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DEVELOPMENT OF UV SPECTROPHOTOMETRIC METHOD FOR QUANTITATIVE ANALYSIS OF FEXOFENADINE HYDROCHLORIDE

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ABSTRACT:

For the purpose of determining the concentration of furofenadine hydrochloride (FEXO) in bulk and suspension formulation, a straightforward, sensitive, and accurate method was created and verified. It was discovered that the FWHM in methanol:water (2:3) was 220 nm. In the concentration range of 2–18 µg/ml, within the 0.08 µg/mL detection limit and the 0.4 µg/mL quantification limit for FEXO, Beer's law was followed. The ICH recommendations were followed in the validation of the analytical method. The results showed that the correlation coefficient (r2) was 0.999, the recovery percentage was 100.1, and the percentage of RSD readings fell under the 2.0% acceptable threshold. When the temperature was changed to test the resilience of the FEXO finding, there was no discernible change even at very tiny temperature variations.

The approach was therefore determined to be reliable. When the results were statistically compared to those produced using the official method, there were no discernible variations in terms of analytical characteristics like accuracy and precision.

Keywords: UV spectroscopy validation of **fexofenadine hydrochloride (FEXO)**

I. INTRODUCTION:

The chemical name of Fexofenadine hydrochloride (FEXO) is [4-(1-hydroxy-4-{4-[hydroxy(diphenyl) methyl]piperidin-1-yl}butyl)-α,α- benzeneacetic acid hydrochloride, molecular weight is 538.13 and molecular formula is C32H39NO4.HCL shown in figure1. It used as an antihistamine Agent second-generation, long lasting H1-receptor antagonist (antihistamine) which has a selective and peripheral H1-antagonist action

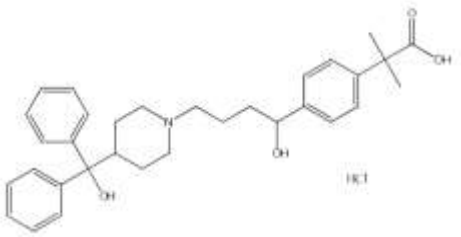

Figure1: Structure Fexofenadine HCl

Literature survey revealed that several methods including for the determination of FEXO. Described method for estimation for FEXO in dosage form are UV spectroscopy [3,4] high-performance liquid chromatography (HPLC)[4-13], liquid chromatography/ mass spectrometry[14-15] (LC/MS), RP-UPLC method[16] and Thin Layer chromatography (TLC)[17], but there is no any analytical method for the determination of FEXO single drug. To the best of our knowledge, the present work was aimed at development and validation of a simple, accurate, sensitive and precise for simultaneous estimation of FEXO in bulk and suspension formulation.

II. MATERIAL AND METHOD:

The marketed pharmaceutical tablet dosage form of FEXO Allegra a Morepen Laboratories Limited from India was purchased from local market, and used within its shelf life period. Solution of FEXO was prepared in solvent ethanol. This solution scanned in UV-spectrophotometer region (200-400nm) and maximum absorbance was determined for this solution

Wavelength of scanning: 220 nm

Scanning and determination of maximum wavelength (λmax):

In order to ascertain the wavelength of maximum absorption (λmax) of the drug, different solution of the drug (2µg/ml, 4µg/ml, 6µg/ml, 8µl/ml……..16µg/ml) in ethanol was scanned using UV-spectrophotometer within the wavelength region of 200-400nm against ethanol as blank. The absorption curve show characteristics absorption at 220 nm for FEXO.[18-20].

Preparation of solution of FEXO:

Tablet of FEXO was weighed on weighing balance. The tablets were grounded with the help of motor and pestle to make them in powder from. This weighed triturated powder of FEXO transferred into a beaker and dissolve in an Ethanol and shaken for 10 min and then sonicated for 15 min. The solution was allowed to stand at room temperature for 20-30 min and filtered through Whatman no. 41 filter paper. 2.0 mL of filtrate stock solutions were transferred into separately volumetric flasks of 100ml. Finally volume make up with ethanol. The analytical procedure was repeated six times for the powder sample. The absorbance of solution of FEXO was determined by U.V. spectroscopy, at wavelength 220nm.

Validation of UV Spectrophotometry:

This method was validated on accuracy, precision, LOD, LOQ, linearity, range and robustness as per ICH guidelines.

Linearity:

The linearity of analytical method is its ability to elicit test results that are directly proportional to the concentration of analyte in sample within a given range. From the 'standard stock' (100µg/ml) solution 0.2 to 1.8ml were transferred in a series of 10ml of volumetric flasks. The volume was making up to the mark with Methanol: water (2:3) the concentration of 2 to 18µg/ml. The peak areas of those solutions were measured at 220 nm.

Range:

The range of analytical method was decided from the interval between levels of calibration curves by plotting the curves. Different concentrations ranging from 2, 4, 6, 8 and 18 µg/ml of FEXO was prepared in 100 ml volumetric flask. The peak areas of those solutions were measured at 220 nm.

Accuracy:

Recovery study was carried out by standardization method by adding the known amount of FEXO at three different concentrations.

Precision:

The precision of an analytical method was studied by performing repeatability and intermediate precision. i. e. intra-day precision and inter-day precision. This parameter was evaluated by carrying out six independent test samples. RSD (%) of six assay values obtained which was calculated. The system precision and method precision was carried out by analysing the sample in different days. The RSD (%) values for method precision and system precision where less than 2% indicating high degree of precision of developed method.

Limit of Detection:

Limit of Detection was determined based on standard deviation of same concentration and LOD calculated by equation 1. LOD=3.3(SD/S)

$$LOD=3.3(SD/S) \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots (1)$$

Where, S.D.= Standard deviation of the Y-intercepts of the 5 calibration curves. Slope = Mean slope of the calibration curves

Limit of Quantitation:

Quantitation limit was determined based on standard deviation of same concentration and LOQ calculated by equation 2.

$$LOQ=10(SD/S) \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots (2)$$

Where, Where, S.D. = Standard deviation of the Y-intercepts of the calibration curves.

Robustness:

Robustness is the method was determined by carried out the analysis at different temperatures i.e. at a room temp. 29°C and 24°C.

III. RESULT AND DISCUSSION:

Preliminary analysis of FEXO:

Preliminary analysis of FEXO such as description, Solubility, Melting point is identified as per IP and other available literature.

UV-Spectroscopy for FEXO

For method Validation:

FEXO being UV absorbing has been successfully employed for its quantitative determination by UV spectrophotometric method. Being freely soluble in methanol: water (2:3), stock solution and working standards were made in methanol: water (2:3). The of the drug for analysis was determined by taking scan of the drug sample solution in the entire UV region (200-400nm).The correlation coefficient of the standard drug was 0.999(Graph).The proposed method showed absorption maxima 220nm and the Concentration range is 2-18 /ml The limit of detection (LOD) was found to be 0.08µg /ml and limit of quantification (LOQ) to be 0.4 µg /ml. All statistical data prove validity of proposed method, which can be applied in industries for routine analysis of FEXO suspension.

Table1 : Observation for standard calibration curve

Sr.no	Concentration (µg/ml)	Absorbance (nm)
1	2	0.09
2	4	0.156
3	6	0.201
4	8	0.255
5	10	0.302
6	12	0.354
7	14	0.401
8	16	0.453
9	18	0.505

The proposed method was also evaluated by the assay of commercially available tablet formulation containing 10 mg of FEXO. It was observed that excipients present in formulation did not interfere with peak of FEXO calibration curve is shown in figure 2.

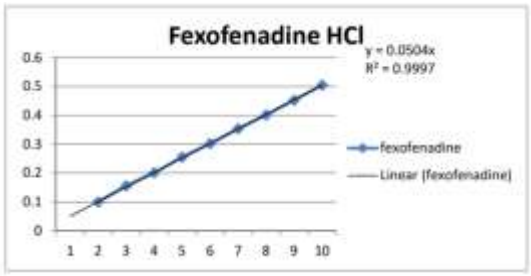

Figure 2: Calibration curve of FEXO

Linear response was observed in the concentration range 2-18 µg/ml with correlation coefficient r2 of 0.999 a typical calibration curve has the regression equation of y = 0.050x. The LOD and LOQ of FEXO were found to be 0.08 µg/ml and 0.4 µg/ml respectively. The results of LOD and LOQ are shown in table 2.

Table 2: Result of Range LOD and LOQ for FEXO

Name of Drug	Linearity range	LOD (µg/ml)	LOQ (µg/ml)
FEXO	2-18	0.08	0.4

For precision and intermediate precision % FEXO. Thus it confirms good precision of the analytical method development. The results of precision studies are shown in table 3.

Table 3: Precision: Inter-day variability and Intra-day Variability of FEXO

Conc.(µg/ml)	Abs (Inter-day)			±SD	Abs (Intra-day)			±SD
	Day 1	Day 2	Day 3		Day 1	Day 2	Day 3	
8	0.258	0.248	0.252	0.007	0.284	0.289	0.296	0.006
10	0.868	0.856	0.874	0.003	0.849	0.836	0.849	0.004
12	1.240	1.249	1.390	0.006	1.390	1.432	1.451	0.009

Robustness of the method was performed by making deliberate changes in flow rate, wavelength, pH and mobile phase ratio and by calculated % RSD values it was found within acceptance criteria of 2.0 %. The results of robustness are shown in table 4.

Table 4: Robustness of developed method by changing Temperature

Concentration (µg/ml)	Abs at 28°c.	Abs at24°c
10	0.433	0.488
12	0.815	0.847
14	1.080	1.077

Figure 3: Spectrum of FEXO at 220nm.

IV. CONCLUSION:

The findings demonstrate the accuracy and precision of the proposed UV-spectroscopic method.

However, well-validated proposed methods seem to be quite sensitive and useful for routinely analyzing fexofenadine HCL in its suspension form. The results of the recovery research improved the recommended strategy's accuracy.

REFERENCES

1. Indian Pharmacopoeia, 2010, "The Indian Pharmacopoeia Comission, Ghaziabad, Govt. of India Ministry of Health and Family Welfare,(2), 1705.
2. British Pharmacopoeia, 2009, London: HMSO Publication,(2),2494 Pawar A. S, Kdam V. J.2010, " Quantitative Estimation of Fexofenadine hydrochloride suspension by UV Spectrophotometry", International Journal Pharmacy Pharm Sci. 422-425.
3. Breier AR, Steppe M, Schapoval EE,2007 , "Validation of UV spectrophotometric method for Fexofenadine hydrochloride in pharmaceutical formulations and comparison with HPLC". Analytical letters.40(12):23,29-37
4. Vekaria H, Limbasiya V, Patel P.2013, "Development and validation of RP-HPLC method for simultaneous estimation of montelukast sodium and Fexofenadine hydrochloride in combined dosage form." Journal of Pharmacy Research.6(1):134-9.
5. Nimje HM, Nimje ST, Oswal RJ, Bhamre ST.2012, "Stability indicating RP-HPLC method for estimation of Fexofenadine hydrochloride in pharmaceutical formulation." E-Journal of Chemistry.9(3):1257-65.
6. Tamilselvi N, Sruthi K.2012, "Development of validated HPLC method for Simultaneous estimation of Fexofenadine hydrochloride and Montelukast Sodium in tablet dosage form." International Journal of Pharmaceutical Sciences and Research. 3(12):4876
7. Buchupalli P, Medidi S,2015, "RP-HPLC method for the simultaneous estimation of ambroxol hydrochloride and Fexofenadine hydrochloride in bulk and in a tablet mixture". Journal of Applied Pharmaceutical Science, 5(2):074-80.
8. Kozan I, Palabiyik IM, Karacan E, Onur F,2008, "Spectrophotometric and high performance liquid chromatographic determination of Fexofenadine hydrochloride in pharmaceutical formulations". Turkish Journal of Pharmaceutical Sciences.5(3):175-89.
9. Kumar KP, Haque MA, Kumar TP, Nivedita G, Hasan S, Prasad VV. 2012, "Simultaneous determination of Montelukast sodium and Fexofenadine hydrochloride in combined dosage form by using RP-HPLC method." World J Chem. 7(2):42-6
10. AlAani H, Alashkar I.2013, " Development and validation of stability-indicating RP-HPLC method for the analysis of levocetirizine dihydrochloride and Fexofenadine hydrochloride in the presence of parabens in liquid dosage forms. group. 1:2.64-66

11. Pathak SM, Kumar AR, Musmade P, Udupa N.2008, " A simple and rapid high performance liquid chromatographic method with fluorescence detection for the estimation of Fexofenadine hydrochloride in rat plasma—application to preclinical pharmacokinetics. Talanta.76(2):338-46
12. Arayne MS, Sultana N, Shehnaz H, Haider A,2011, "RP-HPLC method for the quantitative determination of Fexofenadine hydrochloride in coated tablets and human serum",Medicinal chemistry research, 20(1):55-61
13. Hofmann U, Seiler M, Drescher S, Fromm MF.2002, "Determination of Fexofenadine hydrochloride in human plasma and urine by liquid chromatography–mass spectrometry". Journal of Chromatography B.766(2):227-33
14. reier AR, Paim CS, Menegola J, Steppe M, Schapoval EE,2004 , "Development and validation of a liquid chromatographic method for Fexofenadine hydrochloride in capsules". Journal of AOAC International.87(5):1093-7
15. Vaghela B, Rao SS, Reddy AM, Venkatesh P, Kumar N.2012, "Identification and characterization of an oxidative degradation product of Fexofenadine hydrochloride, development and validation of a stability-indicating RP-UPLC method for the estimation of process related impurities and degradation products of Fexofenadine hydrochloride in pharmaceutical formulations". Scientist pharmaceutica. ;80(2):295-310.
16. MAHMOOD S, AHMAD Z, ARSHAD M.2018, " Estimation of Fexofenadine hydrochloride hcl and pseudoephedrine hcl by spectrophotometer and TLC in combined tablet dosage form." Open J. Chem. 1(1):01-11.
17. Kasture AV, Mahadik KR, Wadodkar SG, More HN. 2003, A textbook of Pharmaceutical Analysis- Instrumental Methods. Part 2, 9th ed. Nirali Prakashan,103-104.
18. Chatwal G, Anand S.2008, "Instrumental methods of Chemical Analysis", Himalaya Publishing House,40-45. 2007, "Indian Pharmacopoeia", Controller of Publication, DELHI, Vol I, II, III.