Quest Journals
Journal of Research in Pharmaceutical Science
Volume 2 ~ Issue 12 (2016) pp: 01-04
ISSN(Online) : 2347-2995
www.questjournals.org

Research Paper

Comparative Study of Estimation of Fexofenadine Hydrochloride By Uv-Visible Spectrophotometry and Hplc Method

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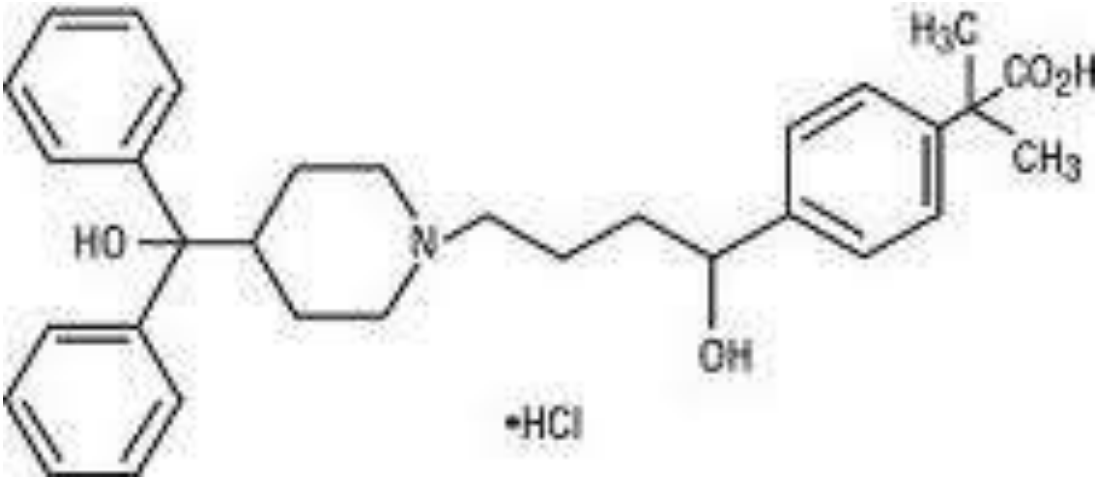
Received 05 February, 2016; **A**ccepted 24 February, 2016 © The author(s) 2015. Published with open access at **www.questjournals.org**

ABSTRACT:- *Simple and accurate spectrophotometric and HPLC method was developed for determination of Fexofenadine in tablets dosage form. The spectrophotometric method was developed by dissolving tablets in 1:1 Methanol to make solution of 10ppm giving absorbance at 220nm. The experimental conditions were optimized and Beers law was obeyed over the applicable concentration range. The application of HPLC procedure depends on using a conventional reverse phase C18 column along with mobile phase consisting of 1:1 Methanol. Both techniques were applied successfully for analysis of Fexofenadine in three different commercially available tablets. From the results obtained for both procedures percentage purity was found out.*

Key words:- *Fexofenadine, Spectrophotometric, HPLC, Methanol.*

I. INTRODUCTION

Fexofinadine Hydrochloride , The Active Ingredient of telfast And Allegra, Is a Second –Generation Histamine H_1 Receptor Antagonist With The Chemical Name α,α- Dimethyl-4-[1-Hydroxy-4-[4-(Hydroxydiphenyl-Methyl)-1- piperidinyl] butyl]-Benzen acetic acid.It is NonSedating Antihistamine. Fexofinadine Hydrochloride is used as The Hydrochloride Salt in the Symptomatic relief of allergic Conditions including Seasonal allergic rhinitis and urticaria. (1,2) Fexofenadine (tradenames Allegra, Fexidine, Telfast, Fastofen, Tilfur, Vifas, Telfexo, Allerfexo) is an antihistamine pharmaceutical drug used in the treatment of allergy symptoms, such as hay fever, nasal congestion, and urticaria.[3] Fexofenadine is sometimes called a third-generation antihistamine because it is less able to pass the blood-brain barrier and cause sedation, compared to first-generation antihistamines.[4] Fexofenadine has been demonstrated to be safe and effective for children ages 2–5 years old and 6–11 years old in treatment of seasonal allergic rhinitis.[5][6]



There are various reports based on the evaluation of Fexofenadine by HPLC method in different dosage forms(Karakus*etal*.,2008)[7].Fexofenadine was detected in biological fluids using HPLC method (Hofmann*etal*.,2002)[8] some spectrophotometric and capillary electrophores is methods were also developed (Mahgoub *et al*., 2003[9]; Mikus *et al*., 2005[10]). Electro spray ionization tandem mass spectrometry methods

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.High- sensitive liquid chromatography was also used for the evaluation of Fexofenadine in plasma(Yamane *et al*., 2007).[11]

II. MATERIAL AND METHODS

1) UV-Visible Spectrophotometer: Shimadzu UV-1800PC spectrophotometer using 1cm quartz cells.
2) HPLC: An Agilent 1200 series rapid resolution LC consisting of; G1312B Binary pump SL, G1315C UV/VIS diode array detector SL, flow cell as indicated in individual chromatograms, Column: Agilent ZORBAX SB- C18, 4.6mm, 150mm,5µm.
3) Diluent: 1:1 Methanol

2.1 Mobile phase: 60:40 (water: Methanol)

2.2 Preparation of standard solutions:

For Spectrophotometric determination: Standard solution of fexofenadine hydrochloride was prepared of 100 ppm concentration. Using that standard solution a series of dilutions ranging from 2 ppm to 10 ppm was prepared.

For HPLC determination: Standard solution of fexofinadine hydrochloride was prepared of 1000 ppm concentration. Using that standard solution a series of dilutions ranging from 20 ppm to 100 ppm was prepared.

2.3 Sample taken for analysis

TABLE NO. 1

Name of Sample	Name of Manufacturer	Batch number	Content per sample
Rhinofex	Astra Zeneca	DPLI002P	Fexofinadine-120mg
Allegra	Aventis	0212024	Fexofinadine-120mg
Allerfex	Kirkland Signature	006081	Fexofenadine-180mg

2.4 ***Preparation of Sample Solution for analysis by UV-Visible Spectrophotometer***

For spectrophotometric determination, exact 100 mg of sample was taken in 25 ml volumetric flask and diluted with diluent. The solution was left in ultrasonic bath for 5 min and then filtered through membrane filter. As per table no. 2 according to Fexofinadine Hydrochloride present in the given sample, the corresponding volume was taken and volume made up to 25 ml by diluent to get solution of 6 ppm of each sample.

TABLE NO. 2

Sample	Wt. of sample tablet (mg)	Fexofenadine present in tablet (mg)	First dilution (ml)	Conc. of solution (ppm)	Volume required for final dilution (ml)	Final dilution (ml)	Final conc. (ppm)
Rhinofex (390mg)	100	30.77	25	1230	0.12	25	6
Allegra (430mg)	100	27.90	25	1116	0.13	25	6
Allerfex (670mg)	100	26.89	25	1074	0.14	25	6

2.5 ***Preparation of Sample solution for analysis by HPLC***

For HPLC determination, exact 100 mg of sample was taken in 25 ml volumetric flask and diluted with diluent. The solution was left in ultrasonic bath for 5 min and then filtered through membrane filter. As per table no. 3 according to Fexofinadine Hydrochloride present in the given sample, the corresponding volume was taken and volume made up to 25 ml by diluent to get solution of 100 ppm of each sample.

TABLE NO. 3

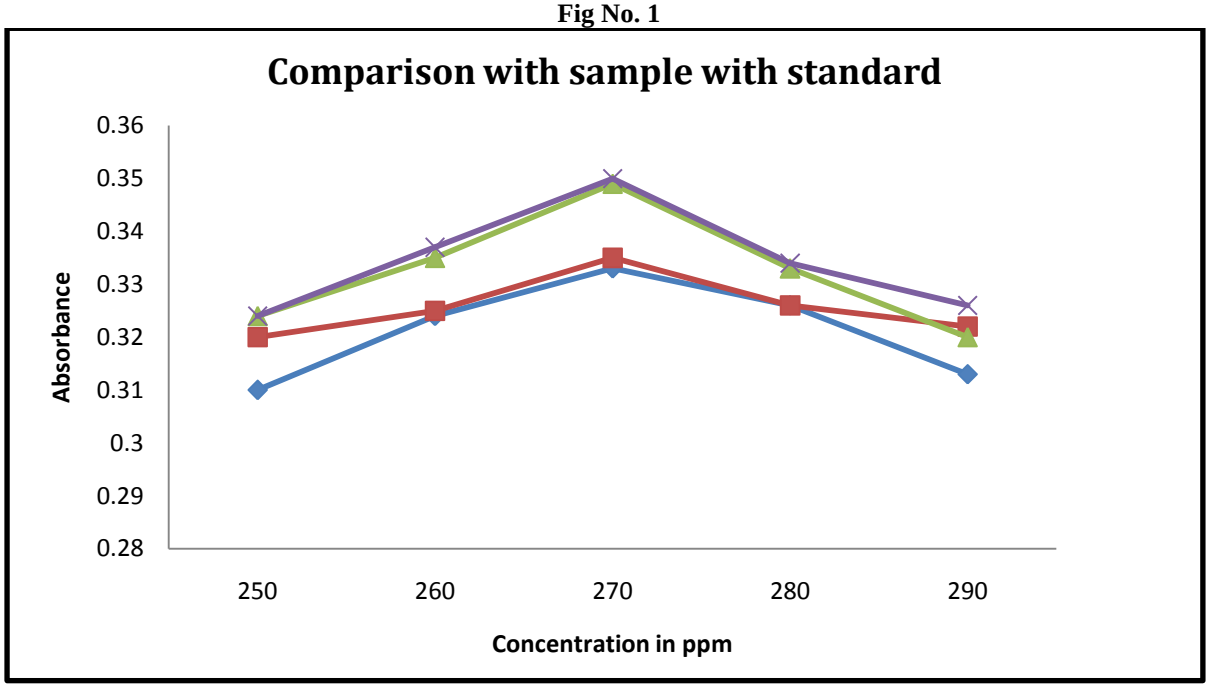
Sample	Wt. of sample tablet (mg)	Fexofenadine present in tablet (mg)	First dilution (ml)	Conc. of solution (ppm)	Volume required for final dilution (ml)	Final dilution (ml)	Final conc. (ppm)
Rhinofex (390mg)	100	30.77	25	1230	2.2	10	100
Allegra (430mg)	100	27.90	25	1116	3.2	10	100
Allerfex (670mg)	100	26.89	25	1074	2.2	10	100

III. RESULT AND DISCUSSION

3.1 Analysis by UV-Visible Spectrophotometer

For UV-Visible Spectrophotometer the λmax value for standard solution of Fexofinadine Hydrochloride was found to be 220nm. Fig 1.shows the comparison of different sample solutions with standard sample. The calibration graph when plotted using different concentration of Fexofinadine Hydrochloride sample was found to be straight line passing through origin obeying Beer's law. Using this calibration graph values for samples were found out which are depicted in table no. 4. They were all found in range using their values percentage recovery was calculated which was found to be in range as shown in table no. 4.

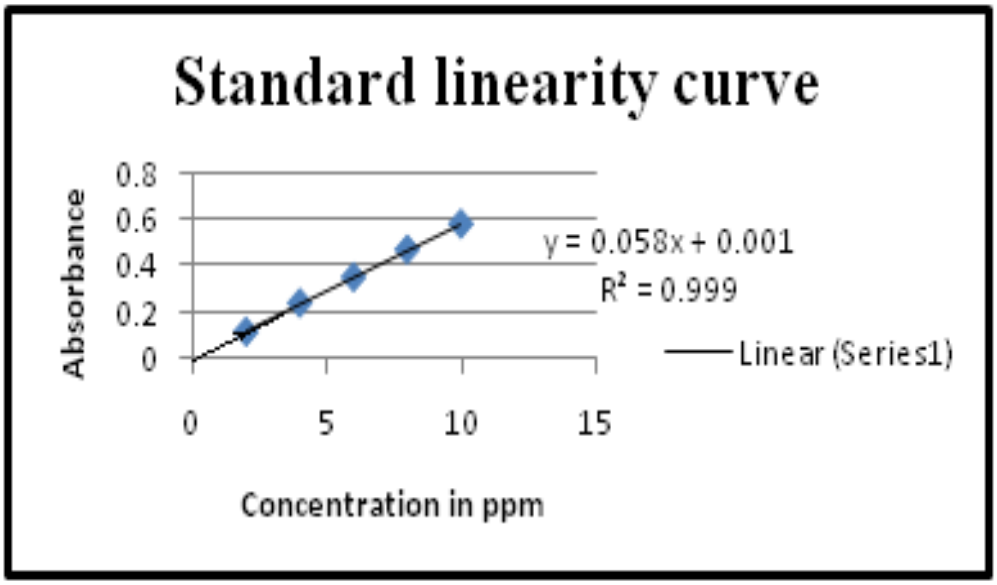
Fig No. 1



3.2 ***Analysis by HPLC method***:

For HPLC measurements, the standard sample solutions of Fexofinadine Hydrochloride were prepared. Ranging from 40ppm to 200ppm. The standards were run and their percentage area was calculated. Using those values a standard linearity curve was plotted. It was observed that it follows Lambert beers law.

Fig No. 2



After the system was set using standard sample the commercial samples were run and following results were obtained.

Sample	Conc. In PPM	% Area
Allegra	100	7656151
Allerfex	100	5079636
Rhinofex	100	5607170

The following formula was used to calculate the percentage recovery of the sample by using both UV-Visible and HPLC method

$$\%\text{Recovery} = \frac{\textbf{\% Assay}}{\textbf{Label claim on sample}} \times 100$$

IV. CONCLUSION

Despite the number of methods described by the other researchers for analysis of Fexofenadine Hydrochloride the proposed UV-Visible Spectrophotometric method and HPLC method for determination of Fexofenadine Hydrochloride in pharmaceutical samples is simple and rapid than other sophisticated instruments. All the samples were analyzed within the range as prescribed on tablet. These methods are very appropriate for routine analysis of active drugs in the laboratories. The procedures are easy to execute and require less sample handling than methods described in the literature. The following table gives the summary of result.

TABLE NO. 5

Sample	% Recovery of Fexofenadine Hydrochloride by UV-Visible Spectrophotometry method	% Recovery of Fexofenadine Hydrochloride by HPLC method
Allegra	96.49	97.20
Allerfex	99.43	99.97
Rhinofex	86.62	94.04

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