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UV spectrophotometric assay of Famotidine formulations

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Abstract
Famotidine belongs to H2-receptor antagonist. It is used widely for the treatment of treatment of (GERD) gastro-esophageal reflux disease and gastric ulceration duodenal ulcer, stress ulcer. A simple, efficient spectrophotometric method for the assay of famotidine has been developed for estimation of famotidine formulations. Comparision of three different brands of famotidine (nocid, famulcer and optifam) has also been done. The assay is carried out in lambda max at about 260 nm using water as solvent. Different formulations of drug was dissolved in water to prepare solutions containing famotidine 20 mg. Similarly, a sample of ground tablets of different brand were dissolved in water and dilutions were made in the range of 200-12.5 μgmL^{-1}. The absorbance of sample preparation was measured at 260 nm against the water (blank solvent) and the assay was determined by the absorbance of each brand. Our results reveals that among all the three brands of famotidine (nocid, famulcer and optifam) famulcer shows highest percentage assay 111.44%. Calibration curves were linear over the range of 12.5-200 $\mu g\ mL^{-1}$with a correlation coefficient ±0.92. Intra and inter-run precision and accuracy results were 98 to 102%. Proposed method was selective, accurate and precise therefore we can use for routine assay as well as quality control and clinical study.

1. Introduction

Histamine H_2-receptor antagonists are reversible competitive blockers of histamine at H_2-receptors and much selective even do not affect at the H_1-receptor. H_2-receptors are found in the stomach, in rat uterus and in heart hence their stimulation causes gastric acid secretion, relaxation of the uterus. They compete with histamine for H_2-receptors and block gastric acid secretion and some cardiovascular effects of histamine.

Famotidine (figure 1) is a H2-receptor antagonist used in ulcer .chemically is N'aminosulfonyl-3-[[[2-[diaminomethylene,amino]-4-thiazolyl,methyl,thio.
Propanimidamide and empirical formula is $C_8H_{15}N_7O_2S_3$ with molecular weight is 337.43. Famotidine is a white to light yellow crystalline compound which is freely soluble in glacial acetic acid, insoluble in ethanol , slightly soluble in methanol and very slightly soluble in water. Histamine H_2 antagonists famotidine (FMT) classified as class III drugs according to the Biopharmaceutics Classification System (BCS) [1,2] and used in the treatment of (GERD)gastro-esophageal reflux disease and gastric ulceration (duodenal ulcer, stress ulcer). [3] Various methods have been reported for the estimation of famotidine by spectrophotometric [4-6]titrimetry, HPTLC[7] and HPLC[8-10]. Our research group has done these types of assay for different commonly used generic and their brands.

These studies are very useful for paharmacist ,doctors and drug prescribers to

choose best drug[11-20].

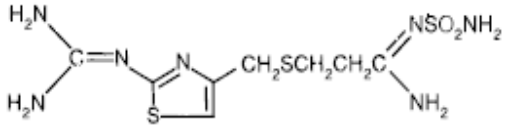

Fig 1. *Structure of famotidine*

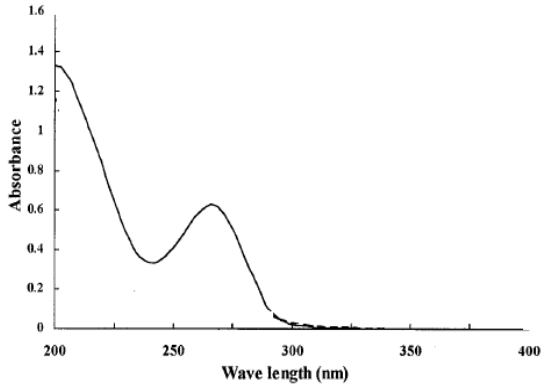

Fig 2. *UV spectra of famotidine*

2. Experimental

UV visible spectrophotometer model 1601 Shimadzu was used to measurement of spectra. The solvent which are used for the preparation of sample for assay was water.

2.1. Wavelength Selection

About 200 ppm of famotidine solution was accurately prepared in water. This solutions were scanned in the 200-700 nm for finding lambda max (fig 2). The wavelength (λmax) was observed at 260 nm and this wavelength was used for absorbance of sample measurement.

2.2. Standard Stock Solution

Accurately weighed 20 mg of famotidine standard was transferred to a volumetric flask and add sufficient water to produce 100 ml.

2.3. Sample Preparation

The five different brands (nocid, famulcer and optifam) were purchased from medical store located in Karachi, Pakistan. All tablets which were used have same batch number and were labeled to conatin famotidine 20 mg per tablet. These three brands have shelf life of 5 years.

20,20 tablets of five different brand of famotidine (nocid, famulcer and optifam) from the marketed sample were weighed and crushed with the help of a mortar and pestle. By calculating the average weight of each brand equivalent to 20 mg of famotidine was transferred into a volumetric flask containing approx 10 mL water. The solutions were sonicated for about 5-10 min and than make up volume upto 100 ml with water.

2.4. Procedure

After preparation of API and tablet solutions, strength of solution 200 ppm in 100 ml absorbance of the sample preparation and standard preparation in 1cm cell at the wavelength of maximum absorbance at about 260 nm, using a spectrophotometer, using the water as a blank solution.

3. Results and Discussion

The absorbance of sample preparation was measured at 260 nm against the water as a solvent blank and the assay was determined. Our results shows that among all the three brands of famotidine (nocid, famulcer and optifam). Famulcer shows highest percentage assay 111.44%. While nocid and optifam shows percentage assay of 106 and 101% respectively (fig 3).

3.1. Range and Linearity

Linearity is generally reported as the variance of the slope of the regression line. For linearity testing concentrations of famotidine brands i.e. 12.5,25,50, 100, and 2 00 μgmL^{-1}, respectively. Six runs were performed for every concentration. Analysed concentrations versus absorbance were plotted and the correlation coefficients were calculated which are shown in table 1 and figure 4-6 and % assay given in table 2.

3.2. Accuracy, Precision and Recovery Studies

The intra-and inter-day precision was calculated by assaying the samples (table 3). In this assay, the intra-day and the inter-day precision recovery was 98-102% in in all formulations. Intra and interday precision was performed and % RSD was found to be less then 2 which indicate the method was sufficiently accurate and precise.

The validity and reliability of the methods are assessed by formulations recovery studies. Drugs recovery for drugs is in good agreement with their label claims, which suggested non interference of formulation additives (Table 3).

The accuracy of an analytical procedure means the measurement of closeness between measured values to the true values. It was calculated as percentage relative error between the measured mean concentrations and taken concentrations.

Minimal of three concentration levels covering the specified ranges were selected and three runs were performed for every concentration and then absorbance was calculated as given in Table 4.

4. Conclusion

A simple and reliable UV method for monitoring famotidine brands has been developed. This method is used for small industrial scale.

Table 1. *Regression statistics*

Brand Name	Regression equations	R^2
Nocid	y = 0.0097x - 0.0556	0.9988
Famulcer	y = 0.0104x - 0.0375	0.9992
Optifam	y = 0.0091x + 0.1556	0.9235

Table 2. *% assay of different brands*

Brand Name	Average wt of tablet g	Absorbance at 260 nm	% assay
Nocid	210.8	1.909	106.05
Famulcer	106.4	2.06	114.44
Optifam	204	1.823	101.27

Table 3. *Precision of different brands*

Drugs	Conc. Injected	Inter-day		Intra-day	
	g mL^{-1}	%RSD	%Recovery	%RSD	%Recovery
A	12.5	0.01	98.44	1.08	100.3
	50	0.01	100.5	1.07	101.05
	100	0.00	99.87	1.29	99.5
	200	0.09	99.2	0.60	101.18
B	12.5	0.01	98.44	0.82	100.9
	50	0.00	101.9	0.34	101.08
	100	0.01	99.52	0.55	100.2
	200	0.00	100.6	0.57	100.52
C	12.5	0.01	98.44	0.81	100.9
	50	0.03	101.9	0.34	101.08
	100	0.00	99.52	0.55	100.2
	200	0.05	100.6	0.58	100.5

Table 4. *Accuracy of different brands*

Drugs	Conc µg/mL	%RSD	% Recovery
Nocid	80	0.11	101.6
	100	0.23	100.4
	120	0.15	101.5
Famulcer	80	0.11	101.5
	100	0.3	100.4
	120	0.11	101.8
Optifam	80	0.12	101.4
	100	0.13	100.4
	120	0.11	101.5

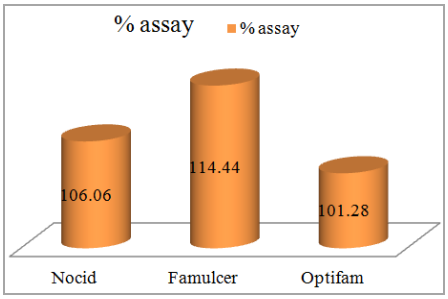

Figure 3. *% assay of different brands*

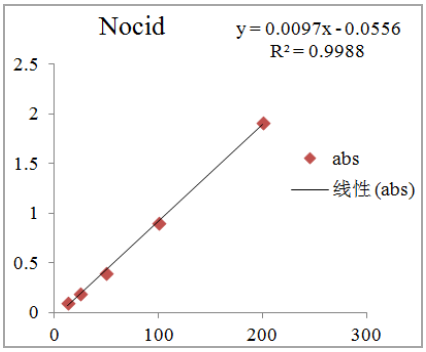

Figure 4. *Calibration curve of Nocid*

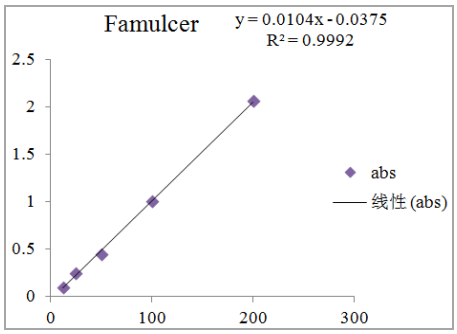

Figure 5. *Calibration curve of Famulcer*

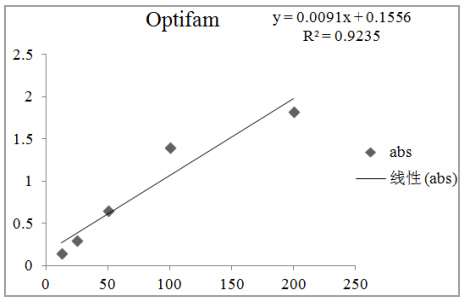

Figure 6. *Calibration curve of Optifam*

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