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QUANTITATIVE DETERMINATION OF LAFUTIDINE IN TABLETS BY FIRST ORDER DERIVATIVE UV-SPECTROPHOTOMETRY USING AREA UNDER CURVE

Prajapati Nitin D, Shirkhedkar Atul A*, Surana Sanjay J
R.C. Patel Institute of Pharmaceutical Education and Research, Dist: Dhule - 425 405(MS), India.

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ABSTRACT
Lafutidine (LTD) is used as antiulcer and mucosal protective. A new simple, economical and rapid UV-Spectrophotometric first order derivative method using 'Area Under Curve' (AUC) technique has been developed for the quantitative determination of LTD in bulk and tablets. Methanol (20% *v/v*) was used as a solvent. Zero order spectrum of LTD was derivatised into first order using UV-probe software of the UV-Vis Spectrophotometer and the AUC was determined between the two selected wavelength 276.80 nm to 306.00 nm. LTD followed linearity in the concentration range of 10 - 80 µg/mL with $r^2 > 0.99$. The quantity of drug estimated by this method was in good accord with label claimed. This method was found to be accurate, precise and ruggedness as shown by low values of % RSD.

Keywords: *Lafutidine; UV-Spectrophotometry; First order derivative; Area under curve.*

INTRODUCTION

Lafutidine (LTD) chemically is 2-[(2-Furanylmethyl)-sulfinyl]-*N*-[(2Z)4-[[4-(1-piperidinylmethyl)-2 –pyridinyl] oxy]-2- butenyl] acetamide[1]. It is used as a histamine H_2 receptor antagonist[2]. Thorough literature survey revealed many analytical methods such as LC–ESI–MS[3], high-performance liquid chromatography-electrospray ionization mass spectrometry[4] and LC–tandem mass spectrometry[5] methods for determination of LTD in bulk, pharmaceutical formulations and in biological samples.

The primary objective of the present work is to develop simple and economical UV-Spectrophotometry first order derivative method using Area Under Curve (AUC) for determination of LTD in bulk and in tablets and also to validate the method for accuracy, precision and ruggedness as per the USP guidelines[6].

EXPERIMENTAL

Chemicals

Lafutidine supplied as a gift sample by Ajanta Pharma Ltd, Mumbai. Methanol (A.R. Grade) was purchased from Merck Ltd., Worli, and Mumbai, India. Tablets (Lafaxid-10) were purchased from local market, containing Lafutidine 10 mg per tablet.

Instrumentation

A UV-Visible spectrophotometer (Shimadzu-2450, UV Probe 2.21 software) with spectral bandwidth 1 nm was employed for all spectroscopic measurements, using a pair of 10 mm matched quartz cells.

Selection of common solvent

Methanol (20% *v/v*) of analytical reagent grade was selected as common solvent for developing spectral characteristics of drug.

Preparation of Stock standard solutions

A stock standard solution was prepared by dissolving 10 mg of LTD in 100 mL methanol (20% *v/v*) to obtain concentration of 100 µg/mL. It was further diluted with same solvent to obtain concentration of 10 µg/mL of LTD, scanned in the UV-region i.e. 400 - 200 nm. Zero order spectrum (**Figure 1**) obtained was derivatized into first order derivative
(□ = 2 nm, scaling factor 2) using UV probe software of the instrument **(Figure 2)**. The two wavelengths 276.80 nm and 306.00 nm were selected for the determination of AUC.

Study of linearity curve

An appropriate volume of LTD stock solution in the range of 1 - 8 mL was transferred into series of eight separate 10 mL volumetric flasks and volume was made up to mark with methanol (20% *v/v*) to obtain concentration of 10 - 80 µg/mL. These solutions were scanned in UV-region 400 - 200 nm; zero order spectrum obtained was derivatised into the first order spectrum. AUC was measured between the chosen wavelengths and a calibration curve was constructed by ploting AUC *versus* concentrations.

Analysis of Tablet formulation

Twenty tablets of brand Lafaxid-10 **(**Batch no. 01A0008**)** containing 10 mg of LTD were accurately weighed and

***Correspondence :** atulshirkhedkar@rediffmail.com

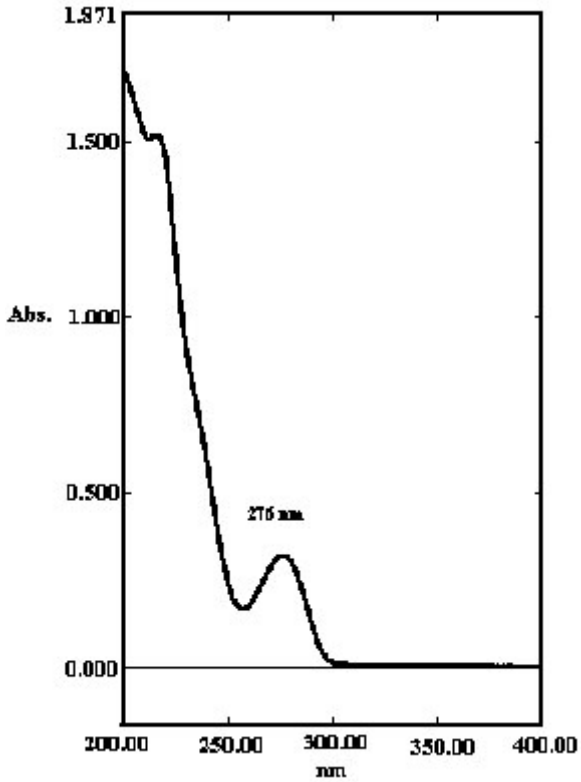

Fig. 1: Zero order spectrum of LTD

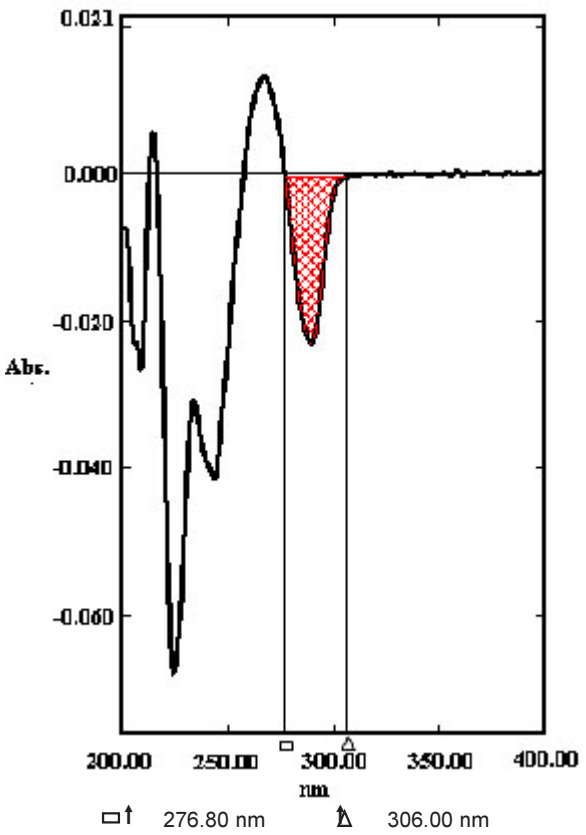

Fig. 2: First Order Derivative Spectrum of LTD

crushed into fine powder. A quantity of powder equivalent to 10 mg of LTD was transferred into 100 mL volumetric flask, containing 40 mL methanol(20% *v/v*), shaken manually for 10 min and volume was adjusted to mark using same solvent and filtered through Whatmann filter paper no. 41. A suitable volume 3 mL was diluted to 10 mL with same solvent (i.e.30 ìg/mL of LTD), earlier adopted procedure was followed for scanning, AUC of the solution was measured between selected wavelengths and the concentration of the LTD was determined using linear regression equation. The analysis procedure was repeated five times.

RESULTS AND DISCUSSION

In methanol (20% *v/v*), first order derivative spectrum was studied and AUC between the two selected wavelengths (276.80 – 306.00 nm) was recorded. LTD obeyed linearity in the concentration range of 10 - 80 µg/mL with linear regression equation 0.020 X + 0.029, (r^2 > 0.99). The amount of the drug estimated using this method was found to be 99.25 ± 0.92, demonstrated that there was no interferences from the excipients usually present in the tablet formulation. This method was validated for precision, accuracy and ruggedness. The precision of the method was studied as repeatability, intra-day, inter-day variations in the sample analysis. The accuracy of the method was studied at different levels i.e. 80 %, 100% and 120%. To the pre-analyzed sample solutions (30 µg/mL) a known of drug standard was added and re-analyzed by the proposed method.

Ruggedness of this method was studied by two different analysts. Method was found to be precise, accurate and rugged as demonstrated by low values of %RSD. The results from the validation of methods are shown in Table 1.

Thus, it can be concluded that the developed analytical method is economical, simple, precise, accurate, and rugged and can be used for routine analysis of LTD in its tablet formulation.

Table 1: *Summary of validation parameter*

Parameter	First order derivative using AUC technique
Precision [% RSD]	
Repeatability [n = 6]	0.45
Intra-day [n = 3]	0.49 – 0.84
Inter-day [n = 3]	0.60 – 1.15
% Recovery [n = 9**]**	99.91
% RSD	0.77
Ruggedness [% RSD]	
Analyst – I [n = 6]	0.44
Analyst – II [n = 6]	0.51

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REFERENCES

1. The Merck Index, *an Encyclopedia of Chemicals, Drugs and Biologicals*, 14th edn. Whitehouse Station, New Jersey, USA: Merck Research Laboratories, , 2006, 926.
2. Sweetman SC, *Martindale – The complete drug reference*, Pharmaceutical press, London, 2007, 1568.
3. Lili WU, *et al*. J Mass Spectrom. 2005; 1637: 1643
4. **Chen WD, *et al.* J Pharm Biomed Anal. 2006;** 256: 260.
5. **Xiuhong S, *et al.*** J. Chromatogr B., 2009; 3953: 3959.
6. The United State Pharmacopeia/The National Formulary, United State Pharmacoepoeial Convention, Inc., Rockville, MD, 2005, 2748-2751