IJBPAS, September, 2025, 14(9): 4838-4844

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

DEVELOPMENT OF UV-SPECTROPHOTOMETRIC METHOD FOR LORATADINE IN PURE AND DOSAGE FORM

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Received 15th March 2024; Revised 20th April 2024; Accepted 11th Aug. 2024; Available online 1st Sept. 2025

https://doi.org/10.31032/IJBPAS/2025/14.9.8847

ABSTRACT

This study primarily focuses on developing a novel UV method for the assay of Loratadine in both pure form and pharmaceutical dosage forms. The process involves preparing standard and working solutions of Loratadine, followed by the analysis of different concentrations of the working solution. The established method is then subjected to validation as per ICH guidelines. The results indicate that the developed method is sensitive and accurate, particularly within the concentration range of 4-24 µg/ml. The correlation coefficient (R2) was determined to be 0.999. Notably, there was no interference observed with the excipients present in the formulation. The proposed method holds potential for the analysis of Loratadine in bulk and formulation, making it suitable for routine analysis

Keywords: Ultraviolet Spectroscopy, validation, Loratadine, method development, assay

INTRODUCTION:

Loratadine (LTD) is a medication used to manage and treat allergic rhinitis and urticaria. It is in the second generation antihistamine class. This activity reviews the indications, action, and contraindications for loratadine as a valuable agent in treating and managing

allergic rhinitis and urticaria. This activity will highlight the mechanism of action, adverse effects, and other key factors such as dosing, pharmacodynamics, pharmacokinetics, monitoring, and relevant interactions pertinent for interprofessional team members in the treatment and care of patients with allergic rhinitis and related conditions **[1-3]**.

Through a comprehensive examination of existing literature, it has been observed that only a small amount of research has been recorded on this topic regarding the assessment of LTD using HPLC **[4-5]**. There are one UV spectrophotometric methods reported for analysis of LTD **[6]**.

This investigation aimed to analyze LTD in both its pure form and pharmaceutical formulation, specifically tablets. Following the development of the UV method, all optimization parameters were taken into account. The validated method proved successful, affirming its appropriateness for determining the overall drug content in commercially accessible LTD formulations. Consequently, the development and validation processes adhered to ICH guidelines **[7-10]**.

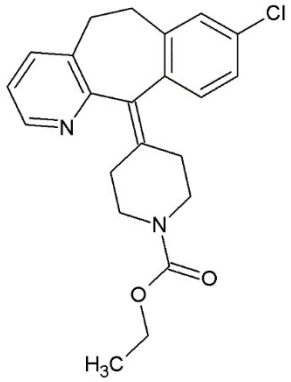

Figure 1: Chemical structure of LTD

MATERIALS AND METHODS:

Instruments and Reagents:

A complimentary sample of LTD with a purity level of 99.98% was obtained from a manufacturing facility located in Visakhapatnam. The instruments employed in the study included UV/Visible spectrophotometer, Lab india, model T60 and analytical balance, Shimadzu, Japan. The investigation utilized analytical-grade chemicals and reagents. LORATIN-branded LTD tablets, each containing 10 mg, were obtained for the formulation.

Standard stock solution (1000µg/ml):

A quantity of 100 mg of the drug was introduced into a 100 ml calibrated flask, where it was dissolved and topped up to the calibration mark with acetonitrile, resulting in

1000 µg/ml. This establishes the standard stock solution of LTD.

Working standard solution (100µg/ml):

A quantity of 2.5 ml was extracted from the standard stock solution mentioned earlier and transferred into a 25 ml calibrated flask. Acetonitrile was added to the flask to achieve a concentration of 100 µg/ml, and the solution was adjusted to the mark.

Calibration curve:

Following that, it was subjected to scanning using a UV Spectrophotometer covering the 200-400 nm range, with acetonitrile employed as the blank. The peak absorbance was pinpointed at a wavelength of 282 nm. To generate different concentrations spanning from 4 to 24 µg/ml, portions were formulated using distilled water as the solvent. These samples were then assessed at the specified wavelength of 282 nm to ascertain their respective absorbance values. The collected data was subsequently used to construct a calibration curve.

RESULTS AND DISCUSSION

Method Validation:

Linearity:

Various samples of LTD were created within the 4-24 µg/ml range using the working standard solution (16 µg/ml). These solutions underwent scanning on a UV-spectrophotometer spanning the 200-400 nm range, with acetonitrile serving as the reference. The spectrum was captured at 282 nm **(Figure 2)**. The data illustrated the relationship between concentration and absorbance, is depicted in **Table 1**. The results indicate a high degree of linearity in the established relationship.

Precision:

The method's precision was showcased through assessments of intra-day and inter-day variations. In the intra-day analysis, six separate solutions with 16 µg/ml were created and assessed twice daily. For the inter-day study, solutions of 16 µg/ml were formulated and was tested six times over two successive days, and the absorbance was noted (refer to **Table 2**). The calculated percentage of relative standard deviations was found to be below 2%.

Accuracy:

The method's accuracy was assessed using the standard addition method, wherein the percent recovery of LTD was computed. Pre-quantified sample solutions of LTD were supplemented with known quantities of standard solutions at 80%, 100%, and 120% levels. These solutions were prepared in triplicate, and the accuracy, as indicated by the %recovery, was calculated and presented in **Table 3**. The %recovery was determined to be satisfactory.

Robustness:

The method's reliability was evaluated through the examination of a sample with a concentration of 16 µg/ml at three distinct wavelengths, including one at λ max, and recording the corresponding absorbance values. The outcomes presented in **Table 4** suggest that the method demonstrated robustness.

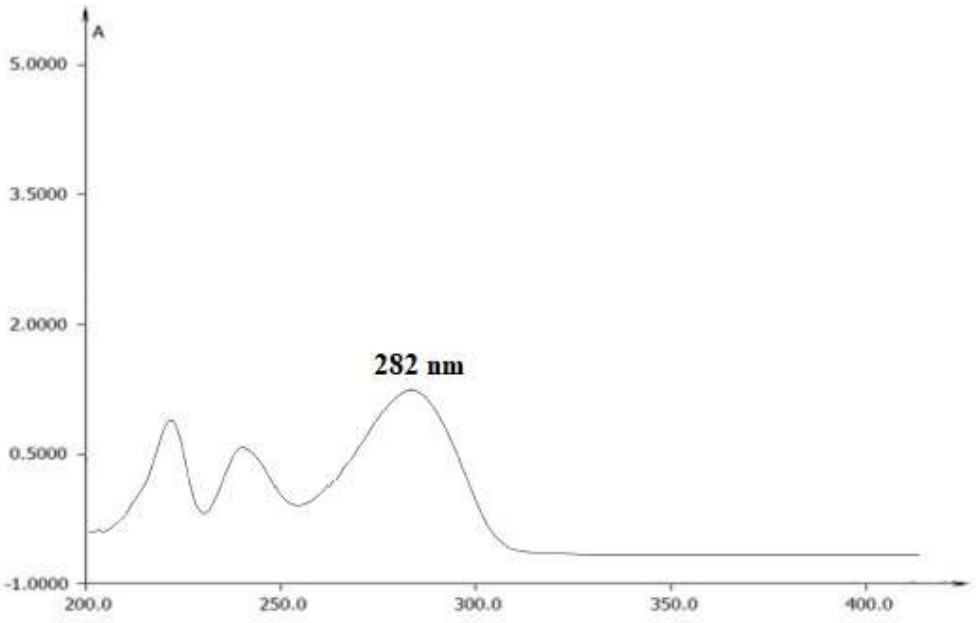

Figure 2: Spectrum obtained for pure drug

Table 1: Linearity

Concentration (µg/ml)	Absorbance
4	0.324
8	0.4517
12	0.5867
16	0.7234
20	0.8445
24	0.9876
Regression equation	Y = 0.0331x + 0.1897
Correlation coefficient(R^2)	0.9997

Table 2: Intermediate Precision

Conc. [µg/ml]	Absorbance	
	Examiner-1/Day-1	Examiner-2/Day-2
16	0.7234	0.7257
16	0.7202	0.7297
16	0.7285	0.7216
16	0.7267	0.7254
16	0.7234	0.7267
16	0.7212	0.7234
Mean	0.7239	0.7254
S.D	0.0031	0.0027
%RSD	0.43	0.38

Table 3: Accuracy of method

Addition Level	Amount of formulation	Quantity added	Hypothetical quantity.	Experimental amount	% recovery
80%	16	12.8	14.4	14.32	99.44
100%	16	16	16	15.85	99.06
120%	16	19.2	17.6	17.46	99.20

Table 4: Robustness Study

Conc. (µg/ml)	Absorbance		
	281nm	282nm	2283nm
16	0.7147	0.7234	0.7354
16	0.7124	0.7202	0.7311
16	0.7189	0.7285	0.7397
16	0.7134	0.7267	0.7369
16	0.7114	0.7234	0.7392
16	0.7184	0.7212	0.7354
AVG	0.71487	0.7239	0.73628
SD	0.00313	0.00318	0.00313
%RSD	0.43806	0.43893	0.42512

Ruggedness:

To assess the ruggedness of the method, the sample was analyzed by two different analysts using the identical apparatus, and by the same examiner using two different cuvettes, with the respective absorbance values recorded. The results from the first analyst revealed a %RSD of 0.26, while the second analyst showed a %RSD of 0.46. These results indicate that the utilized methodology was robust, as no notable distinction is evident among various operators.

Sensitivity:

The drug's LOD and LOQ were determined from the standard curve and found to be 0.445 µg/ml and 1.351 µg/ml, respectively.

Assay of formulation*:*

The analysis of the obtained formulation involved assaying an equivalent weight of 25 mg of LTD formulation in a 25 ml calibrated flask, utilizing acetonitrile as the diluent. The final concentration was adjusted to 16 µg/ml using distilled water. The assessment was conducted at a UV wavelength of 282 nm, revealing an assay result of 99.89%.

CONCLUSION:

The proposed method proved to be simple, exhibiting accuracy, precision, and robustness while being easily implementable. The calibration plot covered a broad range, and the recoveries of samples were consistent. The equipment and reagents utilized are likely to be accessible, even in basic laboratory setups. Therefore, the established method is recommended for regular use in quality control analysis of LTD. Additionally, it is deemed suitable for analyzing samples in accelerated stability studies, routine

formulation analyses, and the assessment of drug substance.

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