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ANALYTICAL METHOD DEVELOPMENT OF FAMOTIDINE USP IN BULK AND SINGLE COMPONENT FORMULATION

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ABSTRACT
Two simple, precise and economical UV method have been developed for the estimation of Famotidine USP in bulk and pharmaceutical formulation. Famotidine USP has the absorbance maxima in the first order derivative spectra is 280nm (Method A). Method B applied was Area Under Curve (AUC) for the analysis of Famotidine USP in the wavelength range of 264.0nm to 269.0nm. Drug followed the Beer-Lambert's law in the concentration range of 10-80µg/ml in both the methods. Results of the analysis were validated statistically and by recovery studies and were found to be satisfactory.

KEYWORDS: Famotidine tablets, UV-Visible Spectrophotometer, first order derivative, Area Under Curve (AUC), Methanol and distilled Water

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INTRODUCTION

Famotidine USP is H_2-receptor antagonist which works by blocking H_2 receptors found on the cells in the stomach lining. Blocking these receptors prevents histamine. It is not official in any of the Pharmacopoeias expect USP and BP and only listed in the The Merck Index [1], and Martindale [2], The Complete Drug Reference. Literature survey revealed that there are no analytical methods for estimation of Famotidine USP as a single component by UV-Visible Spectrophotometry. The methods reported are, RP-HPLC method [3], Kinetic Spectrophotometric determination in commercial dosage forms[4], Synchronous spectrofluorimetric determination of Famotidine, Fluconazole and Ketoconazole in bulk powder and in pharmaceutical dosage forms [5], Polarographic determination of Famotidine in dosage forms Polarographic determination of Famotidine in dosage forms [6], Spectrophotometric estimation of Famotidine and Mefenamic acid in their dosage form [7], HPLC-UV method for the determination of Famotidine in serum [8], spectrophotometric methods for the assay of Farnotidine in bulk drug form and formulaton [9], UV- spectophotomerty of Famotidine tablets [10]. Hence, the present study deals with the development of simple, precise, accurate, sensitive, rapid and economical UV-Visible Spectrophotometric method for the estimation of Famotidine USP in bulk and pharmaceutical formulations.

MATERIALS AND METHODS

Materials

Pure Famotidine USP was obtained as a gift sample from Dr. REDDY'S Lab Ltd. Hyderabad. A Shimadzu UV-1700 UV/VIS Spectrophotometer was used with 1cm matched quartz cells. FAMOTIDINE Tablets of 10 mg strength were procured from local pharmacy i.e.

Method

Accurately about 10mg of Famotidine USP was weighed and transferred to 100ml volumetric flask. To it 25ml of methanol was added to dissolve the drug completely with vigorous shaking. Then the volume was made up to with the glass distilled water up to the mark to give the drug stock solution of concentration 100µg/ml. aliquots of standard stock solution were pipette out and suitably diluted with distilled water to get the final concentration of standard solutions. In the first order derivative method at n=1 showed a sharp peak at 280nm (**Figure 1**). The absorbance difference at n=1 ($dA/d\lambda$) is calculated by the inbuilt software of the instrument which was directly proportional to the concentration of the standard solution. The standard drug solution was diluted so as to get the final concentration in the range of 10-80 µg/ml and scanned in the first order derivative spectra. The calibration curve of $dA/d\lambda$ against concentration of the drug showed linearity. The AUC method involves the calculation of integrated value of absorbance with respect to the wavelength between two selected wavelength λ_1 and λ_2. Area calculation processing item calculate the area bound by the curve and the horizontal axis. The horizontal axis is selected by entering the wavelength range over which the area has been calculated. This wavelength range is selected on the basis of repeated observation so as to get the linearity between area under curve and concentration. Suitable dilution of standard stock solution (100µg/ml) of the drug were prepared and scanned in the spectrum mode from the wavelength range 400-200nm (**figure 2**) and the calibration curve was plotted. All the two method were checked by analyzing the samples with known concentration. As the results obtained were satisfactory, the method was applied for pharmaceutical formulations.

For estimation of Famotidine USP in tablet formulation by the two methods, twenty tablets of the brand were weighed and triturated to fine powder. Tablet powder equivalent to 10mg of Famotidine USP was weighed and dissolved and further diluted with quantity sufficient with distilled water. It was kept for ultrasonification for 45min; this was then filtered through Whatman filter paper no. 41 to get stock solution of concentration of 100µg/ml. Various dilution of the tablet solution were prepared and analyzed for six times and concentration was calculated by using the calibration curve for two methods.

Both the methods were validated according to ICH guidelines[11,12] by carrying out analysis of six replicate samples of the tablets (**Table 1**) recovery studies were carried out at three different levels i.e. 80%, 100%

and 120% by adding the pure drug (8, 10 and 12mg respectively) to previously analyzed tablet powder sample. From the amount drug found, percentage recovery was calculated (**Table 2**).

RESULT AND DISCUSSION

Both the methods A and B for the estimation of Famotidine USP in tablets dosage form were found to be simple accurate and reproducible. Beer- Lambert's law was obeyed in the concentration range of 10-80µg/ml in both the methods. The value of standard deviation was satisfactory and the recovery studies were close to 100%.

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Table 1: Optical characteristics and other parameters for Famotidine USP

Parameters	Method A	Method B
λ_{Max} (nm)/wavelength range (nm)	280	269.0 - 264.0
Beer's – Lamberts range (µg/ml)	10-80	10-80
Coefficient of correlation (r^2)	0.9997	0.9996
Regression Equation y = mx + c		
a. Slope (m)	-0.0020	0.2304
b. Intercept (c)	0.0005	-0.040
LOD	-0.121	0.0015
LOQ	-0.368	0.0046
Molar Absorptivity	-6.7489×10^{-08}	-

A is first order derivative spectrum method with n=1
B is the AUC method
T_1 is the brand of tablet formulation

Table 2: Analysis of standard Famotidine USP

Method	Tablet Formu.	Label claim	Conc. Obt.	% Mean	S.D.	R.S.D.	S.E.
A	T_1	10	10.006	100.06	0.2597	0.2595	0.1060
B	T_1	1o	9.979	99.797	0.4527	0.4536	0.1848

A is first order derivative spectrum method with n=1
B is the AUC method
T_1 is the brand of tablet formulation (FAMOTIDINE Tablet by DR. REDDY'S)
* the results are the mean of six readings (n=6)

Table 3: Recovery studies

Method	Tab. Formu.	Level of reco.	Label claim	Conc. Obt.	% Mean	S.D.	R.S.D.	S.E.
A	**T_1**	80	10	9.990	99.90	0.4053	0.4058	0.2341
		100	10	10.043	100.43	0.1323	0.1317	0.0763
		120	10	10.029	100.29	0.2946	0.2937	0.1701
B	**T_1**	80	10	9.971	99.71	0.6971	0.6990	0.4025
		100	10	9.978	99.78	0.2611	0.2616	0.1508
		120	10	9.993	99.93	0.6312	0.6315	0.3644

A is first order derivative spectrum method with n=1
B is the AUC method
T_1 is the brand of tablet formulation ((FAMOTIDINE Tablet by DR. REDDY'S)
* the results are the mean of six readings (n=6)

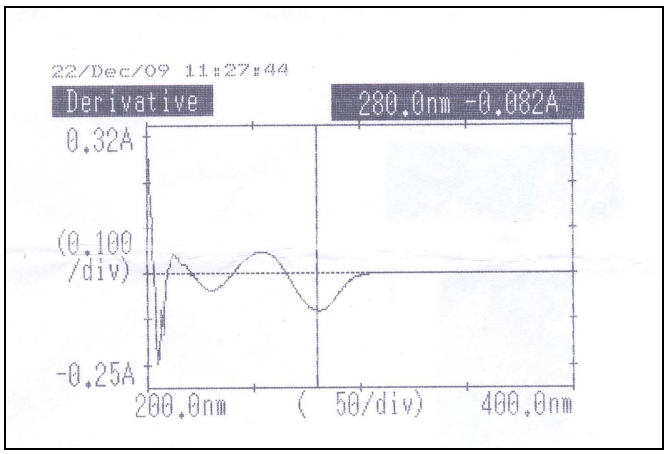

Figure 1: First order derivative spectrum of Famotidine USP

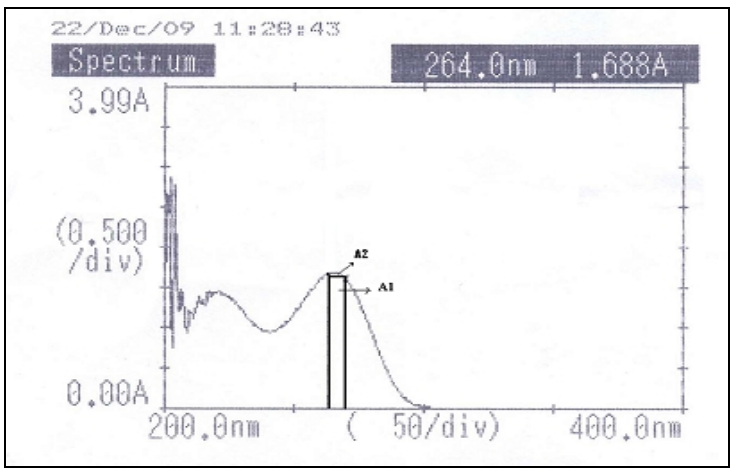

Figure 2: Wavelength range selected for AUC method of Famotidine USP

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