. Tablets were prepared by wet granulation method; the powder blends were initially evaluated for various pre-compression parameters and later evaluated for post-compression parameters like weight variation, thickness, hardness, drug-content and *in vitro* drug release. All the results were found to be within the acceptable limits. A constant weight of 30mg Fexofenadine was fixed for all the formulations F1-F10 a As the amount of disintegrant i.e., pre gelatinized starch, CCS was increased for F6 and F8 formulations the cumulative % drug release of these two batches was found to be greater than 95% at 20mins time interval. The effect of disintegrant used in the formulations is seen clearly. The dissolution data was subjected to regression analysis and were fitted to kinetic models, viz., Zero order and First order. It was following First order (R^2=0.835). It describes the systems where the drug release rate depends on its concentration. The release kinetics follows first order and Higuchi's model of kinetics with an R^2 of 0.9626, 0.8896 respectively.

KEYWORDS: Fexofenadine, Immediate release, *In-vitro*, pre gelatinized starch, Kinetics.

INTRODUCTION

The Oral route is one of the most preferred after route for the systemic effect due to its ease of ingestion, simple, safest, convenient, non-invasive, versatility and most importantly, patient compliance. Solid oral delivery systems are cheaply manufactured since they don't require any kind of sterile conditions.[1] According to the current scenario, increased focus and interest generated in the area of controlled release and targeted drug delivery system in recent years, tablet dosage forms that are intended to be swallowed whole, disintegrate, and release their medicaments fast and furiously in the gastrointestinal tract.[2] An ideal dosage regimen of drug therapy is the one, which immediately nab the desired therapeutic concentration of drug in plasma (or at the site of action) and maintains it constantly for the entire duration treatment.[3] Of late, the scientists have focused their attention on the formulation immediately released tablet. The effort of developing a rapidly disintegrating tablet is accomplished by using suitable diluents and super disintegrants.[4] The term 'immediate release' pharmaceutical formulation is the formulation in which the rate of release of drug and/or the absorption of drug from the formulation, is neither appreciably, nor intentionally, retarded by galenic manipulations.[5,6] Immediate release tablets are invented to disintegrate and release their dosage form with no special rate controlling features, such as special coatings and other techniques. Immediate release tablets are those which disintegrate swiftly and get dissolved to release the medicaments.[7] Immediate release drug delivery system offers improved compliance/added convenience, solubility, stability, bioavailability, allows high drug loading, cost-effective, ability to provide advantages of liquid medication in the form of solid preparation.[8] There are disadvantages along with the advantages like frequent dosing is necessary for a drug with a short half-life, drug release at a time may produce high plasma concentration which may produce toxicity.[9] Granulation technique is a process of size enlargement in which small particles convert into larger agglomerates and make it physically stronger. Wet granulation process make easy fine particles run into severity-feed drug manufacturing. Usually, immediate release formulation is granulated with addition into fine particles accumulation an aqueous solution of a binding polymer.[10]

1. MATERIALS AND METHODS

All the chemicals and materials used in the present investigation were Analytical Reagent (AR) & Laboratory Reagent (LR) grade available in the

laboratory and supplied by the manufacturer. The details are given below.

Table No 1: List of materials used in the study with their supplier names.

S.NO	NAME OF THE INGREDIENTS	CATEGORY
1	Fexofenadine	Drug
2	Magnesium Stearate	Lubricant
3	Water	Solvent
4	Pre Gelatinized Starch	Binder, Disintegrant
5	Micro Crystalline Cellulose	Diluent
6	Cross Povidone	Super Disintegrant
7	CCS	Super Disintegrant
8	Aerosil	Glidant
9	Mannitol	Diluent
10	0.1N HCl	Dissolution Medium

1.1 EXPERIMENTAL METHODS

1.1.1 Preparation of 0.1N HCl: Accurately measured 8.5ml of concentrated hydrochloric acid was transferred into a 1000ml volumetric flask and small amount of distilled water was added to it. And the final volume was made up to 1000ml with distilled water. The pH of the solution was adjusted to 1.2 with dilute HCl or dilute NaOH solution.

1.1.2 Preparation of standard stock solution of Fexofenadine in 0.1N HCL: 100mg of Fexofenadine was accurately weighed and transferred into a 100ml volumetric flask and 20ml of 0.1N HCl was added to it and dissolved, finally the volume was made up to 100ml with 0.1N HCl (1000µg/ml). The standard solution of Fexofenadine was subsequently diluted with 0.1N HCl to obtain a series of dilutions containing 10, 20, 30, 40&50µg/ml. The absorbance of the above dilutions were measured by using UV spectrophotometer at 220nm using 0.1N HCl as the blank.

1.1.3 Determination of melting point: The melting point of Fexofenadine drug was determined by using capillary method.

1.1.4 Physical Appearance: The general appearance of tablets, its visual identity and overall elegance is essential for consumer acceptance. The control of general appearance of tablet involves measurement of number of attributes such as tablet size, shape, colour, presence or absence of odour, taste, surface texture and consistency of any identification marks.

2. EVALUATION OF PREFORMULATION STUDIES: The final blend of all formulations was evaluated for bulk density, Tapped density, Compressibility index, Hausner's ratio and angle of repose.

2.1 Bulk density: About 5gm of blend was passed through a sieve no.40 to break up agglomerates and introduced into a dry 50 ml measuring cylinder .Without compacting, the powder was carefully leveled and the unsettled apparent volume (Vo) was read. The bulk density was calculated, in gram per ml, using the formula.

Bulk density =M / V_o

Where, M=Total mass of the Blend; V_o= Initial volume of blend

2.2 Tapped density: After carrying out the procedure as given in the measurement of bulk density the cylinder containing the sample was tapped using a mechanical tapped density tester. The cylinder was tapped until no change in volume and then tapped volume Vf, was measured to the nearest graduated unit. The tapped density was calculated, in grams per ml using formula.

Tapped density= M / Vf

Where, M=Total mass of the Blend; Vf = Final volume of the Blend

2.3 Measurement of powder compressibility: The Carr's index and Hausner's ratio are measures of the propensity of a powder to be compressed**.**

Carr's index = [(Tapped density-Bulk density)/Tapped density]*100,

Hausner's ratio =Tapped density/Bulk density

2.4 Angle of repose: The fixed funnel method was employed to measure the angle of repose. The funnel height was maintained approximately 2-4 cm from the top of the powder pile in order to minimize the impact of falling powder on the tip of the cone. The blend was carefully pored through the funnel. The height 'h' of the pile from base and radius 'r' of the base of the conical pile was measured .The angle of repose α, was calculated using formula**.**

$\alpha = \tan^{-1} h / r$

Table No 2: Scale of flow properties.

Flow Character	Angle of Repose	Hausner Ratio	Compressibility Index (%)
Excellent	25-30°	1.00-1.11	≤10
Good	31-35°	1.12-1.18	11-15
Fair	36-40°	1.19-1.25	16-20
Passable	41-45°	1.26-1.34	21-25
Poor	46-55°	1.35-1.45	26-31
Very Poor	56-65°	1.46-1.59	32-27
Very, Very Poor	≥66°	≥1.60	≥38

2.5 Hardness Test: This is the force required to break a tablet in a diametric compression. Hardness of the tablet is determined by Stock's Monsanto hardness tester which consists of a barrel with a compressible spring. The pointer moves along the gauze in the barrel fracture.

2.6 Tablet size & Thickness: Control of physical dimensions of the tablets such as size and thickness is essential for consumer acceptance and tablet-tablet uniformity. The diameter size and punch size of tablets depends on the die and punches selected for making the tablets. The thickness of tablet is measured by Vernier Callipers scale. The thickness of the tablet related to the tablet hardness and can be used an initial control parameter. Tablet thickness should be controlled within a ±5%. In addition thickness must be controlled to facilitate packaging.

2.7 Friability: This test is performed to evaluate the ability of tablets to withstand abrasion in packing, handling and transporting. Initial weight of 20 tablets is taken and these are placed in the friabilator, rotating at 25rpm for 4min. The difference in the weight is noted and expressed as percentage. It should be preferably between 0.5 to 1.0%.

%Friability = $(W_1-W_2)/W_1$ X 100

Where, W_1= weight of tablets before test; W2 = weight of tablets after test

2.8 Weight Variation of Tablets: It is desirable that all the tablets of a particular batch should be uniform in weight. If any weight variation is there, that should fall within the prescribed limits. Twenty tablets were taken randomly and weighed accurately. The average weight was calculated by,

% Wt. Variation = [(Individual wt.– Avg. wt.)/Avg. wt.] * 100

2.9 Drug content: From each formulation the powder equivalent to 10 mg of drug was taken and transferred to 100 ml of volumetric flask. Then, the volume was made up to 100 ml with 0.1N HCL. Vigorous shaking was done to dissolve the powdered material in 0.1N HCL. Samples were filtered using filter paper. After proper dilution, absorbance values were measured at the maximum wavelength (λ_{max}) using an ultraviolet-visible (UV-VIS) spectrophotometer at 220 nm.

2.10Disintegration Test: Disintegration time is considered to be one of the important criteria in selecting the best formulation. To achieve correlation between disintegration time *in-vitro* and *in-vivo*, several methods were proposed, developed and followed at their convenience. One tablet was placed into each tube and the assembly was suspended into the 1000ml beaker containing 0.1N HCL maintained at 37±2^{o}c and operated the apparatus for 15 minutes. The assembly was removed from the liquid and the tablets were observed. If one or two tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not less than 16 of the total of 18 tablets tested are disintegrated.

2.11*In vitro* drug release studies: The *in vitro* drug release study was performed for all the prepared tablets using USP Type II dissolution apparatus under the following conditions.

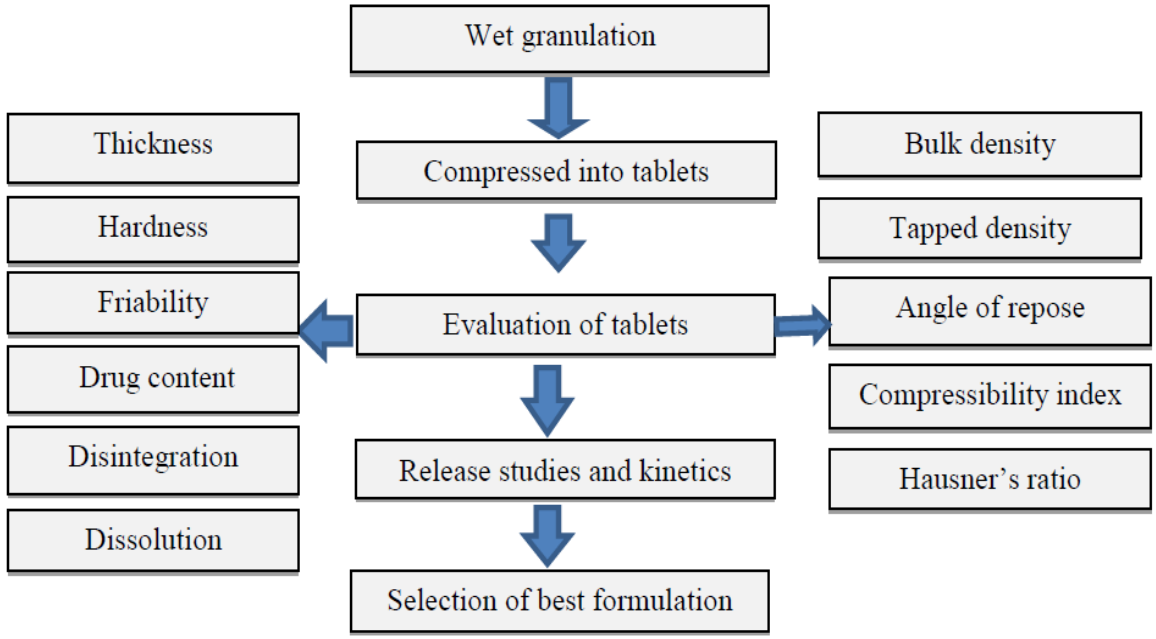
Table no 3: Conditions of dissolution testing.

Test parameters	Specifications
Medium	0.1N HCL
Rotation speed	50 rpm
Temperature	37.5 ± 0.5°C
Sampling volume	5 ml

Table No 4: Composition of formulations used in the present study F1-F10.

Ingredients (Mg)	Formulation Code									
INTRAGRANULAR										
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Fexofenadine	30	30	30	30	30	30	30	30	30	30
MCC PH 101	125.6	126.2	122.8	127.6	125.2	117	121	119.7	118.7	123.8
Mannitol	30	30	30	30	30	30	30	30	30	30
CCS	-	-	-	2.4	3.6	7.6	5.6	6.9	3.86	5.84
CP	2.4	3.6	4.8	-	-	-	-	-	-	-
BINDER SOLUTION										
Pre Gelatinized starch	22	23	25	24	24	27	23	25	24	24
Water	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s
EXTRAGRANULAR										
MCC PH 102	20	20	20	20	20	20	20	20	20	20
CCS	-	-	-	2.4	3.6	4.8	4.8	4.8	3.84	5.76
CP	2.4	3.6	4.8	-	-	-	-	-	-	-
Magnesium stearate	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Aerosol	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Total weight(mg)	240	240	240	240	240	240	240	240	240	240

3. METHOD OF FORMULATION DEVELOPMENT



Wet Granulation Method: Wet granulation is a process of using a liquid binder to lightly agglomerate the powder mixture. The amount of liquid has to be properly controlled, as over-wetting will cause the granules to be too hard and under-wetting will cause them to be too soft and friable. Aqueous solutions have the advantage of being safer to deal with than solvent-based systems but may not be suitable for drugs which are degraded by hydrolysis.

Extra Granulation: It is more common for the disintegrant to be mixed with the dry granules before tablet compression. This procedure will contribute to an effective disintegration of the tablet into small fragments.

Intra Granulation: Disintegrant can be mixed with other ingredients prior to granulation and thus incorporated into the granules.

4. Procedure for wet granulation

Step 1: Weigh the all ingredients in required quantity and then, pass through sieve no #40 and bend the mixture (Drug, MCC, Mannitol) in double cone blender for 15min.

Step 2: Preparation of binder solution: Take the required quantity of pre gelatinized starch and colour in dissolve in purified water.

Step 3: Addition of binder solution to the above mixture and the wet mass was sieved through #40 sieve and it is dried in an oven for 2 hours until the moisture is below 2%.

Step 4: Extra granular portion to the above dried granules was done by passing through #40 and the mixture was blended for 15min in double cone blender.
Step 5: Perform the flow properties evaluation of the granules.
Step 6: Tablets were compressed in round punches 9mm diameter (Compression machine Cadmach 16 station rotatory compression machine).

5. RESULTS AND DISCUSSION

The details of results and discussion of analytical method, formulation methods and evaluation techniques were given in the following sections.

5.1 ANALYTICAL METHOD

Suitable analytical methods were developed for the drug using UV spectrophotometer in 0.1N hydrochloric acid solution. The wavelength maxima of absorption was found to be 220nm. The Fexofenadine obeyed the Beer's-Lambert's Law in the concentration range of 10-50µg/ml (Figure No: 1) at this wavelength. This is well correlated with the reported value (220nm).

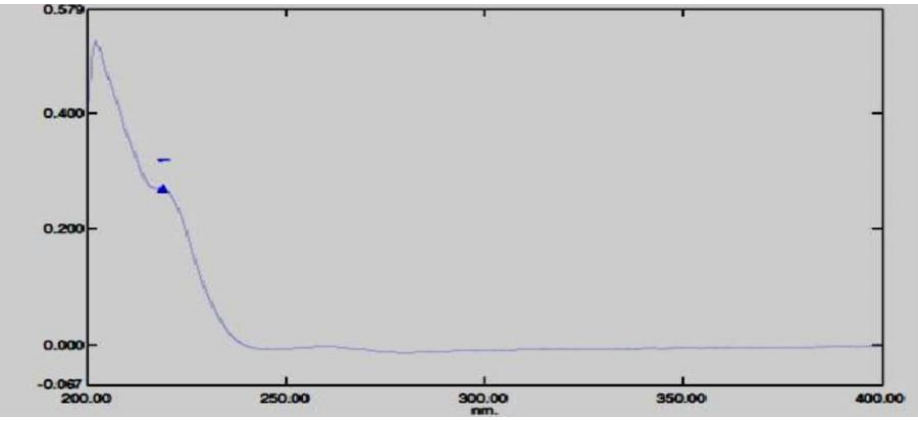


Figure No. 1 UV spectrum of Fexofenadine in 0.1N HCl.

Table No. 5 Data for standard plot of Fexofenadine in 0.1N HCl.

S.No	Concentration (µg/ml)	Absorbance
1	0	0.00±0.000
2	10	0.112±0.112
3	20	0.121±0.212
4	30	0.012±0.328
5	40	0.123±0.439
6	50	0.134±0.55

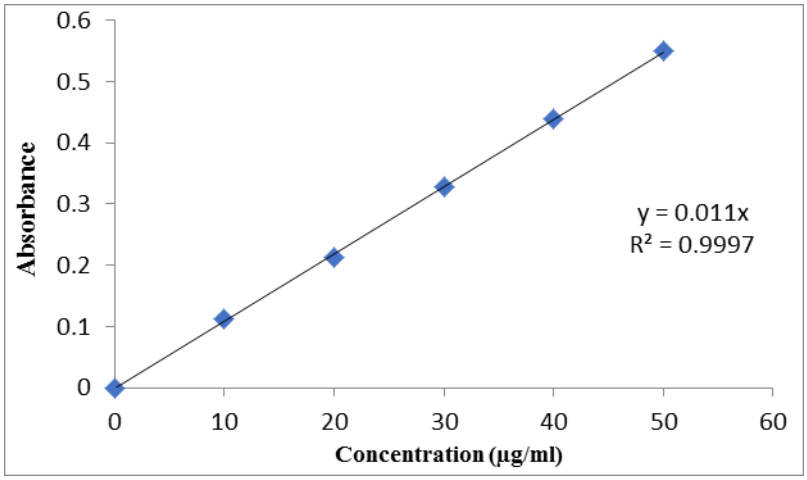


Figure No. 2 Standard plot of Fexofenadine in 0.1N HCl.

Standard plot of Fexofenadine in 0.1N hydrochloric acid was given in figure no 2 indicated that the response was linear over a range of 10-50µg/ml (R^2 = 0.999).

Organoleptic properties

Table No. 6 Results of Organoleptic Properties.

S. No	Parameter	Result
1	Color	White to off White color
2	Odor	Odorless
3	Appearance	Crystalline powder

Determination of melting point: The melting point of Fexofenadine was determined by capillary tube method and it was found to be 149.5ºC and matching with literature value of 148-150ºC.

FT-IR analysis spectra of Fexofenadine pure drug: FT-IR spectra was recorded. The spectra was scanned over the wave number range of 4000-400cm^{-1}. The FT-IR analysis of the drug reveal its characteristics stretching and bending bands and were compared to the standard values which were well collaborated with the reported values and was shown in figure no.3 and table no.7.

Table No. 7: FT-IR Interpretation of Fexofenadine Hydrochloride.

Functional group	FTIR Bands, cm^{-1}	
	Present analysis	Standard
O-H (carboxylic acid)	3074.53-3294.42	2400-3400
C – H (Aliphatic)	2927.94	2960-2850
C = O (Aliphatic)	1705.07	1870-1660
C = N (Aromatic)	1276.88	1600-1430

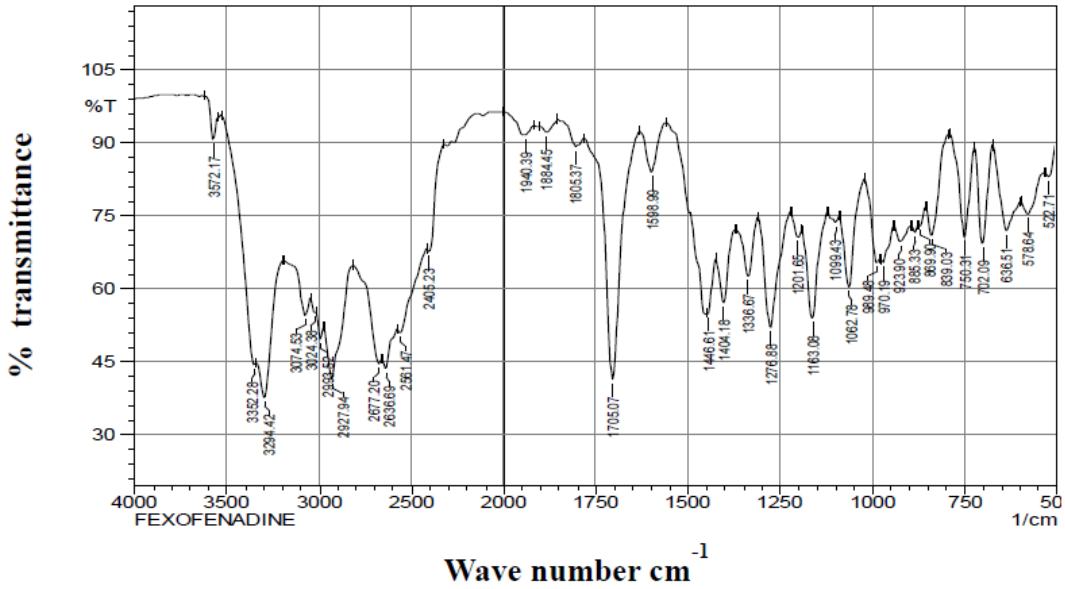


Figure No. 3 FTIR Spectra of Fexofenadinez.

Initially the powder blends were prepared and the prepared powder blend was evaluated for pre-compression parameters. The results of pre-compression parameters were mentioned in table no. 8.

Table No. 8 Evaluation Data of Pre-compression Parameters of Blend

Code	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Hausner's ratio	Carr's Index (%)	Angle of Repose(θ)
F1	0.541±0.123	0.691±0.236	1.276±0.213	16.62±0.202	34^0
F2	0.484±0.166	0.615±0.236	1.27±0.025	14.30±0.021	33^0
F3	0.710±0.121	0.873±0.561	1.25±0.123	12.714±0.021	31^0
F4	0.712±0.264	0.870±0.003	1.206±0.213	15.126±0.251	32^0
F5	0.718±0.235	0.871±0.263	1.223±0.002	14.513±0.002	30^0
F6	0.410±0.002	0.483±0.256	1.178±0.236	15.113±0.001	32^0
F7	0.420±0.243	0.462±0.001	1.131±0.231	15.010±0.250	35^0
F8	0.541±0.296	0.691±0.521	1.276±0.002	11.62±0.502	34^0
F9	0.450±0.154	0.585±0.120	1.300±0.052	13.07±0.321	31^0
F10	0.484±0.042	0.619±0.021	1.266±0.652	14.33±0.003	32^0

Evident from the results shown in table no 8 granules of all batches F1-F10 showed good to excellent flow properties and all the pre-compression values were within the limits. The angle of repose values were ranged from 30-35 and Carr's index values ranged from 11-16 and Hausner's ratio ranged between 1.1 – 1.3.

Table No 9: Data For Physico-Chemical Properties Or Post-Compression Studies.

Code	Weight Variation	Hardness (kg/cm^2)	Friability (%)	Thickness (mm)	Drug Content	Disintegration Time (min)
F1	234±0.123	6.4±0.020	0.72±0.256	2.6±0.210	99.28±0.256	3.1±0.852
F2	237±0.002	6.3±0.321	0.68±0.154	2.6±0.002	97.16±0.285	2.6±0.005
F3	238±0.0521	5.8±0.005	0.69±0.451	2.7±0.262	101.1±0.651	2.4±0.235
F4	242±0.002	5.6±0.212	0.66±0.235	2.75±0.125	97.68±0.002	2.7±0.124
F5	238±0.124	5.7±0.235	0.68±0.238	2.6±0.001	99.41±0.256	2.3±0.120
F6	239±0.152	6.4±0.012	0.65±0.059	2.62±0.121	98.19±0.001	1.4±0.621
F7	237±0.563	5.8±0.541	0.67±0.260	2.6±0.008	102.6±0.002	1.0±025
F8	236±0.365	5.6±0.652	0.69±0.650	2.56±0.231	99.5±0.562	1.2±0.365
F9	243±0.189	6.4±0.256	0.70±0.251	2.59±0.008	99.6±0.256	1.3±0.210
F10	241±0.001	5.9±0.002	0.64±0.124	2.56±0.050	98.5±0.010	2.0±0.012

All the prepared tablets of Fexofenadine were evaluated. The weight variation of all the tablets was found to be uniform with low values of standard deviation and within the prescribed IP limits of ±7.5%. The hardness of the tablet formulations was found to be in the range of 5 to 6.5 kg/cm^2. The friability values were found to be in the range of 0.50 to 0.72 %. The low value of standard deviation indicates uniform drug content within the tablets. The percent drug content of all the tablets was found to be in the range of 97.16 to 101.1 percent (which was within the acceptable limits of ±5%).

Table No. 10: Cumulative % Drug Release Data for F1, F2, F3.

TIME (MIN)	F1	F2	F3
0	0±0.000	0±0.000	0±0.000
5	26±0.012	40±0.001	38±0.256
10	34±0.256	52±0.231	68±0.021
15	51±0.001	63±0.040	79±0.008
20	58±0.009	71±0.621	83±0.895
25	64±0.215	78±0.230	88±0.230
30	76±0.210	83±0.102	93±0.251
35	88±0.265	94±0.520	97±0.26

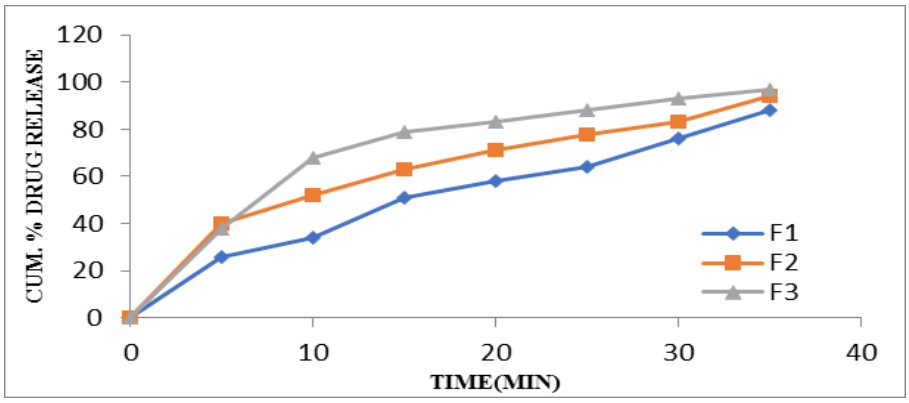


Figure No. 4 *In-vitro* Drug Release Profile of Formulations F1, F2, F3.

From the above obtained cumulative drug release data it is evident that the formulations F1, F2, F3 was showing cum % drug release greater than 85 at 35min time interval for F1 and 94%, 97% for F2, F3 batches respectively. We cannot consider these three batches as the optimized batches because the cumulative % drug release was not even greater than 95% at 15-20 minutes. CP was used as disintegrant here and because of addition of CP, swelling of the tablet occurred when these three batches tablets came into contact with the dissolution medium. The amount of cross povidone (CP) & pre gelatinized starch used in F3 batch was more in comparison with the F1 &F2 batches. As the amount of CP & pre gelatinized starch was increased the cumulative percentage drug release was increased.

Table No.11: Cumulative % Drug Release Data for F4, F5, F6.

TIME (MIN)	F4	F5	F6
0	0±0.000	0±0.000	0±0.000
5	26±0.025	46±0.251	74±0.210
10	33±0.251	58±0.020	88±0.0120
15	47±0.215	67±0.264	93±0.242
20	56±0.256	73±0.025	100±0.230
25	68±0.212	87±0.120	-
30	79±0.210	94±0.521	-
35	86±0.010	99±0.230	-

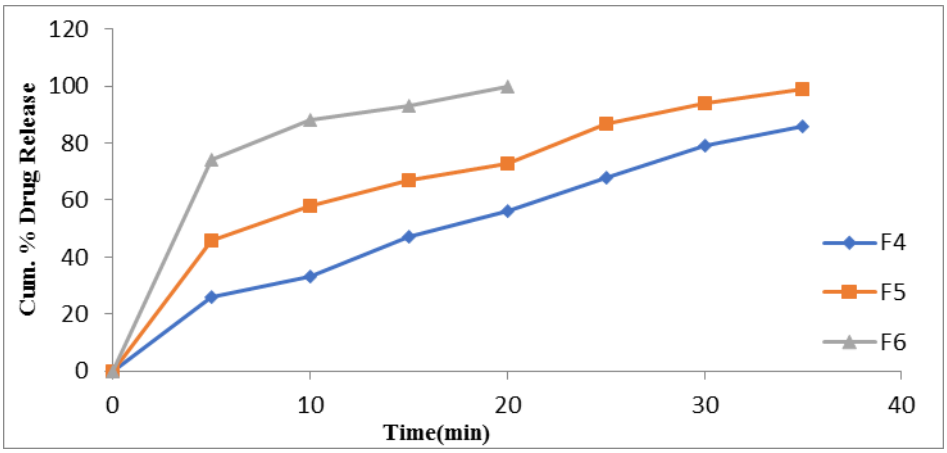


Figure No. 5: *In-vitro* Drug Release Profile of Formulations F4, F5, F6.

100% cumulative drug release was obtained for F6 batch where as 86% and 99% drug release was seen for F4 & F5 batches respectively. The amount of cross povidone was zero for all the three batches and croscarmellose sodium was varied here, greater amount of CCS was used in F6 batch. CCS acts as super disintegrant, the hydrostatic pressure is increased by water wicking phenomena when CCS is used in the wet granulation technique. Rapid disintegration of the tablet (F6) was observed due to the pressure build up inside the tablet. Pre gelatinized starch produces better disintegrant properties than natural starches. As the amount of CCS & pre gelatinized starch were increased the cumulative percentage drug release was increased.

Table No. 12: Cumulative % Drug Release Data for F7, F8, F9, F10.

TIME (MIN)	F7	F8	F9	F10
0	0±0.000	0±0.000	0±0.000	0±0.000
5	55±0.213	53±0.023	28±0.023	32±0.250
10	63±0.125	66±0.562	36±0.256	43±0.365
15	69±0.002	89±0.214	49±0.015	50±0.258
20	78±0.012	94±0.231	57±0.0210	65±0.145
25	86±0.320	100±0.012	68±0.350	73±0.140
30	91±0.056	-	75±0.023	82±0.021
35	98±0.265	-	83±0.245	91±0.268

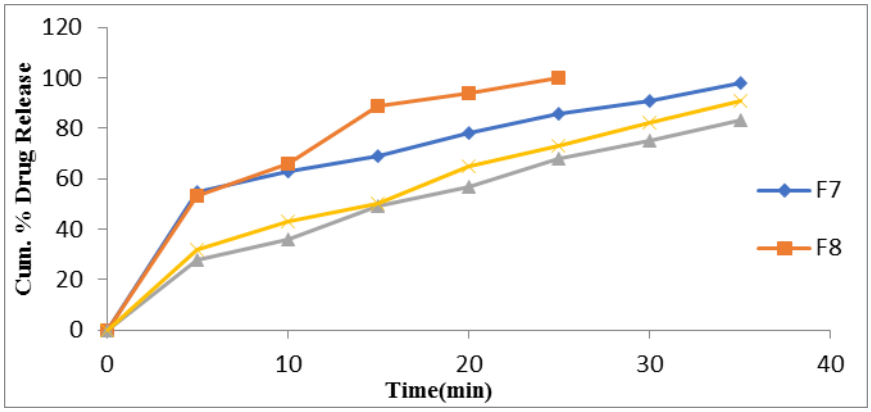


Figure No. 6 *In-vitro* Drug Release Profile of Formulations F7, F8, F9 and F10.

When comparing the cumulative % drug release data obtained from the F7, F8, F9, F10 batches, F8 batch showed 100% drug release within 25 minutes time interval. The amount of CCS and CP used in this batch are greater than the F7, F9, and F10. The effect of CCS and CP can be seen very clearly.

Table No. 13: Comparison of cumulative % Drug Release Data for F6, F8.

TIME (MIN)	F6	F8
0	0±0.000	0±0.000
5	74±0.125	53±0.267
10	88±0.268	66±0.155
15	93±0.895	89±0.795
20	100±0.168	94±0.236
25	-	100±0.002
30	-	-
35	-	-

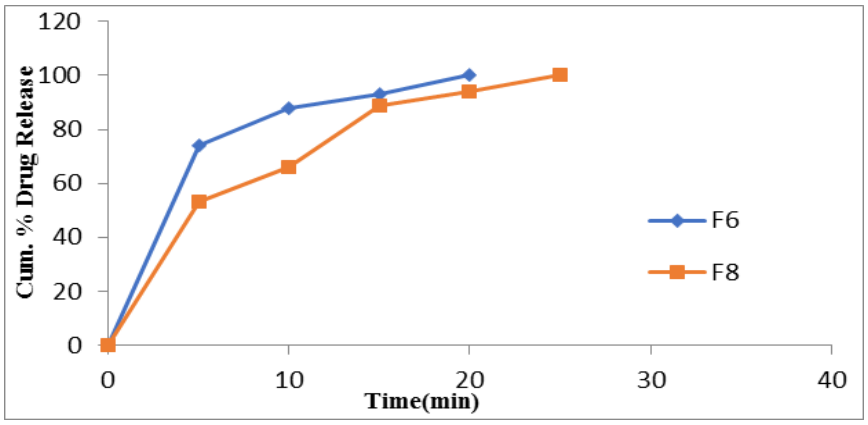


Figure No. 7: *In-vitro* Drug Release Profile of Formulations F6, F8.

Cumulative % drug release of F6 and F8 formulations at 5mins were found to be 74% and 53% respectively. And that 20mins 100% drug release was seen for F6 formulation, 97% drug release was seen for F8 formulation.

From F1-F10 batches, the formulation F6 was selected as the best formulation based on the highest % of drug release within 20mins time interval and F6 was the final optimized formulation. From the comparative dissolution study, we can conclude that there is only a slight difference in the excipients used. Dissolution studies of formulations F1-F10 batches were done by using USP-II type Paddle method. *In-vitro* dissolution studies were performed for formulations F1-F10 in 900ml of 0.1N hydrochloric acid as dissolution media. A constant weight of 30mg Fexofenadine drug was fixed for all the formulations from F1-F10.

Table No. 14 Drug Release Kinetics Profile.

RELEASE KINETICS				
	ZERO	**HIGUCHI**	**PEPPAS**	**FIRST**
	1	**2**	**3**	**4**
	Q Vs T	**Q Vs √T**	**Log C Vs Log T**	**Log % Remain Vs T**
Slope	4.6600	19.0748	0.4282	-0.0260
Intercept	19.2000	16.7116	1.4573	3.1566
Correlation	0.9105	0.9432	0.9560	-0.9811
R^2	0.8290	0.8896	0.9140	0.9626

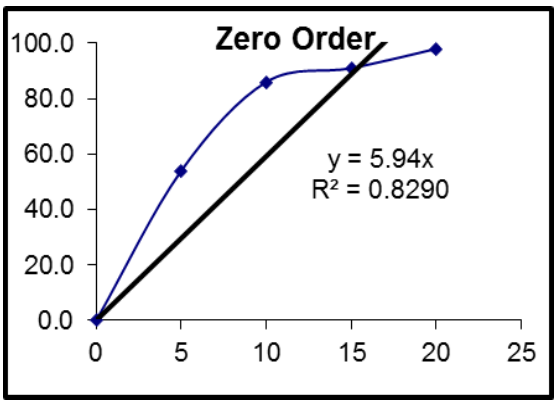


Figure No. 8: Zero Order Kinetic Graph for F6 Formulation.

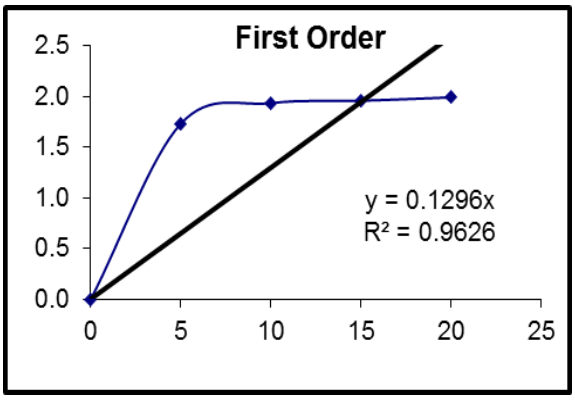


Figure No. 9: First Order Kinetic Graph for F6 Formulation.

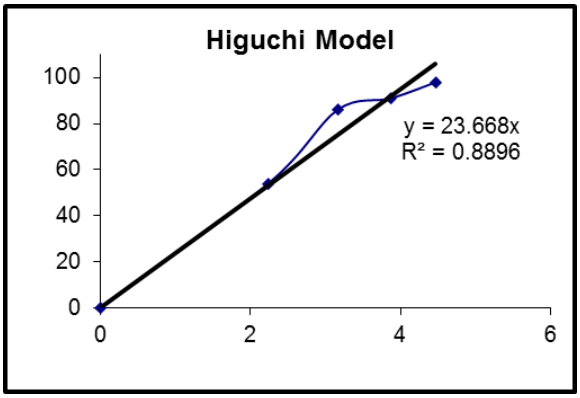


Figure No. 10: Higuchi's Model Kinetic Graph for F6 Formulation.

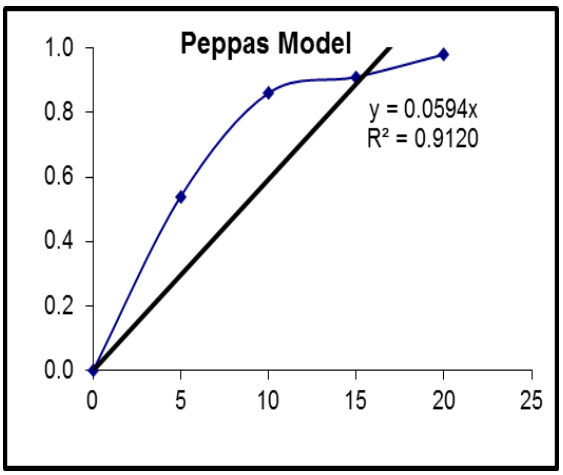


Figure No. 11: Peppas Model Kinetic Graph for F6 Formulation.

The kinetic investigation of the release profile gave useful insight into the mechanism of drug release from the tablets. The release did not show any burst effect or lag time, which is indicative of a homogeneous drug distribution in the polymer matrix. The dissolution data was subjected to regression analysis and were fitted to kinetic models, viz., Zero order and First order. It was found that most of the formulations followed First order (R^2=0.835). It describes the systems where the drug release rate depends on its concentration. The release kinetics follows first order and Higuchi's model of kinetics with an R^2 of 0.9626, 0.8896 respectively.

SUMMARY AND CONCLUSION

An immediate release tablet formulation of a drug is usually not useful until its active component is made available for absorption hence; the disintegrant arguably become the most important excipient in a tablet to facilitate immediate drug release. Disintegration leads to the breakup of the tablet into the component granules, thereby presenting a greater surface area of the tablet to the dissolution medium before the active drug substance is finally released from the tablet. Immediate release dosage forms still occupy a crucial space in drug delivery especially in disease conditions that require rapid onset of action. Proper selection of the excipients will enormously affect the final results.

- Formulation F6 showed good results than rest of the formulations in pre and post compression studies.
- Formulation F6 showed cumulative % drug release as 100% i.e., complete drug release was seen. Formulation F8 shown similar drug release pattern, 100% drug release was seen at 25 minutes time interval in comparison with formulation F6. The optimized formulation F6 follows first order kinetics.

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