International Journal of Recent Advances in Multidisciplinary Topics
Volume 2, Issue 7, July 2021
https://www.ijramt.com | ISSN (Online): 2582-7839

Formulation and Evaluation of Fexofenadine HCL Rapid Dispersible Tablets by Using Direct Compression Method

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***Abstract*: The research is going on to improve the solubility for low soluble drugs. The model candidate was to select to improve the solubility of Fexofenadine HCl and then to design rapid dispersible tablets. It is a competitive and highly selective β1 receptor antagonist with mild vasodilating properties, possibly due to an interaction with the L-arginine/nitric oxide pathway. Nine formulations of Fexofenadine HCl 100 mg were formulated by direct compression technique using different hydrophilic polymer grades such as cross povidone, sodium starch glycolate and cross carmellose sodium were used as polymers in different concentrations and other ingredients are Micro crystalline cellulose (MCC), Mannitol, and Talc and Magnesium stearate before the formulation the granules are evaluated by pre-compression studies. The obtained tablets were evaluated with different post-compression parameters like hardness, friability, thickness, weight variation, in- vitro disintegration studies and In-vitro dissolution studies. The formulation F3 was selected as an optimized formulation because it gives best results in terms of In - vitro drug release in a rapid release manner and best fitted to rapid order model with r value of 0.999.**

***Keywords*: Fexofenadine HCl, cross povidone, sodium starch glycolate, cross carmellose, mannitol and rapid orodispersible tablets.**

1. Introduction

Several pharmaceutical dosages are administered in the form of pills, granules, powders, and liquids. In general, a pill design is for swallowing intact or chewing to deliver a exact dosage of medication to patients. The pills, which consist of tablets and capsules, are able to maintain their shapes under moderate pressure. However, some patients, mostly pediatric and geriatric patients, have trouble in swallowing or chewing solid dosage forms. Many pediatric and geriatric patients are unwilling to take these solid preparations due to panic of choking.2Hence orally orodispersible tablets have come into reality. To accomplish these medical needs, formulators have devoted considerable efforts for emergent a novel type of dosage form for oral administration known as Rapid Dispersible Tablets (RDT). This is a novel technology where the dosage form contain active pharmaceutical ingredients disintegrates quickly, usually in a matter of seconds, without the need for water, provided that optimal convenience to the patient. Innovators and inventor companies have given these tablets a variety of names such as rapid dispersible, mouth Orodispersible, fast melting, fast Orodispersible or disperse. The European Pharmacopoeia defines orodisperse tablet as a "tablet that can be placed in the mouth where it disperses rapidly before swallowing" Researchers have formulated ODT for a variety of category of drugs, which are used for therapy in which quick peak plasma concentration is necessary to achieve desired pharmacological response. These include narcoleptics, cardiovascular agents, analgesics, anti-allergic, and drugs for erectile dysfunction.

Even with these difference most of the existing oral Orodispersible drug delivery systems are in the form of solid tablets and deliberate to dissolve/disintegrate in the patient's mouth without the need to drink or chew. However, the fear of taking solid tablets and the risk of choking for assured patient populations still exist despite their short disintegration/dissolution times. Hence oral film drug delivery is a superior substitute in such cases. The oral availability of several drugs was reduced because of the pH of the stomach, the presence of enzymes, and extensive first-pass metabolism. By tradition, these drugs have been administered as parenteral drug delivery systems, which invariably lead to poor patient compliance. This has made the pharmaceutical industry look for substitute routes of drug delivery like film drug delivery. Fexofenadine is used to relieve the allergy symptoms of seasonal allergic rhinitis ("hay fever"), including runny nose; sneezing; red, itchy, or watery eyes; or itching of the nose, throat, or roof of the mouth in adults and children 2 years of age and older. It is also used to relieve symptoms of urticaria (hives; red, itchy raised areas of the skin), including itching and rash in adults and children 6 months of age and older. Fexofenadine is in a class of medications called antihistamines. It works by blocking the effects of histamine, a substance in the body that

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causes allergy symptoms.

2. Materials and Methods

Fexofenadine Hydrochloride (Hetero Drugs Limited, Hyderabad), Microcrystalline Cellulose (Chemiloids, Vijayawada), Cross Povidone (S.D. Fine-Chem. limited, Mumbai), Sodium Starch Glycolate (Reidel (India) Chemicals, Hapur) Cross Carmellose Sodium (S.D. Fine-Chem. limited, Mumbai), Aerosil (Finer Chemicals Gujarat) Talc (S Reidel (India) Chemicals, Hapur) and Magnesium stearate (S.D. Fine-Chem. limited, Mumbai)

A. Methods: Pre- formulation studies

1) Bulk Density (Db)

It is the ratio of the mass of powder to the bulk volume of powder. It was measured by pouring the weight powder into a measuring cylinder and the volume was noted. It is expressed in gm/ml and is given by

$$Db = M/Vb$$

Where,M= mass of powder. Vb=bulk volume of the powder.

2) Tapped density (Dt)

It is the ratio of total mass of powder to the tapped volume of powder. The tapped volume was measured by tapping the powder to constant volume. It is expressed in gm/ml and is given by

$$Dt = M/Vt$$

Where, M=mass of powder.Vt=tapped volume of the powder.

3) Carr's Index (I)

It in dictates the ease with which a material can be induced to flow. It is expressed in percentage and is given by

$$I= Dt- Db / Dt*100$$

Where, Dt = tapped density of the powder. Db = bulk density of the powder.

4) Angle of Repose (θ)

The friction force sin loose powder can be measured by the angle of repose θ. It is side fine das maximum angle possible between the surface of a pile of powder and the horizontal plane.

$$\text{Tan } \theta = h/r$$

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

Where θ = is the angle of repose, h = is the height, r = is the radius.

The powder mixture was allowed to flow through the funnel fixed to a stand at definite height. The angle of repose was then calculated by measuring the height and radius of the heap of powder formed.

5) FT-IR Spectral studies

The IR spectra for the formulation excipients and pure drugs were recorded on Jasco FT-Infrared spectrophotometer using KBr palette technique (1:100) at their solution rate of 4cm-1. Spectrum was integrated in transmittance mode at the wave number range 400-4000 cm-1utions were.

6) Analytical method for estimation of Fexofenadine Hydrochloride

Standard calibration curve using 6.8 ph phosphate buffers: Procedure for construction of calibration curve of Fexofenadine Hydrochloride in 6.8pH Phosphate Buffer:

7) Standard stock solution

A stock solution containing 50mg of pure drug Fexofenadine Hydrochloride was prepared by Orodispersible in 10ml of methanol and 40ml of 6.8 pH phosphate buffer to produce 100ml (1000mcg/ml) solution in a volumetric flask.

Stock solution: From the stock solution, 10ml of stock solution was further diluted to make up to 100ml using 6.8pH phosphate buffer with concentration 100mcg/ml. Aliquots of 1ml, 2ml, 3ml, 4ml, 5ml were diluted up to 10ml with buffer to give concentrations in the range of 10µg/ml, 20 µg/ml, 30 µg/ml, 40µg/ml, 50µg/ml concentration of Fexofenadine Hydrochloride respectively. The absorbance was measured in the UV-Visible spectrophotometer at 224 nm using methanol and 6.8 pH phosphate buffer as a blank solution and graph of concentration versus absorbance was plotted.

B. Formulation of Fexofenadine Hydrochloride Orodispersible Tablets

1) Preparation of Orodispersible tablets

In the present study, the rapid dispersible tablets of Fexofenadine Hydrochloride are prepared by direct compression method, using different polymer and concentrations.

2) Preparation of tablets by the direct compression technique

The steps followed in the formulation of ODT's by direct compression technique includes: Dry screening, weighing, mixing, mixing of Super disintegrates, lubricant and glidant then compressing.

3) Procedure

All the required ingredients were passed through 40 mesh size to get uniform size particles and weighed accurately. Measured amount of drug, superdisintegrants, Aerosil, sweetner and flavor except glidant and lubricant are mixed in increasing order of their weights in a mortar. To this mixture talc and magnesium stearate were added. The final mixture is manually shaken for 10mins in plastic bag. Final blend was compressed into tablets using 8mm round flat punches using Karnavathi, Rimek Compression Tablet Punching Machine.

C. Evaluation of Fexofenadine Hydrochloride Rapid Orodispersible tablets

1) Physical appearance

Physical appearance of tablets is determined by visual identity which involves the measurement of number of factors such as tablet size, shape, colour, odour, taste, surface texture and any identification marks present on the tablet.

2) Weight variation test

The weight variation test is performed by taking 20 tablets from each formulation and weighing the individual tablets by using electronic balance. Their average weight was calculated as

$$\%\ \text{Weight variation} = (WA- WI) \times 100/ WI$$

Where,

WI = Individual weight of the tablets

WA = Average weight of the tablet

Table 1
Formulation of Fexofenadine Hydrochloride Rapid Orodispersible tablets by using different concentrations of super disintegrates.Table title

Ingredients	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Fexofenadine HCl	30	30	30	30	30	30	30	30	30
Cross povidone	6	8	10	-	-	-	-	-	-
Sodium starch glycolate	-	-	-	6	8	10			
Cross carmellose sodium	-	-	-	-	-	-	6	8	10
Magnesium stearate	2	2	2	2	2	2	2	2	2
Aerosil	2	2	2	2	2	2	2	2	2
Microcrystalline cellulose	57	55	53	57	55	53	57	55	53
Talc	2	2	2	2	2	2	2	2	2
Mannitol	1	1	1	2	2	2	3	3	3
Total weight (mg)	100	100	100	100	100	100	100	100	100

Table 2
Weight variation specifications (B.P)

Average weight of tablet	Maximum difference allowed
Less than 130	5
130-324	7.5
More than 324	10

Table 3
Weight variation specifications (I.P)

Average weight of tablet(mg)	Percentage deviation
130 or less	10
130 to 324	7.5
More than 324	5

Table 4
Micromeritic properties of the granules of Fexofenadine Hydrochloride formulation

S. No	**Formulation**	**Angle of repose (θ)**	**Bulk density (gm/cc)**	**Tapped density (gm/cc)**	**Carr's index (%)**	**Hausner's ratio**
1	F1	21.43	0.65	0.72	10.22	1.11
2	F2	20.55	0.69	0.79	12.65	1.14
3	F3	21.45	0.69	0.81	14.81	1.17
4	F4	20.67	0.70	0.82	14.63	1.17
5	F5	20.84	0.64	0.72	11.11	1.12
6	F6	20.82	0.64	0.73	12.32	1.14
7	F7	22.29	0.65	0.74	12.16	1.13
8	F8	22.32	0.71	0.83	14.45	1.16
9	F9	21.27	0.70	0.80	12.50	1.14

3) Hardness (kg/cm^2)

Hardness of the tablets was tested using a Monsanto hardness tester. Five tablets from each batch were tested for hardness.

D. % Friability

Friability of the tablets was determined in a Roche friabilator Ten tablets were weighed initially (w1) and placed in the friabilator that revolves at a speed of 25 RPM, dropping those tablets at a distance of six inches height with each revolution and rotated in the friabilator for 100 revolutions. After completion of rotations, the tablets were dedusted and weighed (w_2). The percent loss in weight or friability (f) is calculated by using the formula.

% Friability= (Initial weight- Final weight)/ Initial weight × 100

1) In-vitro disintegration studies

In -vitro disintegration time was performed by apparatus specified in USP. The water was used as disintegration medium, and the temperature was maintained at 37±2°C and the time in seconds taken for the complete disintegration of the tablet, with no palpable mass remaining in the apparatus, was measured in seconds.

E. In-vitro dissolution studies

In-vitro dissolution study was performed by using USP type II dissolution test apparatus (paddle type) [Lab, India (DS-8000, Mumbai)] at 100 RPM. 900ml of 0.1N HCL buffer was used as the dissolution medium which was maintained at 37±0.5ºC. Aliquots of dissolution medium (5mL) were withdrawn up to 1hr at regular intervals and replaced with equal volume to maintain the constant volume of dissolution medium and were filtered. The amount of drug dissolved was determined by UV spectrophotometer by measuring the absorbance of the sample at 262nm.

3. Results and Discussion

Formulations of Fexofenadine Hydrochloride Rapid Orodispersible tablets are prepared by using superdisintegrants like CP, CCS and SSG was impact on In- Vitro dissolution rate.

1) Pre-formulation studies

The Active pharmaceutical ingredient (Fexofenadine Hydrochloride) and excipients were blended and evaluated for different parameters as clarified before. Bulk density was found in the limit of 0.64 -0.71 g/cm^3 and the tapped density between 0.72- 0.83 g/cm^3. By using both density data Carr's compressibility was determined. The compressibility record

was found between 10.22 - 14.81 % and the Hausner's ratio was found to be 1.11 -1.17. The result shows good flow properties of blend. The good flow properties of powder were also evident from angle of repose that range from 20.55°-22.32º. In the present examination all powder mixes indicated excellent flow property. The outcomes are appeared in Table 4

B. Pre – compression parameters

1) FT-IR Spectral studies:FT-IR studies

From the FT-IR spectra, it was concluded that similar characteristic peaks with minor difference for the drug and the FT-IR formulation. Hence, it appears that there was no chemical interaction between the drugs and excipients used. The IR Spectra of with, Cross povidone, Sodium starch glycolate and Cross carmellose sodium shown. The following peaks were observed in as well as Fexofenadine Hydrochloride with excipients.

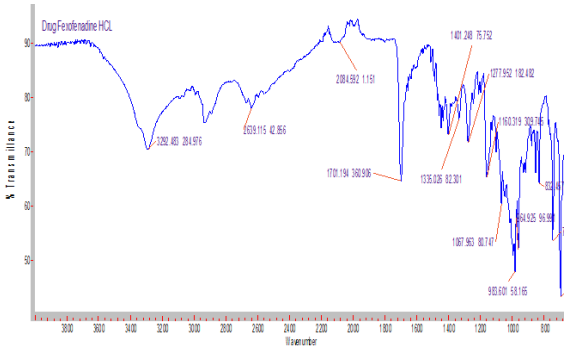

Fig. 1. FT-IR Reports of Fexofenadine Hydrochloride

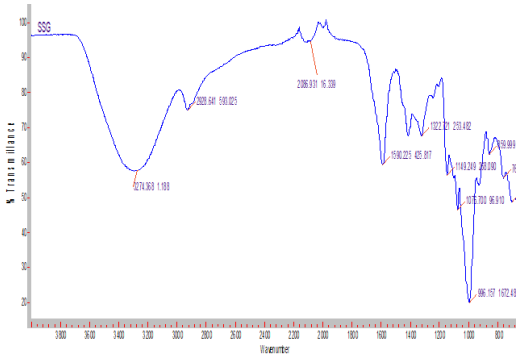

Fig. 2. FT-IR Reports for Fexofenadine Hydrochloride Optimized formula.

2) Analytical method development

Fexofenadine Hydrochloride was estimation using UV/VIS spectrophotometer method. It was found that under UV/VIS spectrophotometer standard absorbance of the peak of Fexofenadine Hydrochloride was 0.719 µg/ml,

Table 5
Standard Calibration Data of Fexofenadine Hydrochloride in 0.1N HCl

Concentration (µg/ml)	Absorbance
0	0
2 (µg/ml)	0.259
4 (µg/ml)	0.501
6 (µg/ml)	0.719
8 (µg/ml)	0.971
10 (µg/ml)	1.226

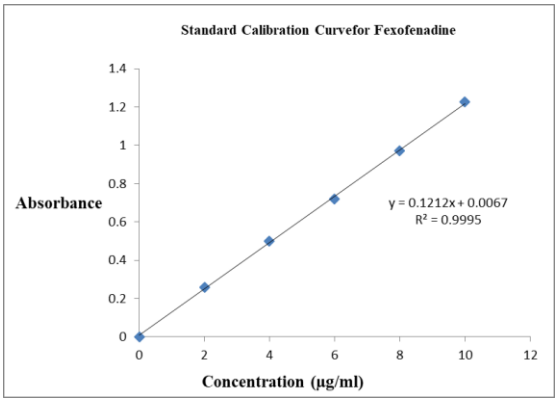

Fig. 3. Standard Calibration Data of Fexofenadine Hydrochloride in 0.1N HCl

3) Evaluation of post-compression parameters Fexofenadine Hydrochloride rapid Orodispersible tablets

The preliminary studies were carried out by preparing various formulations with different process variable and subjecting the formulation to all post-compression parameters has fulfilled according to IP standards.

4) Weight variation

Average weight of 20 tablets of Fexofenadine Hydrochloride was calculated for each formulation which varied from mg 99.10 ±1to 101.80 ±3 mg. the complied the official requirements as per IP.

5) Tablet thickness

The thickness of the Fexofenadine Hydrochloride formulation varied from 2.38 ± 0.03 mm to 2.5 ±0.02 mm

6) Tablet hardness (kg/cm^2)

The hardness of the tablet developed formulation shows 2.52 ±1.0 kg/cm2 to 3.46±1.0 kg/cm^2.

7) % Friability

The friability of the developed formulation varied from 0.45 ±0.1% to 0.68 ± 0.01% loss which was less than 1% as per official requirement of IP.

8) In-Vitro Disintegration studies Fexofenadine Hydrochloride rapid Orodispersible tablets

In-vitro disintegration study was performed by using USP disintegration test apparatus [Lab, India] 900ml of water was used as the disintegration medium which was maintained at 37±0.5ºC. The tablet was disintegrated in the medium was found to be 98.4 to 103.2 sec.

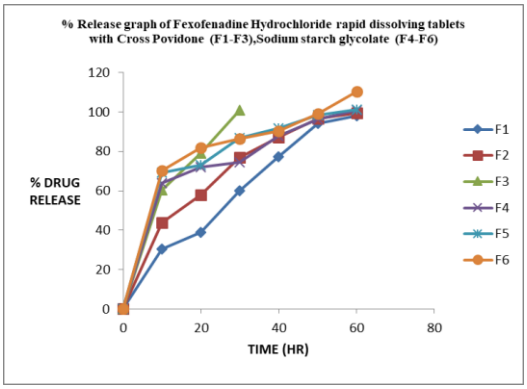

Fig. 4. % Release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Cross Povidone (F1-F3), Sodium starch glycolate (F4-F6)

Table 6
Post compression parameters of Fexofenadine Hydrochloride rapid Orodispersible tablets

S. No	Formula	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm^2)	DT (sec)	Friability (%)
1	F1	99.10±0.20	2.38±0.03	2.56±0.13	98.4	0.45
2	F2	101.09±0.33	2.47±0.01	2.52±0.11	99.2	0.53
3	F3	101.80±0.34	2.5±0.02	3.46±0.25	99.3	0.49
4	F4	100.33±0.76	2.46±0.04	3.32±0.21	100.1	0.57
5	F5	100.34±0.48	2.38±0.12	2.91±0.15	101.2	0.68
6	F6	101.67±0.27	2.5±0.02	2.96±0.17	102.1	0.62
7	F7	100.43±0.71	2.33±0.14	3.46±0.25	103.1	0.51
8	F8	100.19±0.21	2.5±0.02	3.05±0.21	98.8	0.63
9	F9	99.26±0.20	2.4±0.02	3.04±0.21	103.2	0.65

Table 7
Dissolution studies for Fexofenadine Hydrochloride rapid Orodispersible tablets.

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
10	30.57	43.65	60.36	64.05	69.02	70.15	33.12	48.85	56.3
20	39.05	58.05	79.2	71.95	73.15	82.05	46.24	57.75	61.4
30	60.09	76.95	100.98	74.4	86.75	86.62	66.1	70.11	74.65
40	77.16	87.15	-	87.95	91.85	90.22	74.94	79.21	79.7
50	94.13	96.5	-	96.45	98.6	99.01	96.8	98.57	99.9
60	98.25	99.65	-	101.0	101.15	110.35	100.4	110.15	101.3

C. Post – compression parameters:

1) In-Vitro Dissolution studies of Fexofenadine Hydrochloride rapid Orodispersible tablets

Drug release from RDTs was studied by using USP type-II dissolution rate test apparatus at 50rpm (USP XXIII Dissolution Test Apparatus) using 900ml of phosphate buffer pH 6.8 as dissolution medium. RDTs of desired formulation were taken and placed in the vessels of dissolution apparatus. Samples were collected from the vessels at different time intervals, replenished with same volume of the blank solution and analyzed using UV-Visible spectrophotometer. Drug concentration was calculated from the standard graph and expressed as % of drug dissolved or released. The release studies were performed in replicates and means values were taken.

The all six formulation are prepared by using different concentrations of polymers like Cross povidone, Sodium starch glycolate, Cross carmellose sodium. Fexofenadine Hydrochloride rapid Orodispersible tablets the drug released in formulation f1 is 98.25 % in 60 min, f2 is 99.65 % in 60 min and f3 formulation drug released is 100.98 % in 30 min ,f4 formulation the drug released was 101 % in 60 min, f5 formulation the drug released was 101.5 % in 60 min and f6 formulation the drug released was 110.35 % in 60 min. f7 formulation the drug released was 110.4 % in 60 min. f8 formulation the drug released was 110.15 % in 60 min. f9 formulation the drug released was 101.3 % in 60 min.

The optimized formulation f3 the prepared with Cross povidone the dissolution medium was 0.1 N HCL the drug released in formulation f3 is 100.98 % in 30 min,

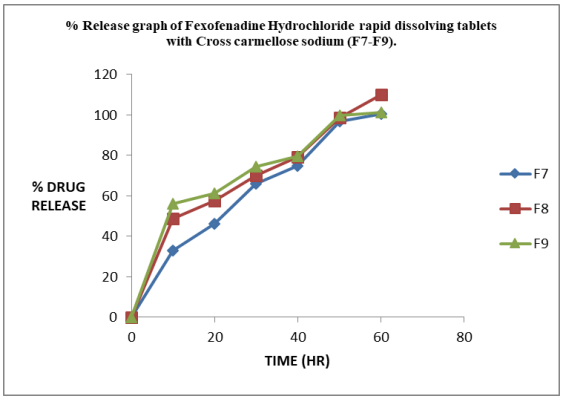

Fig. 5. % Release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Cross carmellose sodium (F7-F9).

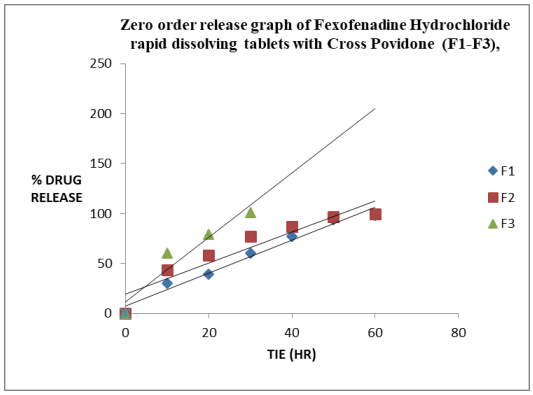

Fig. 6. Zero order release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Cross Povidone (F1-F3).

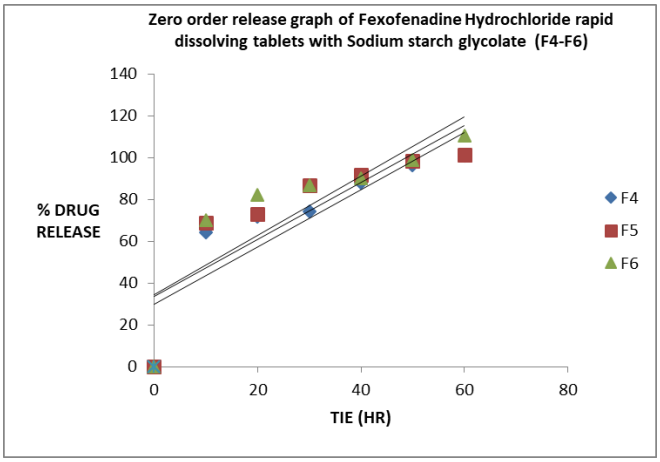

Fig. 7. Zero order release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Sodium starch glycolate (F4-F6)

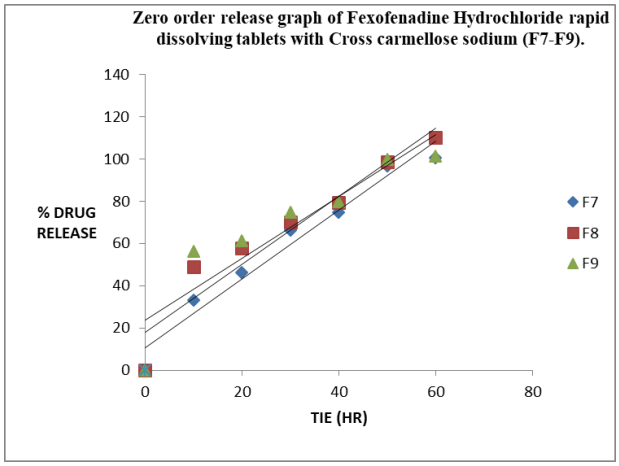

Fig. 8. Zero order release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Cross carmellose sodium (F7-F9).

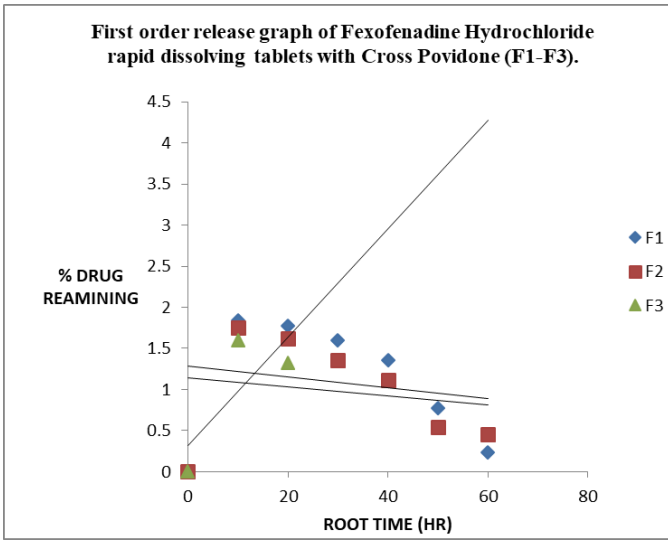

Fig. 9. First order release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Cross Povidone (F1-F3)

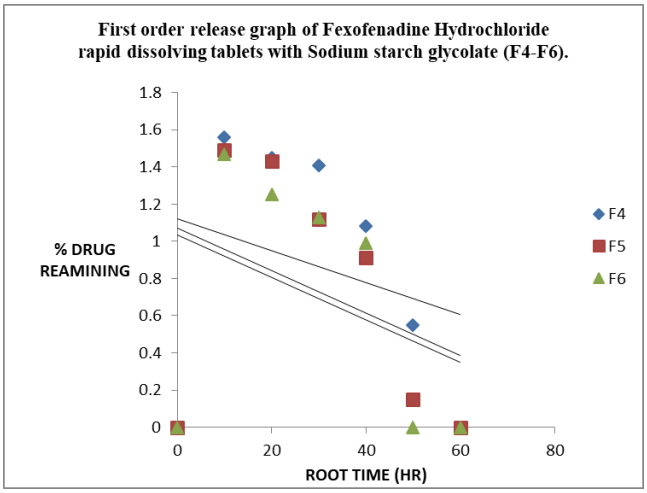

Fig. 10. First order release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Sodium starch glycolate (F4-F6)

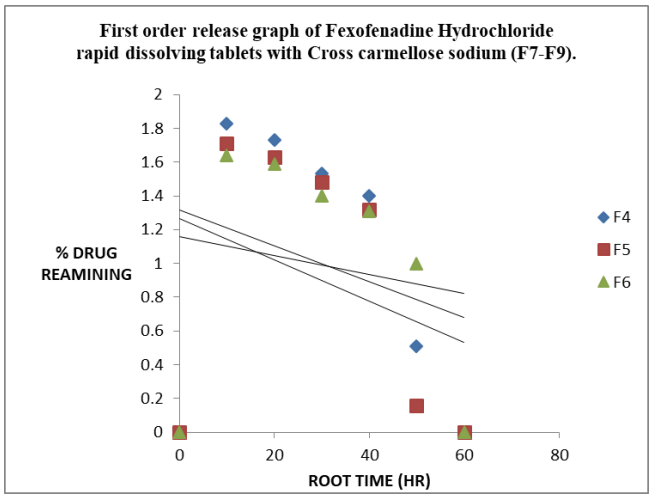

Fig 11: First order release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Cross carmellose sodium (F7-F9).

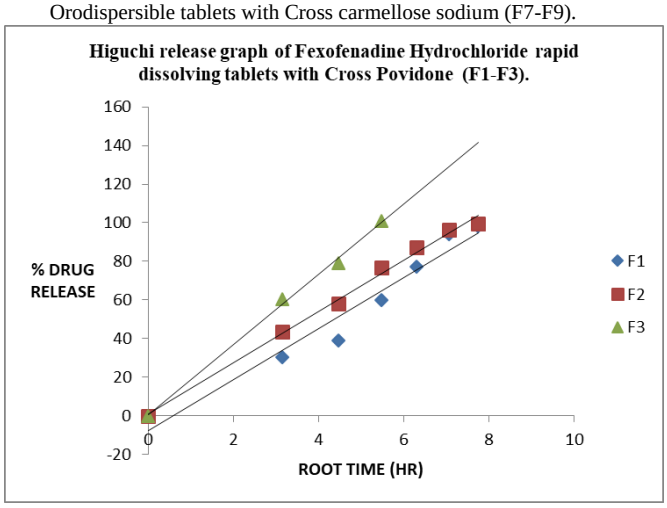

Fig. 12. Higuchi release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Cross Povidone (F1-F3).

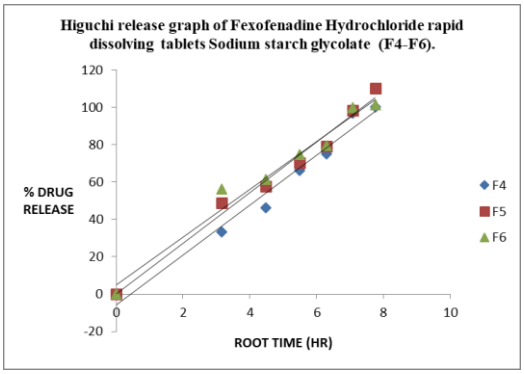

Fig. 13. Higuchi release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets Sodium starch glycolate (F4-F6)

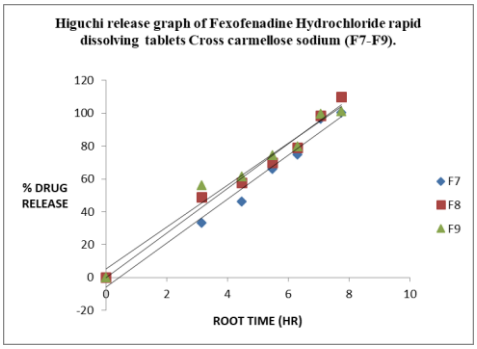

Fig. 14. Higuchi release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Cross carmellose sodium (F7-F9).

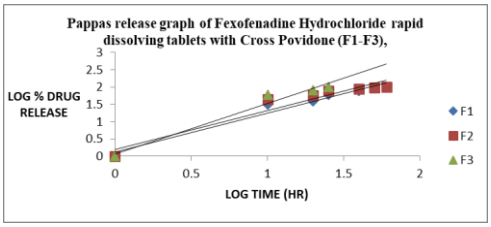

Fig. 15. Pappas release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Cross Povidone (F1-F3).

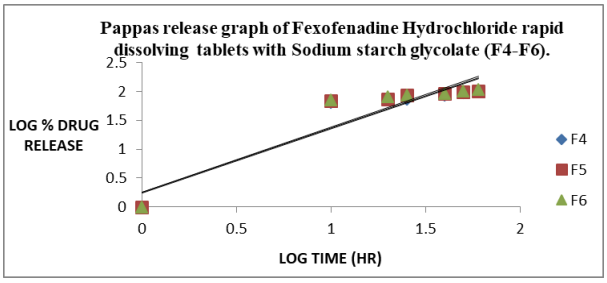

Fig. 16. Pappas release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Sodium starch glycolate (F4-F6)

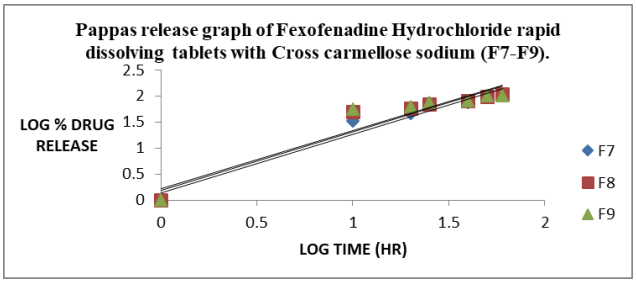

Fig. 17. Pappas release graph of Fexofenadine Hydrochloride rapid Orodispersible tablets with Cross carmellose sodium (F7-F9).

2) Curve-Fitting Analysis

According to different kinetic models, the kinetics of the f1 and f9 drug release was evaluated by drug release rate models namely zero order, first order kinetics, and higuchi, papas mechanisms. The dissolution kinetics data was defected given below. The optimized formulation F3 showed highest r value i.e. 0.990 for first order plot indicating that release of drug follows first order kinetics, and mechanism of release was fitted to Pappas equation with the r value of 0.999 indicating anomalous fickian diffusion mechanisms and may indicate that the drug release is higher by more than one process.

4. Conclusion

The objective of the present research work was to prepare intra oral rapid dispersible tablets and films of Fexofenadine Hydrochloride, as this drug has few negligible side effects formulating this drug into oral disintegrating drug delivery system makes it superior and effective candidate for pediatric, geriatric, bedridden, psychotic patients and for those who are travelling and has no access to water. Pre-formulation studies of Fexofenadine Hydrochloride were performed, from the FT-IR, the interference was verified and found that Fexofenadine Hydrochloride did not interfere with the polymers used. Nine batches of rapid dispersible tablets of Fexofenadine Hydrochloride were successfully prepared using Cross Povidone, Cross carmellose Sodium and Sodium Starch Glycolate as Superdisintegrants in different concentrations and in different combinations by Direct Compression method. Based on the results, the formulation containing 10 % crospovidone (f3) was identified as ideal and better formulation among all formulations of Fexofenadine Hydrochloride. In-vitro release of optimized formulation of Fexofenadine Hydrochloride rapid dispersible tablets of F3 was found to be

Table 8
Dissolution kinetics of Fexofenadine Hydrochloride rapid Orodispersible tablets (F1-F9).

Correlation co-efficient				
Formulation	Zero order	First order	Higuchi	Pappas
F1	0.924	0.932	0.971	0.996
F2	0.942	0.990	0.966	0.999
F3	0.959	0.975	0.938	0.971
F4	0.868	0.986	0.937	0.966
F5	0.926	0.987	0.791	0.938
F6	0.957	0.980	0.931	0.997
F7	0.942	0.975	0.971	0.971
F8	0.959	0.986	0.966	0.966
F9	0.926	0.987	0.938	0.938

100.98% drug release within 30 mins with in vitro disintegration time being 90 secs. Drug – excipients compatibility studies were conducted by FT-IR spectroscopy, results indicated that the Fexofenadine Hydrochloride and polymers were found to be compatible. The Micromeritic properties of granules were evaluated, all the formulations exhibited good flow properties. The evaluation parameters for the prepared tablets such as % weight variation, hardness, % friability, thickness, and disintegration and dissolution studies were found to be in satisfactory limits. The maximum drug release was found to be 100.98 % over a period of 30 min in

cross povidone tablets. This indicates combination of cross povidone required preparing the rapid Orodispersible tablets of Fexofenadine Hydrochloride. All the formulations were also subjected to model fitting analysis to know the order and mechanism of drug release from the formulations by treating the data according to Zero order, First order, Higuchi and Pappas Equations, The data clearly shows that, the release kinetics revealed that the formulations containing CP, SSG, CCS follows first order release kinetics and release rate was higher. Thus, in the present investigation, finally concluded that fast Orodispersible tablets of Fexofenadine Hydrochloride were successfully designed by direct compression method and evaluated. It can be concluded that cross povidone can be used as an effective release to rapid Orodispersible tablets of Fexofenadine Hydrochloride for the period of 30 min.

Acknowledgement

I express my sincere thanks to M.Srinivasa Rao (Chairman), Dr. M.B.V Raju (principal) Avanthi institute of pharmaceutical sciences, Jawaharlal Nehru Technological University for providing me necessary research facility and also thankful to my research guide and parents.

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