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IN-VITRO BIOEQUIVALENCE STUDY OF DIFFERENT BRANDS OF FEXOFENADINE HYDROCHLORIDE TABLETS USED FOR ALLERGIC RHINITIS

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ABSTRACT

Fexofenadine Hydrochloride is indicated to relieve signs and symptoms of related to seasonal allergic rhinitis. The aim of the present study is to establish the pharmaceutical equivalence of different brands of Fexofenadine Hydrochloride 120 mg tablets available in the market. The quality control tests performed are weight variation, friability, hardness, disintegration and invitro dissolution studies. In-Vitro dissolution studies of Fexofenadine Hydrochloride 120 mgg tablets were carried out in 6.8 p^H phosphate buffer. Two samples are compared with the Innovator product. During the evaluation no major difference was noticed in weight variation, friability, hardness, disintegration and in dissolution between the two market products and the innovator product.

Keywords: Fexofenadine Hydrochloride, weight variation, friability & invitro dissolution studies

INTRODUCTION

Allergies, commonly referred to as allergic diseases, are a group of illnesses brought on by the immune system's hypersensitivity to normally benign environmental chemicals. It is a abnormal response of the immune system. Rhinorrhea, obstruction of nasal

passages, naso pharyngeal and conjunctival itching and lacrimation are the symptoms of allergic rhinitis when exposed to allergens Histamine is the fundamental mediator released during the immediate allergic response from tissue mast cells and during the late phase response chiefly from received basophils Antihistamines are the drugs of choice for the treatment of various allergic reactions like the allergic rhinitis and chronic urticaris **[1]**.

Fexofenadine is a selective H1- antagonist for the symptomatic treatment of seasonal Allergicrhinitis andchronic idiopathicurticaria. Fexofenadine is an over-the-counter second-generation antihistamine used in the treatment of various allergic symptoms. It is selective for the H_1 receptor, carries little-to-no activity at off-targets, and does not cross the blood-brain barrier this is in contrast to previous first-generation antihistamines, such as diphenhydramine, which readily bind to off-targets that contribute to side effects such as sedation. Fexofenadine is the major active metabolite of terfenadine and is administered as a racemic mixture in which both enantiomers display approximately equivalent antihistamine activity **[2-4]**.

MATERIALS AND METHODS

Construction of calibration curve using 6.8 P^H Phosphate buffer:

Preparation of 6.8 P^H Phosphate Buffer: Accurately weighed 6.845gms of Potassium Dihydrogen phosphate and 0.896gms of sodium hydroxide are taken in 100ml volumetric flask and made up to 1000ml with distilled water. Standard solution: Accurately weighed 100mg of Fexofenadine was dissolved in 5ml of ethanol and volume was made up to 100ml using 6.8 P^H Phosphate Buffer which gives a concentration of 1000µg/ml Stock solution: From this standard solution, 10ml was pipetted out in 10ml volumetric flask and volume was made up to 100ml using 6.8 P^H Phosphate Buffer to obtain a concentration of 100µg/ml. From the above stock solution, aliquots of 0.5ml, 1ml, 1.5ml, 2ml, 2.5ml, 3ml each were transferred to a separate 10ml volumetric flask and solution was made up to 10ml using 6.8 P^H Phosphate Buffer to obtain concentration of 5, 10, 15, 20, 25, 30ug/ml respectively. The absorbance of each solution was measured at 221nm.

Sample Collection:

To perform the study Fexofenadine Hydrochloride 120mg tablets of three different manufacturers were purchased from the drug stores and the three were labelled as F1, F2 and F3.

Physical Parameters:

The physical parameters that are the colour, shape and size were noted in **Table 2**.

Weight variation:

Ten tablets were randomly selected and weighed individually. The average weight of 10 tablets were calculated. Individual weights of tablets were compared with the average weight.

% deviation = (individual weight- Average weight /Average weight)100

Hardness:

The force necessary to break a tablet in a given situation is known as the tablet's ''hardness''. diametric compression test. The crushing strength that causes a tablet to break was measured in N (Kg/cm^2) when a tablet was placed between two anvils of a hardness tester. six tablets from each formulation are taken to calculate it. Monsanto hardness tester, which uses an internal spring to apply force in two opposite directions to the tablet.

Friability:

Tablets require certain amount of strength or hardness and resistance to withstand mechanical shock of handling in manufacturing, packaging and shipping. A pre-weighed sample (5 tablets) were placed in friabilator and operated for 100 revolutions, then again, the tablets are weighed and the % friability was calculated using the formula:

% friability=W_o-W/W_o × 100

Where W_o-weight of tablet before test

W-Weight of tablet after test

Disintegration Test:

One of the most crucial requirements for the fast-dissolving tablets is the time it takes for the pill to dissolve. These dose forms must dissolve in a minute or less. Using disintegration test equipment, the disintegration time was calculated. Six tubes made up the equipment, and one disc was attached to each tube along with a tablet. The amount of time in seconds required for the tablet to completely dissolve. Leaving no discernible mass inside the devices.

In vitro drug release studies:

The In vitro dissolution study was conducted as per the United States Pharmacopoeia (USP). The paddle method was used to study the drug release from the tablets. The dissolution medium consisted of 900ml of 6.8p^H phosphate buffer. The release was performed at 37^0 C ± 0.5^0 C, at a rotation speed of 50RPM. 5ml samples were withdrawn at and analysed for fexofenadine after appropriate dilution by UV spectrophotometer at 221nm respectively. The % drug release was calculated using the calibration curve of the drug in 6.8p^H phosphate buffer.

Fit factor:

Similarity factor f2: For comparison of in-vitro dissolution profiles, similarity and difference factors are emphasized by US FDA. As the name specifies, similarity factor (f2) stresses on the comparison of closeness of two comparative formulations. The f2 parameter is commonly used to establish similarity of two dissolution profiles. The FDA defines Similarity factor as " the logarithmic reciprocal square root transformation of one plus the mean squared (the average sum of squares) differences of drug percent dissolved between the test and the reference products". The formula to find similarity factor is as follows **[5]**:

f2 = 50 + log {[1+ (1/n) ∑t=1 * n (Rt-Tt) 2] -0.5 ×100}

Rt and Tt are the cumulative percentage dissolved at each of the selected n time points of the reference and test product respectively. Two profiles are considered to be same when f2=100. f2 value results in 50 at an average difference of 10% for all measured time points. f2 value between 50-100 indicates similarity between two dissolution profiles. In other words if difference at each sampling time is less than or equal to 10% f2 value will be between 50 and 100. Therefore, a quick way to establish similarly of two profiles is to see if differences in dissolution results at each sampling time are less than 10%. The limit of 50-100 range for f2 may be in conflict with the commonly accepted pharmacopoeia (e.g. USP) standards, where the acceptable deviation is significantly higher than 10%. f2 is suggested for evaluating products with formulation and to find out whether there exists any manufacturing differences. f2 is 100 when two comparative groups of reference and test are identical. F2 becomes zero as the dissimilarity increases **[6]**.

Dissimilarity factor (f1):

Dissimilarity factor focuses on the difference in percent dissolved between reference and test at various time intervals. Therefore, the factors directly compare the difference between percent drug dissolved per unit time for a test and a reference product. f1 factor is used to calculate the approximate % error in drug release profile. f1 should be between 0 and 15. Dissimilarity factor f1 is given as **[5]**

f1= {[Σ t=1 n |Rt-Tt|] / [Σ t=1 nRt]} ×100.

Mathematical model fitting of obtained drug release data

In vitro release kinetic studies: The mechanism of drug release from the formulations during the dissolution in pH 6.8 Phosphate buffer was determined using First order, Zero order, Korsemeyer peppas

plot, Higuchi equation. The in vitro release studies data was fitted into various mathematical models to determine which the best-fit model. The various parameters n-time exponent, k-release constant and r-correlation coefficient, were also calculated.

Zero order equation

This equation describes the systems where the release rate is independent of the concentration of the dissolved species. The dissolution data are fitted into the zero order equation:

Q = Q0 .K0t

Where,

Q = Amount of drug released at time tQ0 = Amount of drug released initiallyK0 = zero order rate constant.A graph of concentration vs. time would yield a straight with a slope equal to K0 and the intercept at the origin of the axes. The zero order plots is derived from plotting the cumulative percent drug dissolved vs. time.

First order equation

The First order equation describes the release from systems where the dissolution rate is dependent upon the concentration of the dissolving species. Release behaviour generally follows the following first order release equation

ln M = ln M0 - K1t

Where,

M is the amount of drug undissolved at timet, M0 is the amount of drug undissolved at t =

0 K1 is the corresponding release rate constant

A graph of log concentration of drug remaining vs. time a straight line with a negative slope

Korsemeyer-Peppas model fitting

The data obtained from in vitro release studies was fit into Peppas model. Kores Meyer-Peppas equation:

Mt/ M∞ = 1 – A (exp-Kt)

1og (1 - Mt/ M∞) = 1og A – kt/2.303

Mt = Amount of drugs released at time tM∞ = Total amount of drug loaded

K = Diffusion constant/Release rate constant

R = regression co-efficient; n = time exponent

The value of 'n' determined from Korsemeyer-Peppas equation if found to be below 0.45, it indicates that the drug release from the formulation follows Fickian diffusion, if 'n' value is between 0.5-085, indicates non-Fickian diffusion or anomalous mechanism (relaxation controlled) and if 'n' value is above 0.89, indicates Super case II transport.

Higuchi plots: An attempt was made to ascertain whether the drug release confirm to

the diffusion equation proposed by Higuchi which is given by

f1 = KH √t

Where, f1 = Amount of drug released. KH = Higuchi dissolution rate constant. √t = Square root of time.

RESULTS AND DISCUSSIONS

The calibration curve followed beerlamberts law and regression coefficient was found to be 0.9956 shown in **Table 1 and Figure 1**.

The weight variation, friability hardness and disintegration time of all the three beands of tablets were found to be within the limits shown in **Table 3** and graphically represented **Figure 2-5**.

The dissolution studies values given in **Table 4** and in **Figure 6** show that the amount of the drug released in 15min was not less than 80% of the labelled amount, which is in accordance to pharmacopoeial requirements which states that atleast 80% of the drug is to release within 30 minutes of dissolution. The calculated similarity factor for all formulations is presented in **Table 5**. From the presented data, it is noted the difference factor for F2 & F3 formulations compared to the reference (F1) data was within the range of 0–15 and the dissolution profiles for all formulations were comparable to that of the reference with a similarity factor ($f2$) value greater than 50.

Table 1: Standard graph of fexofenadine in 6.8P^{H} Phosphate buffer

SL. NO.	CONCENTRATION	ABSORBANCE
1	4	0.0356
2	8	0.2419
3	12	0.3935
4	16	0.5557
5	20	0.6992

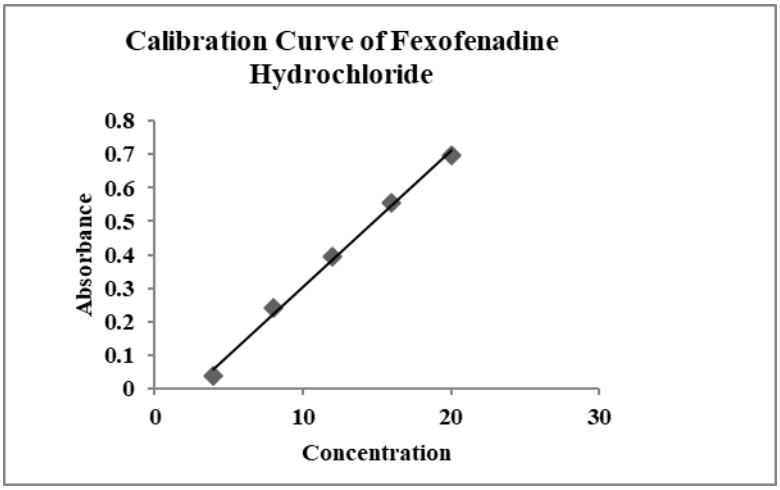

Figure 1: calibration curve

Table 2: Physical Parameters

Brand code	Shape	Colour	Diameter	Thickness
F1(Innovator)	Oval	yellow	9mm	5.8 mm
F2	Oval	ponceou	9mm	5.76mm
F3	Oval	yellow	9mm	5.72mm

Table 3: post compression parameters

Formula	Weight variation (%)	Friability (%)	Hardness kg/cm^2	Disintegration Time(sec)
F1(Innovator)	0.25±0.47	0.27±0.47	6±0.685	83±0.147
F2	0.42±0.85	0.43±0.85	4±0.156	92±0.584
F3	0.36±0.64	0.35±0.69	4±0.965	118±0.965

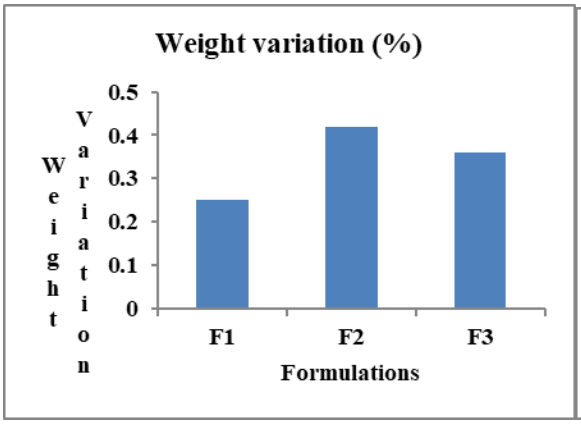

Figure 2

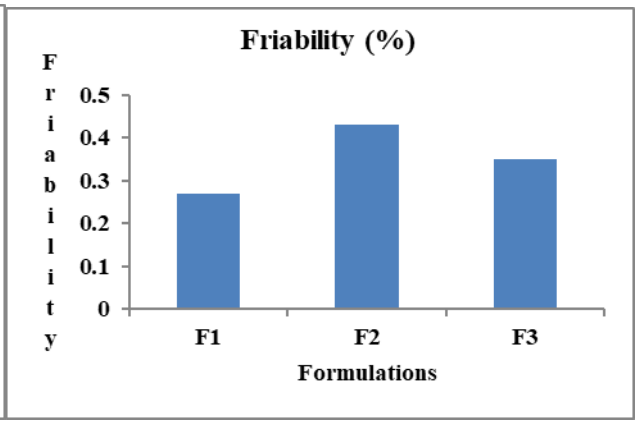

Figure 3

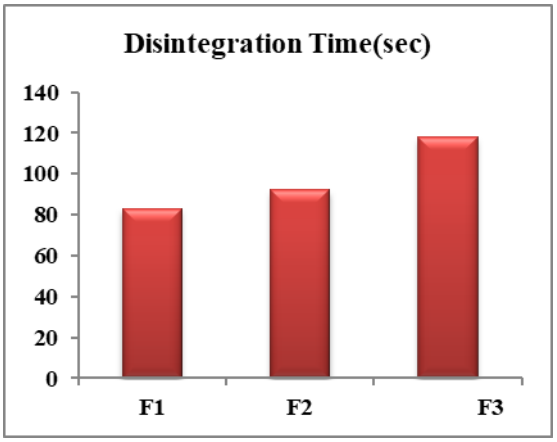

Figure 4

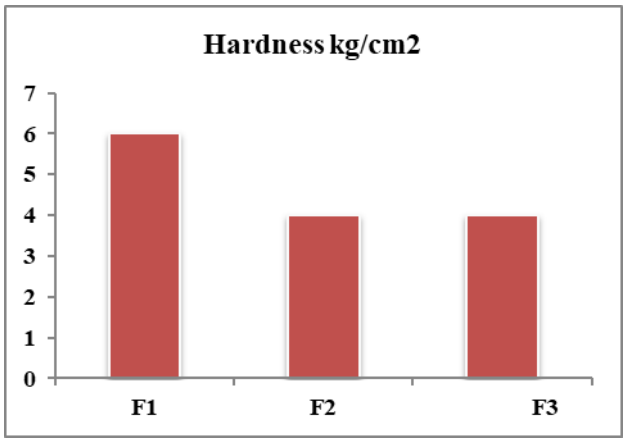

Figure 5

Table 4: Drug Dissolution Tests

Time(sec)	% Drug Released		
	F1	F2	F3
0	0	0	0
5	45.7±0.147	38.9±0.159	46.1±0.658
10	68.9±0.659	62.7±0.354	70.5±0.258
15	80.8±0.558	79.6±0.755	82.1±0.789
30	89.5±0.671	88.8±0.059	91.5±0.658
45	97.8±0.147	96.8±0.654	99.89±0.458
60	100±0.456	100±0.614	100±0.951

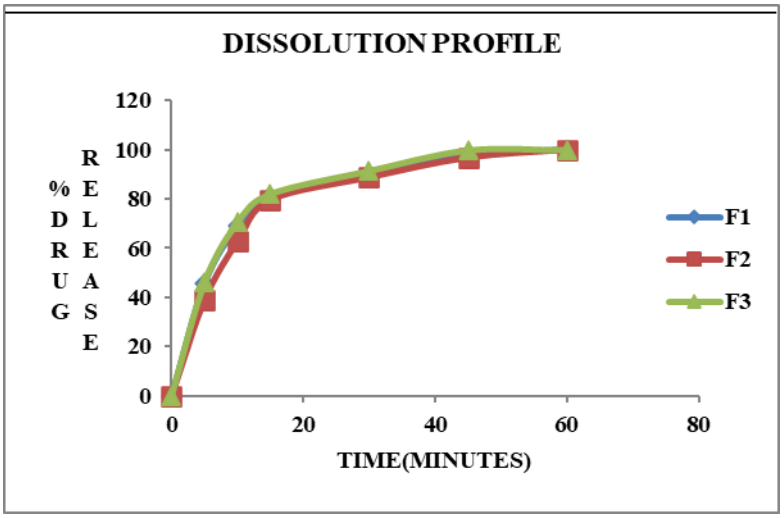

Figure 6: Dissolution Profiles of F1, F2 & F3

Table 5: Dissimilarity & Similarity

Formulation Code	f1	f2
F1-F2	3.5	98.5
F1-F3	8.2	81.2

Table 6: Kinetic Models

Formulation Code	Zero Order	First Order
F1	0.6444	0.8665
F2	0.6887	0.8675
F3	0.6321	0.9518

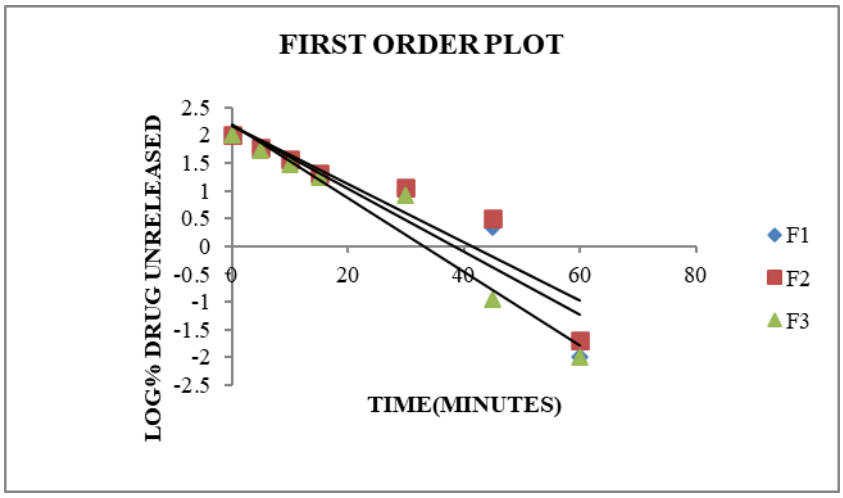

Figure 7: First Order Plot

The first order plots were found to be fairly linear as indicated by their high regression values (0.867 to 0,951). The Values of R^2 for first order kinetic equations were greater than zero order kinetics for all the three products indicating that the drug release from the three

brands of tablets was dependent on the concentration of drug present in the formulation.

SUMMARY AND CONCLUSION

Fexofenadine Hydrochloride is the most popular choice for the treatment of allergic symptoms. It is mostly indicated to relieve signs and symptoms of related to seasonal allergic rhinitis. The objective of the present study is to compare the *in-vitro* bioequivalent parameters of three marketed fexofenadine hydrochloride 120 mg tablets. The two formulations are compared with reference product in different parameters like Physical, post compression and in vitro dissolution. This is done because a number of formulations are available in the market and continues post market surveillance should be done in order to see that they are equivalent with that of innovator product . The result of the study will give us a rationale for the interchangeability of the selected brands with the innovator product. The effectiveness of the product will depend on the disintegration and dissolution of the product. The F2 and F3 marketed products were found to be similar to that of the F1 i.e the innovator product. The post compression parameters i.e. the weight variation, hardness and friability were found to be within the acceptable range. The values of F2 and F3 were found to be similar to that of the innovator product. The disintegration time of F1 is 83 seconds, F2 is 92 second and of F3 is 118seconds even though there is little variation in disintegration time of F2 and F3 from the innovator product the disintegration time is within the limits.

The dissolution of the drug from F2 and F3 products is found to be almost similar to that of the innovator product. More than 50% of the drug was released by the end of 10 min. The percentage of drug released for F1 is 68.9, F2 is 62.7 and for F3 is 70.5 by the end of 10 minutes. By the end of 30 minutes nearly 90% of the drug was released. 89.5% of the drug was released from F1(innovator), 88.8% was released from F2 and 91.5% was released from F3. The similarity index of F1 nd F2 is 98.5 and the similarity index between F2 and F3 is 81.2. Based on *in-vitro* dissolution studies it is concluded that no significant variation exists between the innovator, F2 and F3. More similarity exists between the three brands of Fexofenadine hydrochloride 120 mg tablets. All the three brands of drugs were found to have high dissolution rate and hence good bioavailability. F2 and F3 can be considered to be bioequivalent with the innovator product. Hence, F1, F2 and F3 can be interchangeable or substituted with one

another in the therapy for allergic conditions. However, there is a need to carry out in-vivo studies in order to substantiate the *in-vitro* predictions

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