International Journal of Current Trends in Pharmaceutical Research

Journal Home Page: www.pharmaresearchlibrary.com/ijctpr

Research Article **Open Access**

Development and Validation of Estimation of Lafutidine by Spectroscopic Method in Tablet Dosage Form

[1]Ms. Heta Shah*, [2]Ms. Archita Patel, [3]Ms. Advaita Patel

[1]Department of Pharmaceutical Chemistry, Saraswati Institute of Pharmaceutical Sciences, Gandhinagar, India
[2]Department of Pharmaceutical Chemistry, K. B. Institute of Pharmaceutical Education and Research, Gandhinagar, India
[3]Department of Pharmaceutical Chemistry, Kalol Institute of Pharmacy, Kalol, India

A B S T R A C T

Spectroscopic estimation of Lafutidine in bulk and tablet was developed and validated. Methanol was used as a solvent for analysis. Detection was carried out at 273 nm for Lafutidine. Linearity was observed at concentration range 10-80 µg/ml. Correlation coefficient for Lafutidine was found 0.9975. The method was found to be Simple, Sensitive, Accurate and Precise as per ICH guideline Q2B (R1). The method can successfully applicable to routine analysis.

Keywords: Lafutidine, Methanol, UV spectrophotometry

A R T I C L E I N F O

CONTENTS

Article History: Received 07 January 2015, **Accepted** 18 March 2015, **Available Online** 15 May 2015

***Corresponding Author**
Ms. Heta Shah
Dept. of Pharmaceutical Chemistry,
Saraswati Institute of Pharmaceutical Sciences, Gandhinagar, India
Manuscript ID: IJCTPR2468

PAPER-QR CODE

Citation: Heta Shah, et al. Development and Validation of Estimation of Lafutidine by Spectroscopic Method in Tablet Dosage Form. *Int. J. Curnt. Tren. Pharm, Res.*, 2015, 3(3): 868-872.

1. Introduction

Lafutidine is a novel antiulcer drug that exhibits long-lasting gastric antisecretory effects due to blockade of the histamine H_2 receptor thus it is Second generation H_2 receptor antagonist [1]. Lafutidine increases plasma

concentrations of cGRP and somatostatin in humans, which may result in inhibition of postprandial acid secretion and gastroprotective activity. It is chemically ((+)-2-(Furfuryl sulfinyl)-*N*-[4-[4-(piperidinomethyl)-2-pyridyl]oxy-(*Z*)-2-butenyl]acetamide. Structure of Lafutidine is illustrated in fig.1.[2].

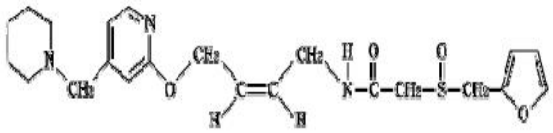

Figure 1: Structure of Lafutidine

So far, to our present knowledge, no spectroscopic method for estimation of Lafutidine has been reported with wider range.[3-12]. So an attempt was made to develop simple, accurate, rapid, and precise spectroscopic method for the determination of Lafutidine.

2. Materials and Methods

Instruments:

Jasco V-530, model UV-2075 Double beam UV–visible spectrophotometer instrument was used in this method. Spectra Manager was used as a software for analysis.

Reagent and chemicals:

Lafutidine was a gift sample from A1 Calibrators, Ahmedabad. All chemicals and reagent used were analytical grade and were provided from K.B. Institute of Pharmaceutical Education and Research, Gandhinagar. Tablet formulations were procured from Indian market.

Preparation of standard stock solution:

Accurately weighed 25 mg of Lafutidine working standard in 25 ml volumetric flask and make up the volume with methanol which gives final strength about 1000 µg/ml. Further dilution was done the get a working standard solution of concentration 100 µg/ml.

Selection of wavelength

Appropriate volume of Lafutidine about 5 ml was taken in 10 ml volumetric flask and volume was made up to mark with methanol. The resulting solution was scanned in UV range (200 nm- 400nm). In the spectrum of Lafutidine 273 nm is selected for estimation.

Preparation of calibration curve

To construct calibration curve suitable amount of solution was diluted with methanol in 10 ml volumetric flask as mentioned in table 1. In the series, Lafutidine solutions having various concentrations of 10 -80 µg/ml were prepared by mixing appropriate volumes of corresponding standard solution in a series of 10 ml volumetric flasks and diluted to volume with methanol.

Analysis of commercial formulation: Twenty tablets were weighed and the average weight was calculated a quantity of mixed content of 20 tablets equivalent to 25 mg of Lafutidine was accurately weighed and transferred in to 25 ml volumetric flask. The solution is dilute up to 25 ml with methanol. Than 2.5 ml of above solution was diluted up to 25 ml with methanol which gives 100 µg/ml of Lafutidine. Than 4 ml of above solution was diluted up to 10 ml with methanol which gives 40 µg/ml of Lafutidine in the formulation was determined by use of calibration curve.

Table 1: Preparation of Calibration Curve

S.No	Lafutidine Stock Solution (ml)	Lafutidine Composition µg/ml	*Absorbance at 273 nm
1	1.0	10	0.0924
2	2.0	20	0.1741
3	3.0	30	0.2849
4	4.0	40	0.3805
5	5.0	50	0.4616
6	6.0	60	0.5467
7	7.0	70	0.6798
8	8.0	80	0.7588

(*The values are average of three replicates

3. Result and Discussion

The method was validated as per ICH guidelines by establishing linearity, accuracy, sensitivity, interday and intraday precision of measurement of sample application.[13].

Linearity calibration curve:

The stock solutions were diluted in concentration range of 10-80 µg/ml for Lafutidine and data was evaluated by regression analysis. Five concentration points were assayed in triplicate. Lafutidine showed good linearity in tested range. The regression coefficient (R2) Value was found to be 0.9975. Overlay Linearity curve Lafutidine was shown in figure no 2. Calibration curve for Lafutidine was shown in figure 3.

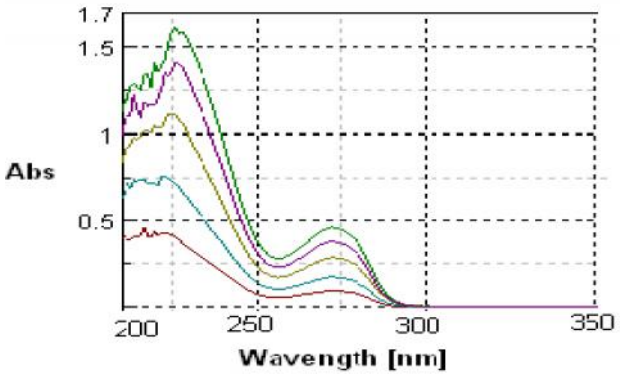

Figure 2: Linearity of Lafutidine

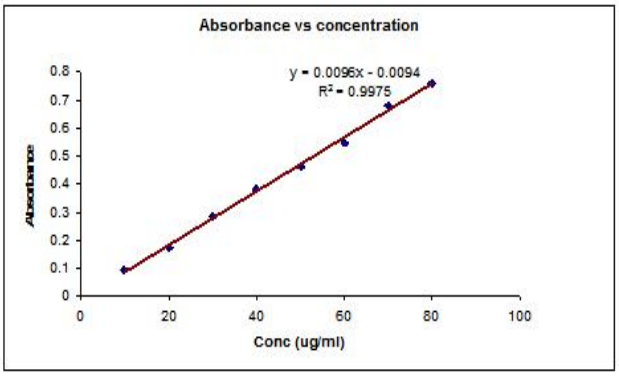

Figure 3. Calibration curve of Lafutidine

Accuracy:

Recovery study was carried out for accuracy parameter. The study was carried out at three level. To powder formulation the standard drug Lafutidine were added 50%, 100%,150% levels, dilution were made and analyzed by the method. The % recovery were calculated and found to be within the limit. Result for accuracy study is shown in table 2.

Table 2: Results For Recovery Study

Level	Spike (mcg/ml)	Absorbance of Spike(At 273 nm)	Found Concentration	%Recovery
50%	20.00	0.5714	20.27	101.35
	20.00	0.5701	20.34	101.70
	20.00	0.5709	20.33	101.65
100%	40.00	0.7635	40.50	101.25
	40.00	0.7630	40.37	100.90
	40.00	0.7661	40.66	101.65
150%	60.00	0.9602	60.94	101.56
	60.00	0.9606	61.00	101.66
	60.00	0.9601	60.89	101.48

Sensitivity:

LOD and LOQ were calculated using following equation as per ICH guidelines. LOD = 3.3 ×σ /S and LOQ = 10 ×σ /S, where σ is the standard deviation of response and S is the slope of the calibration curve.

Precision: Intraday precision was found by analysis of standard drug at six times on the same day, While interday assay precision was carried out on six different day. The RSD was found to be less than 2 for both interday precision and intraday precision. Result for the interday precision and intraday precision is shown in table no 3, 4 respectively.

Table 3: Results of Interday Precision

Concentration	Absorption	Found Concentration	% Assay
100%	0.3801	40.57	101.4
100%	0.3799	40.55	101.3
100%	0.3802	40.58	101.4
100%	0.3798	40.54	101.3
100%	0.3800	40.56	101.4
100%	0.3804	40.60	101.5
Average			101.4
SD			0.04
%RSD			0.039

Table 4: Results of Intraday Precision

Concentration	Absorption	Found Concentration	% Assay
100%	0.3810	40.66	101.6
100%	0.3802	40.58	101.4
100%	0.3805	40.61	101.5
100%	0.3807	40.63	101.6
100%	0.3801	40.57	101.4
100%	0.3809	40.65	101.6
Average			101.5
SD			0.11
%RSD			0.10

Table 5: Summary of Validation Parameters

Sr. No	Validation parameter	Specific Characteristics	Lafutidine
1	Linearity	Range	10-80 µg/ml
		Correlation coefficient	0.9975
2	Sensitivity	Limit of quantification	9.79 µg/ml
		Limit of detection	3.2 µg/ml
3	Precision (%RSD)	Repeatability	0.047
		Interday precision	0.039
		Intraday Precision	0.10
4	Accuracy	% recovery	101.4%
5	Assay	% amount of drug found in tablet	99.43%

4. Conclusion

A relatively simple Spectroscopic method was optimized and validated with system suitability for the determination of the Lafutidine according to the ICH guidelines. The validation data indicate good precision, accuracy and reliability of the method. The developed method offers several advantages in terms of wider range, better recovery, simplicity in mobile phase, easy sample preparation steps and comparative short run time which makes the method specific and reliable for its intended use in determination of Lafutidine in tablet dosage forms. Summary of validation parameters is shown in table 5.

5. Aknowledgment

The authors heartily thankful to HOD of Pharmaceutical Chemistry, K.B. Institute of Pharmaceutical Education and Research, Gandhinagar for providing the Instrument for research work. The authors thankful to Dr. Gaurang Shah for providing chemicals and other facilities for research work.

6. References

1. T Shimatani **,** M Inoue, T Kuroiwa, X Jjing ,M Nakamura , S Tazuma , et al. Lafutidine, a Newly Developed Antiulcer Drug, Elevates Postprandial Intragastric pH and Increases Plasma Calcitonin Gene-Related Peptide and Somatostatin Concentrations in Humans, Comparisons with Famotidine. *Digestive Diseases and Sciences*., **2006**, 51(1): 114-120.
2. T h e Merck Index- An encyclopedia of chemicals, drugs and biologicals, published by Merck Research Laboratories, 14th edition. Merck and Co. Inc., 2006, Lafutidine, Monograph Number: 005347,926.
3. PM Talaviya, K Mangukiya, J Vachhani. Development and validation of UV Spectroscopic method for simultaneous estimation of Lafutidine and Rabeprazole sodium in bulk and Pharmaceutical dosage form. *Int.l J. Drug Development & Res*., **2013**, 5(2):202-210.
4. KM Patel, K Shah, S Patel. Spectrofluorimetric method for determination of Lafutidine in pharmaceutical dosage form. *Int. J. Pharmacy and Pharma Sci*., **2013**, 5(3): 902-903.

5. H Antala, K Raval, K Dhudashia, N Patel. Development and Validation of Derivative Spectroscopic Method for the Simultaneous Estimation of Lafutidine and Rabeprazole Sodium in Combined Dosage Form. *International Journal for Pharmaceutical Research Scholar.*,**2013**, 2(1): 113-120
6. M Sumithra, PS Shanmuga, K.Srinivasulu. Analytical Method Development and Validation of Lafutidine in Tablet dosage form by RP-HPLC. *Int. J. Chem Tech Res*., **2011**, 3:1403-1407.
7. SA Moon, SG Chate, BS Kuchekar, SA Karande. Spectrophotometric simultaneous determination of Lafutidine and Domperidone in combined tablet dosage form by absorbance corrected method and first order derivative method. *Der Pharma Chemica*., **2012**, 4(3), 930-934
8. V Kranthikumar, R Sundaraganapathy, SA Thangadurai, MM Basha. Development and validation of RP-HPLC method for simultaneous estimation of Domperidone and Lafutidine in pharmaceutical tablet dosage form. *Int. J. Pharmacy and Pharma Sci*., **2012**, 5(2): 68-72.
9. X Sun, T Yuan, Z Zunjian, C Yun. A single LC–tandem mass spectrometry method for the simultaneous determination of four H2 antagonists in human plasma. *Journal of Chrom B*., 2009, 877, 3953-3959.
10. CX Pan, XZ Xu, HM He, XJ Cai, XJ Zhang. Separation and identification of *cis* and *trans* isomers of 2-butene-1,4-diol and lafutidine by HPLC and LC-MS. *Pharmaceutical Journal*, **2005**, 6(1): 74-78.
11. Z Zhang, XI Qian, YD Li. Determination of Lafutidine in human serum by HPLC-FD method and study of pharmacokinetics. *C. J. Hospi. Pharmacy.*, **2005**, 25(12): 1141-1142.
12. Duan MY, Chen XY, Zhong DF. Enantiomeric separation of trimebutine, lafutidine and ondansetron by HPLC using chiral stationary phase. *C. J. Pharm. Ana.*, **2005**, 26(9): 1187- 1191.
13. ICH Q2B, Validation of Analytical Procedures. Methodology, adopted in 1996, Geneva Q2B, incorporated in Q2 (R1) **2005**.