



DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHOD FOR QUANTITATIVE ESTIMATION OF LAFUTIDINE FROM TABLET FORMULATION

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Abstract One simple and sensitive spectrophotometric method has been developed for the quantitative estimation of Lafutidine from tablet. The method was developed and based on the solubility of Lafutidine in 0.1 N HCl (pH 1.2). The drug showed maximum absorbance at 286 nm and linearity (Lambert Beer's Range) was found in concentration range of 10-60 µg/ml and the standard curve equation was found to be $y = 0.015x - 0.015$ and R^2 value 0.997. The results of analysis were validated statistically and by recovery studies. The result of analysis was validated as per ICH guidelines and this method can be used for the routine analysis of Lafutidine formulation.

Keywords Lafutidine, Buffer pH 1.2, UV method, Validation

Introduction

Lafutidine is a H₂ receptor antagonist [1] chemically Lafutidine is 2-[(furyl methyl) sulfinyl]-N-(2z-4-[[4-(piperidin-1yl methyl) pyridin-2-yl] oxy] but-2-en-1-yl) acetamide [2]. It is useful in esophageal lesion induced by high gastric acid secretion. Lafutidine also showed his usefulness in burning mouth syndrome [3].

The earlier studies suggest that therapy with Lafutidine (Lafaxid™) is effective and well tolerated in patients with Acid Peptic Disorders (APDs). It is also effective in those patients who were previously not controlled on Proton Pump Inhibitors (PPIs) and first generation H₂ Receptor Antagonist. Therefore Lafutidine can be used as an empiric therapy to treat APDs [4].

Literature survey reveals that few spectroscopic and chromatographic methods for analysis of Lafutidine in different dosage form like LCMS [2], HPLC [4] and RP-HPLC [5] were reported. But there is no single reported method by UV. So in this work we attempt to develop a UV Spectrophotometric method for quantitative estimation of Lafutidine from tablet Formulation.

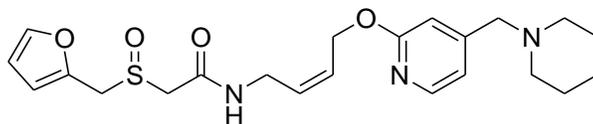


Figure 1: Chemical structure of Lafutidine [2]



Material and Methods

Apparatus

A Shimadzu UV/Visible double beam spectrophotometer (Model 1700) with 1 cm matched quartz cells was used in present study for spectral and absorbance measurements.

Reagents and Materials

All chemicals and reagents used were of analytical grade and double distilled water was used throughout the investigation.

- Buffer (pH 1.2): It was prepared according to I.P.1996
- Standard Stock Solution: Accurately weighed (100 mg) pure drug sample of Lafutidine was transferred to 100 ml (1000 µg/ml) calibrated volumetric flask, dissolved and made up to the mark with Buffer pH 1.2.

Developed Method

(1) Scanning for determination of maximum absorbance for pure drug in 0.1 N HCl (pH 1.2) and preparation of calibration curve.

By using the stock solution of 1000 µg/ml, transferred 10 ml into 100 ml volumetric flask and made up the volume (100 µg/ml) and subsequently dilution was carried out by withdrawing different aliquots (1.0, 2.0, 3.0, 4.0, 5.0, 6.0 ml) from standard solution were transferred into a series of 10 ml calibrated flasks and all were made up to the mark with 0.1 N HCl (pH 1.2) and absorbance was measured at 286 nm against blank. A calibration curve was plotted from the absorbance values so obtained. A representative spectra and calibration curve of Lafutidine is reported in Figure 2 & 3 respectively.

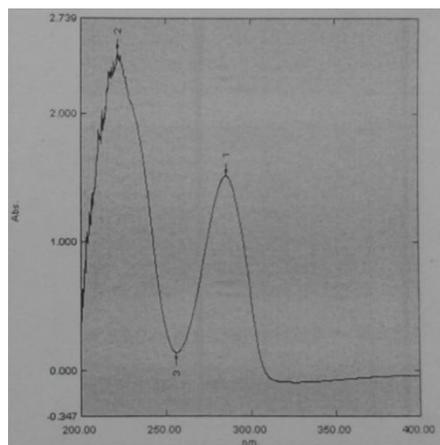


Figure 2: Spectra of Lafutidine (pure drug) in 0.1 N HCl

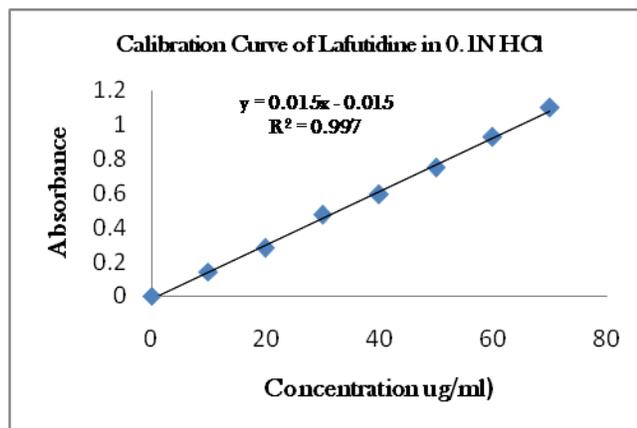


Figure 3: Calibration curve of Lafutidine

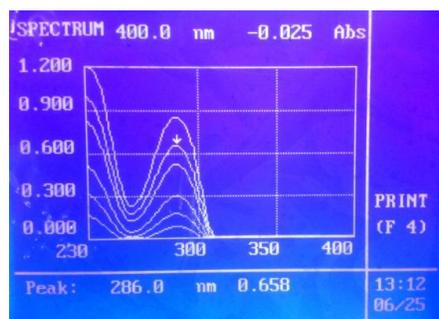


Figure 4: Overlay Spectra of Lafutidine (pure drug) in 0.1 N HCl 10-60 µg/ml**Analysis of Tablet Formulation**

Twenty tablets were weighed accurately and grounded into fine powder. An amount of the powder equivalent to 10 mg of Lafutidine was weighed and dissolved in about 75 ml Buffer pH 1.2. The solution was shaken thoroughly for about 15-20 min, and filtered using Whatman No. 41 filter paper; residue was washed with 20 ml 0.1 N HCl (pH 1.2). Filtrate and washing were transferred to a 100 ml calibrated volumetric flask and 0.1 N HCl (pH 1.2) was added up to the mark (100 µg/ml).

The 4 ml of above filtrate was diluted to 100 ml with 0.1 N HCl. Absorbance was measured at 286 nm wavelength maxima and the concentration of the drug in sample solution was determined from calibration curve. The results of analysis are presented in Table 2 respectively.

Accuracy (recovery test): Accuracy of the method was studied by recovery experiments. The recovery experiments were performed by adding known amounts of the drugs in powdered tablets. The recovery was performed at three levels, 60, 80 and 100% of Lafutidine standard concentration. The recovery samples were prepared in aforementioned procedure. Three samples were prepared for each recovery level. The solutions were then analyzed and the percentage recoveries were calculated from the calibration curve.

Table 1: Quantitative parameters of spectrophotometric method

Parameters	Value
λ_{\max} , nm	286
Beer's law limits, µg/ml	10-60
Regression equation	$y = 0.015x - 0.015$
Slope	0.015
Intercept	0.015
Correlation coefficient (r^2)	0.997

Table 2: Results of Analysis of Tablet Formulation and Recovery Studies

Brand	Label claim	% Label claim Estimated*	Standard Deviation	% Recovery**
Lafaxid	100 µg/ml	99.35	0.230	98.95
Lafutax	100 µg/ml	99.14	0.190	99.16

*Average of six determinations

** Average of Recovery Studies at three different concentration levels

Results and Discussion

UV method has been developed for the quantitative estimation of Lafutidine from Tablet formulation. The developed method is based on the solubility of Lafutidine in 0.1N HCl. The results of analysis from tablet formulation were within the permissible limits and the results of recovery studies reflect nil interference from excipients. The developed method was found to be simple, accurate and economical hence can be used for routine analysis of Lafutidine from pharmaceuticals.



References

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