



A Review on Analytical Techniques for the Assay of Loratadine

Pappala Heshitha and Mukthinuthalapati Mathrusri Annapurna*

Department of Pharmaceutical Analysis, GITAM School of Pharmacy, GITAM

(Deemed to be) University, Visakhapatnam, Andhra Pradesh, India

*Corresponding Author: Mukthinuthalapati Mathrusri Annapurna, Department of Pharmaceutical Analysis, GITAM School of Pharmacy, GITAM (Deemed to be) University, Visakhapatnam, Andhra Pradesh, India.

DOI: 10.31080/ASPS.2023.07.1011

Received: November 20, 2023

Published: November 27, 2023

© All rights are reserved by Pappala Heshitha and Mukthinuthalapati Mathrusri Annapurna.

Abstract

Loratadine belongs to second generation antihistamines category. It is a drug used to treat allergies. A brief review of the analytical techniques such as spectrophotometry, liquid chromatography, mass spectrometry so far developed for the estimation of Loratadine were summarized in the present study.

Keywords: Loratadine

Introduction

Loratadine (CAS: 79794-75-5) (Figure 1) is used to treat high blood cholesterol [1,2]. Loratadine is chemically ethyl 4-(8-chloro-5,6-dihydro-11H-benzo [5,6] cyclohepta [1,2-b] pyridin-11-ylidene)-1-piperidinecarboxylate with molecular weight 382.88 grams/mole. It is not soluble in water, but very soluble in acetone, alcohol, and chloroform. Loratadine ($C_{22}H_{23}ClN_2O_2$) is used for the symptomatic treatment of allergic conditions such as hay fever (allergic rhinitis), urticaria (hives), chronic idiopathic urticaria and other skin allergies [1-4]. Loratadine works by specifically targeting the H_1 histamine receptors to provide its desired effect. Loratadine is available with brand names, Loratec-10, Lorfast Meltab, Lorapil-10 etc.

Loratadine was estimated by different spectrophotometric methods using various reagents. Noor Jahan., *et al.* developed a spectrophotometric method [5] using 0.1N Methanolic HCl for the estimation of Loratadine (λ_{max} 275 nm) and Beer-Lambert's law was obeyed over the concentration range 2-10 μ g/ml. Georgeta., *et al.* developed a spectrophotometric method [6] using potassium tetra iodo mercurate in 0.05M HCl medium for the estimation of Loratadine (λ_{max} 362 nm) and Beer-Lambert's law was obeyed over

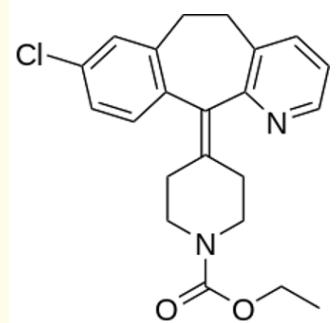


Figure 1: Chemical structure of Loratadine.

the concentration range 10-100 μ g/ml. Prathap., *et al.* developed a spectrophotometric method [7] using 0.1N HCl and ethanol for the estimation of Loratadine (λ_{max} 276 nm) and Beer-Lambert's law was obeyed over the concentration range 0.5-2.5 μ g/ml. The details of these spectrophotometric methods were shown in Table 1.

Different authors have developed various liquid chromatographic methods [8-16] using different mobile phases, column, flow rates and some of the parameters were summarized in Table 2.

Table 1: Spectrophotometric methods.

Reagent	Linearity ($\mu\text{g/ml}$)	$\lambda_{\text{max}} (\text{nm})$	Reference
0.1N Methanolic HCl	2-10	275	5
0.05M HCl	10- 100	362	6
0.1N HCl Ethanol	0.5-2.5	276	7

Some liquid chromatography-mass spectrometric methods [17-23] have also been developed for the estimation of Loratadine and a brief summary of these analytical methods were discussed in Table 3.

Mobile phase (v/v)		Column	Linearity	Ref
Phosphate buffer (pH 2.9): Acetonitrile	280	XDB-C8	0.12-0.60	[8]
Water: Acetonitrile: 0.5 M KH_2PO_4 : Conc. H_3PO_4 (48:44:8:0.1)	220	C18	0.001-0.4 (Water) 0.0013-0.4 (Plasma)	[9]
Acetonitrile: Water: 0.5 M Phosphate buffer (44:48:8)	200	Supelcosil LC-18-DB	0.0005-0.05	[10]
Acetonitrile: Methanol: Phosphate buffer solution (0.01M, pH 7.2 ± 0.1) (35:45:20)	245	C18 ODS	4.0-24	[11]
Acetonitrile: ortho phosphoric acid (35:65) (Internal standard: Benzophenone)	250	C18	5-50	[12]
Methanol: TEA (95:5) (pH adjusted with ortho phosphoric acid)	242	Chromosil C18	5-30	[13]
Acetate buffer: Methanol (15:85)	248	C18 Eclipse XDB	0.1-50	[14]
0.1% Perchloric acid: Acetonitrile (55:45)	280	Kromosil C18	5-1022	[15]
0.05 M Phosphate buffer: Acetonitrile: Methanol: TEA (38:45:17:0.5) (pH 3.6 adjusted with ortho phosphoric acid)	220	Inertsil ODS-3V	1.2	[16]

Table 2: Liquid chromatographic methods.

Mobile phase (v/v)	Linearity (n)	Reference
Acetonitrile: Water: TFA (90:10:0.1)	1.0	[17]
Methanol: Water: 1M Ammonium trifluoro acetate (70:30:0.1)	0.05-15	[18]
0.4% Formic acid: Acetonitrile (20:80)	0.5-100	[19]
0.1% Formic acid: Acetonitrile	0.2-20	[20]
0.5% Formic acid: Acetonitrile (10:90)	0.05-10	21
Acetonitrile: 0.2% Formic acid	0.10-10	22
Acetonitrile with 0.2% Formic acid: 0.2% Formic acid in water (45:55)	0.04-400	23

Table 3: Mass spectrometric methods.

Conclusion

The present study represents a detailed review of the analytical methods so far developed for the estimation of Loratadine in pharmaceutical dosage forms as well as human plasma.

Bibliography

1. Randall KL and Hawkins CA. "Antihistamines and allergy". *Australian Prescriber* 41.2 (2018): 41-45.
2. Church MK and Church DS. "Pharmacology of antihistamines". *Indian Journal of Dermatology* 58.3 (2013): 219-224.
3. Pons-Guiraud A., et al. "Emedastine di fumarate versus Loratadine in chronic idiopathic urticaria: a randomized, double-blind, controlled European multicentre clinical trial". *European Journal of Dermatology* 16.6 (2006): 649-654.
4. Naclerio RM. "The role of histamine in allergic rhinitis". *The Journal of Allergy and Clinical Immunology* 86 (1990):628-632.
5. Noor Jahan., et al. "Spectrophotometric determination of Loratadine in bulk and pharmaceutical dosage form". *International Journal of Pharma Sciences and Research* 9.05 (2018): 65-73.
6. Georgeta Pavalachea., et al. "Determination of Loratadine in pharmaceuticals by a spectrophotometric method". *Ovidius University Annals of Chemistry* 26.1 (2015): 27-31.
7. Prathap B., et al. "Analytical method development and validation for the estimation of Loratadine using UV spectrophotometer". *World Journal of Pharmaceutical Research* 12.6 (2023): 701-714.
8. Georgeta pavalache., et al. "Validation and application of a new DAD-HPLC method for the determination of Loratadine from pharmaceuticals". *Farmacia* 63.3 (2015): 366-370.
9. Moazameh peyrovi., et al. "Extraction optimization of Loratadine by supramolecular solvent-based microextraction and its determination using HPLC". *Journal of Chromatography* 980 (2015): 41-47.
10. Kunicki PK. "Determination of Loratadine in human plasma by high-performance liquid chromatographic method with ultraviolet detection.". *Journal of Chromatography B* 755 (2001): 331-335.
11. Samridhi., et al. "Validation of isocratic RP-HPLC method and UV spectrophotometric method for the estimation of Loratadine in pharmaceutical formulations". *Research Journal of Pharmacy and Technology* 8.4 (2015): 452-461.
12. NA El Ragehy., et al. "Stability indicating methods for the determination of Loratadine in the presence of its degradation product". *Journal of Pharmaceutical and Biomedical Analysis* 28.6 (2002): 1041-1053.
13. Guptha AVN., et al. "New RP-HPLC method development and validation for the analysis of Loratadine in formulations". *International Journal of Research And Reviews In Pharmacy And Applied Sciences* 1.3 (2011): 179-185.
14. Adrian Florin Spac., et al. "Validation and application of an RP - HPLC method with UV detection for Loratadine determination". *Revista de Chimie* 67.6 (2016): 1227-1231.
15. Nagadani Swarnalatha., et al. "Development and validation of an HPLC method for estimation of Loratadine and its application to a pharmacokinetic study". *Current Science* 116.2 (2019): 243-248.
16. Gajjela Ramulu., et al. "A new validated liquid chromatographic method for the determination of Loratadine and its impurities". *Scientica pharmaceutica* 79 (2011): 277-291.
17. Weng Naidong et al. "A sensitive LC/MS/MS method using silica column and aqueous/organic mobile phase for the analysis of Loratadine and Des carbo ethoxy-Loratadine in human plasma". *Journal of Pharmaceutical and Biomedical Analysis* 32 (2003): 609-617.
18. Bhavin NP et al. "LC-MS-ESI for the determination of Loratadine and Des carbo ethoxy-Loratadine in human plasma". *Journal of Chromatographic Science* 48.1 (2010): 35-44.
19. Rajaa F Hussein et al. "Rapid determination of Loratadine level in human plasma by LCMS/MS assay". *American Journal of Pharmatech Research* 8.3 (2018): 221-232.
20. Wenkui Li et al. "LC-MS/MS bioanalysis of Loratadine (Claritin) in dried blood spot (DBS) samples collected by subjects in a clinical research study". 983-984 (2015): 117-124.

21. Nagwa AS *et al.* "Determination of Loratadine in human plasma by Liquid chromatography-tandem mass spectrometry (LC/MS/MS) and its pharmacokinetic application". *International Journal of Pharmaceutical Sciences Research* 1.102 (2014): 1-6.
22. Isam Ismail Salem *et al.* "Determination of Loratadine in human plasma by liquid chromatography-electrospray ionization ion-trap tandem mass spectrometry". *Journal of Pharmaceutical and Biomedical Analysis* 34 (2004): 141-151.
23. Dandan Yang *et al.* "Quantitative determination of Loratadine in rat plasma by LC-MS/MS method and its application in a bioavailability study". *Chromatographia* 83 (2020): 183-190.