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DEVELOPMENT AND VALIDATION OF UV/ VISIBLE SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF FESOTERODINE IN BULK AND PHARMACEUTICAL FORMULATIONS

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ABSTRACT

Fesoterodine Fumarate is the competitive muscarinic receptor antagonist with muscle relaxant and urinary antispasmodic properties and rapidly hydrolyzed in vivo into its active metabolite 5-hydroxy methyl tolterodine, which binds and inhibits muscarinic receptors on the bladder detrusor muscle, thereby preventing bladder contractions or spasms caused by acetylcholine. This results in the relaxation of bladder smooth muscle. A simple, sensitive, accurate and reproducible UV/visible spectrophotometric method was developed for the determination of Fesoterodine in bulk and pharmaceutical dosage forms. The solvent used was distilled water and wavelength corresponding to maximum absorbance for the drug was found at 210 nm. Drug obeyed Beer's law in the concentration range of 10 - 80 µg/ml. with a correlation coefficient of 0.9995. The linear regression equation obtained was y=0.0093x+0.0064, where y is the absorbance and x is the concentration of the pure drug solution. The method was validated for several parameters such as Linearity, Accuracy, Precision and Robustness as per the ICH guidelines. The % recovery value which is close to 100% indicates reproducibility of the method and absence of interference of the excepients present in the formulation.

KEYWORDS: Fesoterodine, Spectroscope, Absorbance, Wavelength.

INTRODUCTION

Fesoterodine is an anticholinergic and antispasmotic agent used to treat urinary incontinence and overactive bladder syndrome. Fesoterodine has not been implicated in causing liver enzyme elevations or clinically apparent acute liver injury. It was approved by the European Medicines Agency in April 2007, the US Food and Drug Administration on October 31, 2008 Chemically it is 2-enedioic acid;[2-[(1~{R})-3-[di(propan-2-yl)amino]-1-phenylpropyl]-4-(hydroxymethyl)phenyl] 2-methylpropanoate. Fesoterodine fumarate is a white to off-white powder, which is freely soluble in water.

MATERIALS AND METHODS

Instrumentation

UV Visible Double Beam Spectrophotometer was employed with a matched pair of 1 Centimetre quartz cell was used to measure the absorbance of all the solutions.

Chemicals and Reagents

The gift sample was obtained from Chandra labs Hyd and Analytical reagent grade Acetonitrile in distilled water was used as a co solvent.

Preparation of Standard Stock Solution

10 mg of Fesoterodine the standard stock solution was taken and dissolved in 20 ml of AR grade acetonitrile volume was made up to100 ml with distilled water. The final concentration of this stock solution being 100 µg/ml.

Determination of λmax

By appropriate dilution of standard stock solutions of Fesoterodine in distilled water containing 20µg/ml of Fesoterodine, dilutions were made and scanned on Shimadzu 160A a visible double beam spectrophotometer in the range of 200- 400 nm against distilled water as blank. Wavelength of maximum absorption was determined for drug. Fesoterodine showed maximum absorbance at 210 nm.

Preparation of Standard Solution

The series of the concentration solution was prepared from 10 – 100 µg/ml with different aliquots and scanned on spectrophotometer and their absorbencies were measured at about 210nm using acetonitrile in distilled water as blank and calibration curve was found to be linear in the range of 10 – 80 µg/ml. All estimations were done in triplicate and the average values were reported.

Method Validation

The method was validated for several parameters like Linearity, Accuracy, Precision, Robustness according to ICH guidelines

RESULT AND DISCUSSION

Linearity

The linearity of the analytical method was to establish the linearity of the proposed method, various aliquots of the standard solution of the drug were prepared from stock solution and analysed by plotting the absorbance versus the concentration data and were treated by linear regression analysis. linearity in the range of 10-80 µg/ml. with a correlation coefficient of 0.9991. The slope, intercept, correlation-coefficient and optical characteristics are summarized in Table 1and 2 and Figure 1.

Accuracy

Accuracy of the proposed method was determined using recovery studies. Accuracy was determined By spiking known amounts of the analyte into the placebo formulation (F1, F2 and F3) across the specified range of the analytical procedure to obtain 40, 50 and 60 µg/ml (80, 100 and 120%) the proposed method was determined with all the recovery studies. accuracy was evaluated in terms of percent recovery. (Table 4)

Percent Recovery was calculated using the formula

[%Recovery = 100 x Mean Experimental Concentration/ Theoretical Concentration].

Precision

Precision studies were carried out to ascertain the reproducibility of the proposed method. Both Intra day and Inter day methods were carried out for the precision studies. The intraday precision was evaluated by analyzing six samples of 50 µg/ml of the test concentration (n=6) at an interval of half an hour each.

Similarly interday precision was evaluated on two consecutive days (*n* = 12). Interday precision was evaluated by 3 samples at an interval of 1 hour on day 1 and 3 samples at an interval of 1 hour on day 2.The concentration of the drug was determined and the value of relative standard deviation (%R.S.D) of the assay method was calculated. The precision result showed a good repeatability with percent relative standard deviation less than 2. (Table 5).

Robustness

Robustness was determined by carrying out analysis by two different analyst and also by carrying out the analysis on two different instruments and the respective absorbance was noted and the results was indicated as SD. Four sample solutions each containing 50 µg/ml were prepared and analyzed in two different U.V. visible spectrophotometers (Hewlett Packard 8453 and Shimadzu 160A) immediately after preparation. (Table 6).

Table 1: Concentration and absorbance obtained for standard plot of Fesoterodine in distilled water.

Sl.No	Concentration microgm/ml	Absorbance
1	0	0
2	10	0.094
3	20	0.202
4	30	0.282
5	40	0.381
6	50	0.459
7	60	0.522
8	70	0.558
9	80	0.652

Table 2: Optimum conditions, optical characteristics and statistical data of the regression equation for Fesoterodine.

Sl.No	Parameters	Value
1	Absorbance Maximun	210 nm
2	Beer lamberts law limit	10 -80
3	Correlation coefficient	0.995
4	Regression Coefficient	Y=ax-b
5	Slope	0.0093
6	Intercept	0.0064

Table 3: Calibration curve of Fesoterodine according to the proposed method

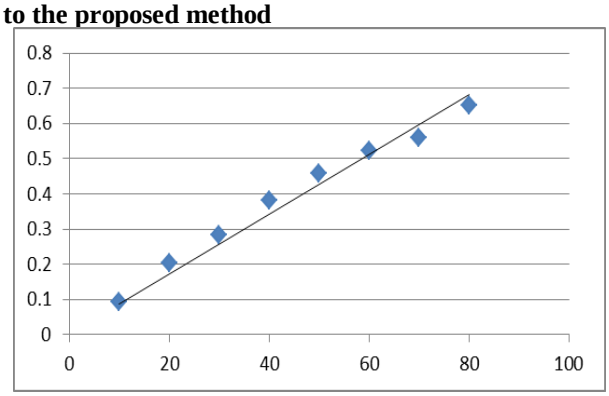

Table 4: Accuracy data for Fesoterodine.

Sl.No	Initial amount	Add of Known Drug 100 mg	Total theoretical drug µg/ ml	% Recovery
1	0	4 mg	40	100
2	0	5 mg	50	96
3	0	6	60	96

Table 5: Precision data for Fesoterodine.

Sl.no	Time in Mins	Absorbance N=3	Total theoretical drug	Total experimental drug
1	30	0.4614,0.4610,0.4614	50	49.99
2	90	0.4714,0.4712,0.4714	50	49.97
3	150	0.4614,0.4612,0.4612	50	49.98

Table 6 Robustness data for Fesoterodine.

Sl.No	Spectrophotometer		Shimadzu 3000 +	
	Elico	UV/Vis	Abs	Conc
	Abs	Concentration		
1	0.4655	49.6	0.4616	49.16
2	0.4635	49.2	0.4625	49.02

CONCLUSION

The linear calibration curve was obtained at concentration range 10-80 µg/ml. with a correlation coefficient (0.9991), Slope (0.0093) and Intercept (0.0064).

The proposed method was reproducible because results obtained with in inter-day and intra-day were in acceptable limit. The results of assay and % recovery were found to be satisfactory, indicating that the proposed method is precise and accurate and hence can be used for the routine analysis of La,motrigine in bulk and pharmaceutical formulation.

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