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Original Research Article

A concise review- An analytical method development and validation of loratadine

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Abstract

One to one and a half hours is when peak plasma concentrations of the long-acting antihistamine loratadine, which is quickly absorbed when taken orally, reach. There is no discernible buildup after repeated dosages, and its pharmacokinetics are dose proportional. Similar in its kinetics, descarboethoxy-loratadine (DCL), the primary metabolite, is likewise pharmacologically active. Poop and urine are the main ways that the medication is eliminated after significant metabolism.

This study focuses on the most current advancements in analytical methods for figuring out the presence of loratadine in different biological media, such as human plasma and urine, as well as in bulk and commercial dose forms. High performance liquid chromatography (HPLC), high performance thin layer chromatography (HPTLC), liquid chromatography linked to tandem mass spectrometry (LC-MS), and electrophoresis will all be thoroughly examined in this paper. Matrix, stationary phase, mobile phase composition, RF value for detection wavelength, retention time, DL, carrier gas, flow rate, capillaries wavelength, separation voltage, temperature, and pressure are some of the factors that are included in these procedures.

Keywords: Loratadine, HPLC, LC-MS/MS, HPTLC, LC-MS, Spectrophotometry, Electroanalytical method, Plasma.

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1. Introduction

Loratadine is the second-generation antihistamine which antagonise the H1 receptor. Loratadine also called Ethyl 4 - (8 chloro -5, 6 - dihydro-11H-benzo [5,6] cyclohepta [1,2-b] pyridine -11 - ylidene) piperidine -1 - carboxylate, and having chemical formula $C_{22}H_{23}ClN_2O_2$[1] In the hepatocytes, loratadine undergoes extensive metabolism and absorbed quickly. Because it effectively treats allergy diseases without having any major negative effects on the central or autonomic nervous systems, such as drowsiness or anticholinergic effects, this oral active H1 receptor blocker is extensively utilized.[2] Human metabolic research has shown that although this medication is quickly absorbed, it goes through a significant amount of first-pass metabolism. One of the primary byproducts of LOR enzymatic conversion is descarboethoxyloratadine (DCL), which possesses greater pharmacological potencies than the original medication. The enzymes CYP2D6 and CYP3A4 are in charge of converting LOR to DCL.3-4 Desloratadine's extensive usage has led to the emergence of central and anticholinergic side effects, nevertheless, which are connected to the drug's inhibitory actions on the peripheral H1 and M3 receptors.[5]

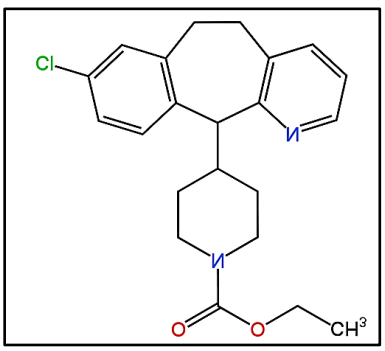

Figure 1: Loratadine structure

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2. Loratadine Pharmacodynamics

Regular studies of antihistaminic activity have revealed that loratadine is more potent than medications like terfenadine, astemizole, and diphenhydramine, and that its effects last longer (18 to 24 hours with promethazine loratadine vs. 6 to 8 hours with azatadine or terfenadine).[6] Potent and long-acting, loratadine has a poor affinity for CNS HI-receptors in vitro or in vivo but a strong selectivity for peripheral histamine HI-receptors.7 In animal models used to evaluate its anticholinergic effects, the medication has no action at either acetylcholine or ai-adrenergic receptors. Poor CNS penetration is experienced by loratadine. In vivo antihistamine action of loratadine was proven in animal models.[11] Loratadine exhibits minimal to no affinity for central nervous system (CNS) receptors but binds specifically to peripheral histamine HI-receptors in vitro.[12]

2.1. Armodafinil pharmacokinetics

2.1.1. Absorption

After being taken orally, loratadine is quickly absorbed in humans. A single oral dosage, it becomes detectable in plasma within 15 minutes and reaches its highest levels in an hour. The maximum plasma concentration (Cmax) and the area under the plasma concentration-time curve were shown to be linearly correlated with the loratadine dosage.[13-14] The ranges of blood Cmax values for DL and LOR were 1.68–7.75ng/ml and 1.07–5.82ng/ml, respectively. Furthermore, the quick absorption of loratadine and the development of DCL seem to be in line with the drug's stated start of action, which similarly happens one to two hours after administration. Loratadine has an elimination half-life of around nine hours.[15-18] The active metabolite has a half-life of eighteen hours. The increase in dose once per day, does not shown any substantial change in the pharmacokinetics of both DCL and loratadine.[18]

3. Distribution

The distribution half-lives of loratadine and DCL are 1.02 and 3.8 hours, respectively, for the mean plasma concentration versus time findings following numerous oral doses of loratadine, as reported by Radwanski et al. (1987).[17] The maximum concentrations of DL and LOR in serum were attained at 1.5 and 1.6 hrs. In male volunteer plasma, DCL is only 73–76% bound to the proteins, but loratadine is 97–99% bound. The plasma Cmax values for DL and LOR were 1.68–7.75 milligrams and 1.07–5.82 milligrams, respectively, indicating that humans absorb loratadine quickly after administered by mouth.[16] Despite the fact that loratadine's substantial clearance values following oral administration suggest the drug's widespread distribution and human metabolism, distribution inside tissue studies on the drug have not yet been published.[19]

3.1. Metabolism

The intricate and widespread metabolism of loratadine in all species studied involves glucuronidation, oxidation (hydroxylation and N-oxidation), and decarboethoxylation to generate desloratadine (DL)7 (7). A profile of over 50 metabolites was created.8 Further enzymes involved in the metabolism of loratadine include CYP1A1, CYP2C19, and, to a lesser degree, CYP1A2, CYP2B6, CYP2C8, CYP2C9, and CYP3A5. Desloratadine (DL) and the subsequent hydroxylation of both DL and the parent medication (loratadine) were linked to the metabolism of loratadine9 Based on metabolite analysis and characterization, LOR was shown to be highly metabolized, with significant species and gender differences in the detected metabolites.[10,22]

3.2. Excretion

At 1.5 and 1.6 hours, the highest plasma LOR and DL concentrations were reached. These identical tmax results show that LOR was metabolized as quickly as it was absorbed. Plasma metabolite profiles revealed that glucuronidation, oxidation, and descarboethoxylation were the main modes of LOR metabolism.[19-20] Dihydroxy-DL-glucuronides, 3-hydroxy-desloratadine glucuonide (3-OH-DL-Glu), and several metabolites arising from the oxidation and descarboethoxylation of the piperidine ring were among the most prevalent metabolites in circulation. By six hours after the dosage, LOR had fully metabolized. Nearly comparable amounts of LOR-derived radiocarbon were eliminated in the feces (43%), and urine (41%). The amount excreted in the urine as 3-OH-DL-Glu was about 13% of the dosage.24 A mere two percent of the dosage found in the urine was recovered by DL, and only traces of LOR were found. About 17% of the dosage was 3-OH-DL, which was the main metabolite in the feces.20-21 An extra 10.7% of the dosage was in the stool due to the combined quantity of 5- and 6-hydroxy-DL. In the form of unmodified medication and DL, respectively, around 5.4% and 2.7% of the dosage were eliminated in the feces.[22-23,25]

3.3. Analytical accounts on Loratadine

The widespread literature survey exposed multiple analytical techniques like UV spectrophotometry method, HPLC, HPTLC, LC-MS/MS, and capillary electrophoresis for the determination of Loratadine in bulk and pharmaceutical formulation. These reported methods describe the evaluation of Loratadine in various dosage forms like tablets and matrix like human plasma.

3.4. Chromatographic overview

3.4.1. HPLC Method

In their study, Georgeta Pavalache et al. details an HPLC technique for figuring out the amount of loratadine in tablet dosage forms. The procedure uses a C18 column (250 mm x 4.6 mm) 5µm XDB - C18 Agilent (Zorbax Eclipse XDB-18) for separation and 264 nm for detection at a flow rate of 1.0

mL/min. The mobile phase consists of a mixture of f [0.01% triethylamine solution adjusted to pH 2.75 with orthophosphoric acid acetonitrile (46:54)]-isopropanol (90:10, v/v). The technique has a recovery rate of more than 70% for loratadine and is exact, accurate, and specific. During the study, it was discovered that the procedure was exact, accurate, and particular.[26]

In their research, Ramulu Gajjela et al. present a validated RP-LC method for identifying loratadine and its contaminants in pharmaceutical products. Utilizing a gradient elution gradient Inertsil ODS-3V, 250 × 4.6 mm, 5µ column, with UV detection set at 220 nm, and a flow rate of 1.0 mL min−1. The buffer (0.05 M monobasic potassium phosphate), acetonitrile, methanol, and triethyl amine (38:45:17:0.5 v/v) are the components of the mobile phase. The pH of the mixture is adjusted to 3.6 using ortho phosphoric acid. For impurity quantification, the approach is linear and accurate, with recovery rates ranging from 85 to 115%. It is easy to use, accurate, and selective when testing large medication samples of loratadine.[27]

A high-performance liquid chromatographic method with fluorescence detection was developed and validated by Yin O.Q. et al. using an analytical methodology to simultaneously measure loratadine and its metabolite, descarboethoxyloratadine, in human plasma. Using toluene and a gradient mobile phase of methanol, acetonitrile, and phosphate buffer, it employs a two-step liquid–liquid extraction process. The technique exhibits great accuracy (98.3–105.7%), precision (coefficient of variation <8.3%), and acceptable linearity (0.5–16 ng/ml). It is a dependable and enhanced method for simultaneous determination in a single run because the lower limit of quantification is 0.5 ng/ml for both.[28]

El-Sherbiny, Dina T. et al. describes a quick HPLC method for quality monitoring of pharmaceutical formulations including loratadine and its metabolite, desloratadine. A cyanopropyl column (250 mm × 4.6 mm i.d., 5 µ m particle size) and a guard column with UV detection at 247 nm and a flow rate of 1 ml/min are used to achieve the separation. Octanol, n-propanol, triethylamine, and sodium dodecyl sulphate in phosphoric acid (pH 3.0) make up the optimum mobile phase. Specificity, linearity, precision, and accuracy of the method are validated; good resolution (factor = 3.85) and reproducibility (R.S.D. < 2.0%) are demonstrated. It works quickly (10 min), and the mean recoveries match those of a reference approach. A co-formulated medication called pseudoephedrine doesn't affect the assay.[29]

A straightforward, accurate, and precise RP-HPLC method for the quick assay of loratadine in tablet dosage form is described by Guptha, A., et al. The method uses an orthophosphoric acid-pH-adjusted mobile phase of methanol and TEA (95:5% V/V) with isocratic elution at a flow rate of 1.0 ml/min on a Chromosil C18 column. With a 4.2-minute retention period, detection is carried out at 242 nm. The technique is validated in accordance with ICH principles and exhibits great precision and accuracy (RSD < 2%). It has been effectively used for loratadine routine analysis in tablets and bulk medication.[30]

A novel stability-indicating gradient ion-pair RP-HPLC method for loratadine assaying and identifying process impurities and degradation compounds is introduced by Lu, Jun, et al. In just 20 minutes, this process successfully isolates loratadine from eight related compounds. It makes use of a Sun Fire C18 column as a backup to the YMC-Pack Pro C18 column, and it uses acetonitrile as the mobile phase along with an aqueous solution of sodium acetate and sodium dodecyl sulfate at pH 5.5. This method, which has been validated in accordance with ICH guidelines, can be used for regular quality control and exhibits the ability to indicate stability through analysis of aged samples.[31]

An HPLC-UV method for detecting loratadine in human plasma is described by Paweł K. Kunicki et al. Using 2-methylbutane–hexane, it is a liquid–liquid extraction process that is then evaporated and redissolved in 0.01 M HCl. A Supelcosil LC-18-DB column is used for the separation, and an isocratic mobile phase consisting of CH3CN, water, KH2PO4, and H3PO4 is used. With a quantification limit of 0.5 ng/ml, UV detection occurs at 200 nm. The technique demonstrates adequate accuracy in the 0.5–50 ng/ml range.[32]

Table 1: HPLC method for analysis of Armodafinil

Sr. No.	Drug	Dosage form	Stationary Phase	Mobile Phase	Detection (nm)	Flow Rate (ml/min)	Ret. Time (min.)	Detector	Ref. No.
1.	Lorata dine	Tablet	C18 chromatography column (250 x 4.6) 5µm, 80Å pore size, surface area 180 m2	(0.01% triethylamine solution adjusted to pH 2.75 with orthophosphoric acid) / acetonitrile (46/54)] - Isopropanol (90/10, v/v).	264 nm	1.0 ml/ min	3.9 min.	DAD Thermo stat	[26]
2.	Lorata dine	API	Inertsil ODS-3V, 250 x 4.6 mm, 5µ column	Buffer (0.05 M monobasic potassium phosphate), Acetonitrile, Methanol and Triethyl amine (38:45:17:0.5 v/v) adjusted to a pH of 3.6.	220 nm	1.0 ml/min	21.687 min.	UV-PDA detector	[27]
3.	Lorata dine	Human Plasma	Symmetry C18 column (150mm × 3.9mm, 5 µ m;) preceded with an Alltech 0.2 mfilter column.	Acetonitrile and phosphate buffer (20:80 v/v) and methanol, acetonitrile and 0.05M potas sium dihydrogen phosphate buffer (pH 2.0),	290nm	1.2 ml/min	3.0 min.	Waters 474 fluoresc ence detector	[28]
4.	Lorata dine	Tablet	Cyanopropyl column (250 mm × 4.6 mm i.d., 5 µ m particle size) combined with a guard column	Acetonitrile–20 mM sodium dihydrogen phosphate–triethylamine (43:57:0.02, v/v/v), pH 2.4	247 nm	1.0 ml/min	9.2 min.	UV-PDA detector	[29]
5.	Lorata dine	Tablet	Chromosil C18 (250x4.6mm, 5µm in particle size)	Methanol: TEA: 95:5% (V/V)	242 nm	1.0 ml/min	4.2 min.	UV-PDA detector	[30]
6.	Lorata dine	-	YMC-Pack Pro C18 column (15 cm 4.6 mm id, 3 mm particle size, 120 Å pore size); SunFire C18 column (15 cm 4.6 mm id, 3.5 mm particle size, 100 Å pore size; Waters Corp.).	Mobile phase A, aqueous 10 mM sodium acetate and 5 mM SDS, pH adjusted to 5.5 with acetic acid–neat acetonitrile (60 + 40, v/v); mobile phase B, aqueous 10 mM sodium acetate and 5 mM SDS, pH adjusted to 5.5 with acetic acid–neat	270 nm	1.5 ml/min	12.2 min.	photodi de array detector and/or 2487 dual wavelen gth UV detector .	[31]

				acetonitrile (25 + 75, v/v).					
7.	Lorata dine	Human Plasma	Supelcosil LC-18-DB (25034.6 mm, 5 mm) column protected with guard column LC-18-DB (2034.6 mm, 5 mm) pre-column	0.01 M ammonium formate (pH 4.5, Adjusted with acetic acid) :methanol (45:55 % v/v)	200 nm	1.8 ml/min	4.1 min.	UV-PDA detector	[32]
8.	Lorata dine	Tablets	Hypersil C18 (1504.6 mm, 5 mm), Hypersil C8 (1504.6 mm, 5 mm), Tracer Extrasil CN (1504.6, 5 mm), and a guard column manually packed with CN material (4 cm).	Mobile phase consisted of acetonitrile:10 mM ammonium acetate buffer (80:20 v/v), pH a	250 nm	1.5 ml/min	-	L-7400 UV detector ,	[33]
9.	Lorata dine	API	C18 reversed phase chromatographic column (4.6 mm ID 250 mm L), with 5 mm sized particles	Mobile phase consisted of phosphate buffer and acetonitrile(A-80:20, v/v) and (B-20:80, v/v)	247 nm	1.0 ml/min	19.0 min.	UV detector	[34]
10.	Lorata dine	Tablets	m-Bonda Pak C18 (300 x 3.9 mm, 10 mm) column	Mixture of H2O:methanol:phosphoric acid:Ammonium dihydrogen phosphate (300:220:2:3 g) (v/v/v/w), 60 and 40% acetonitrile.	247 nm	2.0 ml/min	3.517 min.	486 UV detector .	[35]
11.	Lorata dine	Human Plasma	Shimpack CLC-C8 (250 × 4.6 mm i.d.; 5m particle size) with a guard column Shimpack C8 (10 × 4 mm, 5m)	Mobile phase comprised of acetonitrile-20 mM sodium dihydrogen phosphate-triethylamine (43:57:0.02, v/v), adjusted to pH 2.4 with concentrated phosphoric acid and 4 M sodium hydroxide	290 nm and 460 nm	1.0 ml/min	10.9 min.	RF-10Axl fluorescence detector	[36]
12.	Lorata dine	-	ACE 3 C18 column [(150 x 4.6 mm, 3 mm,)]	Mobile phase: aqueous solution containing 10 mM of sodium citrate and SDS with pH adjusted to 6.2 or 3.0	270 nm	1.5 ml/min	7.20 min and 9.70 min.	-	[37]

				by 25% sulfuric acid and acetonitrile					
13.	Desloratadine	Tablets and Human Plasma	cyanopropyl column (250 mm4.6 mm ID, 5 mm particle size) and RP-18 pre-packed column (250 mm4 mm ID, 5 mm particle size)	Mobile phase composed of acetonitrile–water (60 : 40, v/v)	375 nm.	1.0 ml/min	3.7 min and 4.8 min	UV detector.	[38]
14.	Loratadine	-	Symmetry C18, 250 /4.6 mm, 5 mm, analytical column (Waters make)	Mobile phase is a mixture of aqueous 0.025 M sodium dihydrogen phosphate (buffer pH adjusted to 3.7 using dilute orthophosphoric acid) and acetonitrile in the ratio 20:80 (v/v)	225 nm.	1.0 ml/min.	-	Photodiode array detector	[39]
15.	Loratadine	Complex mixture	Inertsil ODS-3V (GL Sciences) 150mm x 4.6mm, 5µm column	Mobile phase : 0.01M Potassium di-hydrogen phosphate buffer (adjusted the pH to 3.0 with diluted ortho-phosphoric acid) and acetonitrile	210nm	0.60 ml/min	17.00 min	photo diode array (PDA) detector	[40]
16.	Loratadine	Human serum	125 mm x 4 mm i.d., 5-µm particle, Nucleosil-100 C18 analytical column	70:30 (v/v) acetonitrile–water adjusted to pH 2.7 with 85% orthophosphoric acid	265 nm and 454 nm	1.0 ml/min	2.95 min and 3.65 min	fluorescence detector (RF-551)	[41]
17.	Loratadine	Tablet, syrup	Type-C8 chromatography column (Zorbax Eclipse XDB-C8 4.6 mm x 150 mm, particle size 5 µm)	Mobile phase: acetonitrile / (aqueous solution of ammonium dehydrogenate phosphate 10 g/L was added to 5 mL of phosphoric acid): 11/15 (v/v)	280 nm	1.5 mL/min	-	DAD Detector	[42]
18.	Desloratadine	-	Hypersil BDS C18 (250 mm × 4.6 mm I.D., 5 µm particle size) column	Mobile phase composed of orthophosphoric acid and water in the ratio of 20:80 v/v	280 nm	1.0 ml/min	4.439 min	UV detector	[43]
19.	Loratadine	-	Arcus EP-C18 Ion Pac column, 5m, 4.6mm, 250mm	Mobile phase Methanol: Acetonitrile (60:40) v/v. Dibasic	340 nm	1.0 ml/min	3.8 min	UV detector	[44]

				potassium phosphate buffer, pH 7.2					
20.	Lorata dine	Tablet	Symmetry C18 (4.6×250mm) 5µ	Methanol and water (60:40)	224nm	1.0ml/min	4.7 min	PDA detector	[45]
21.	Lorata dine	syrup	Kromasil C8 (250 × 4.6 mm; 5 µm particle size) analytical column	Mobile phase consisted of 0.1% orthophosphoric acid and acetonitrile in the ratio of (60:40 v/v)	290 nm	1.2 mL/min	13.981 min	PDA detector	[46]
22.	Lorata dine	Rabbit plasma	Azilent C18 250 mm × 4.6 mm 5 µ, BDS C18 150 mm × 4.6 mm 5 µ, kromosil C18 250 mm × 4.6 mm 5 µ)	0.1% orthophosphoric acid : acetonitrile (40 : 60); 0.01 N potassium dihydrogen phosphate : acetonitrile (55 : 45); 0.1% perchloric acid : acetonitrile (55:45)	280 nm	1 ml/min	6.67 min	-	[47]
23.	Lorata dine	-	Reversed-phase variant, 2 × 75 mm column filled with a non- polar sorbent Prontosil 120-5 C18 AQ, 5 µm	Acetonitrile-methanol-ammonium acetate (18:36:46)	222 nm	1.5 mL/min	22.9 min	UV-diode-array detector	[48]
24.	Deslor atadine	Tablet	Inertsil ODS-3 V column (250 mm length, 4.6 mm id, 5 lm particle size)	Methanol–phosphate buffer of pH 7.0 (70:30 v/v)	254 nm	1.0 mL/min	4.225 min	UV detector	[49]
25.	Lorata dine	Tablet	150 mm x 4.6 mm ID, 5 µm Symmetry C18 HPLC Column	Mobile phase consisted of 0.1M potassium dihydrogen phosphate buffer with a pH adjusted to 6.2 using 0.1% orthophosphoric acid and acetonitrile in a 55:45, v/v ratio	246 nm	1.0 ml/min	3.202 min	PDA detector	[50]
26.	Lorata dine	Syrup	Partisil 10 SCX column (10 µm particle size, 250 mm×4.6 mm I.D.)	53.5% v/v water-methanol containing 30.12 mM/L sodium dihydrogen orthophosphate adjusted to pH 5.22	254 nm	1.0 ml/min	4.3 min	UV–Vis detector	[51]
27.	Lorata dine	Tablet, human urine, plasma	RODRP-18 (Merck, Germany) end-capped column	Micellar mobile phase consisted of 0.15 M sodium dodecyl sulfate, 0.3%	Initial 440 nm after excitati	1.2 mL/min	-	fluorescence detector	[52]

		and breast milk	(100 mm × 4.6 mm)	TEA and 10% n-Butanol in 0.02 M orthophosphoric acid, adjusted at pH 3.5	on at 280 nm.				
28.	Lorata dine	Syrup	C18 (250 x 4.6 mm i.d, 5 µ particle size) analytical column and a pre-column	Mobile phase 0.1 M Dipotassium Phosphate buffer (pH 7) and acetonitrile in the ratio of 70:30 v/v	245nm	1 ml/min	7.0503 min	UV detector	[53]
29.	Lorata dine	-	Type-C8 chromatography column (Zorbax Eclipse XDB-C8, 4.6 mm x 150 mm, particle size 5 µm	Mobile phase: acetonitrile / (an aqueous solution of ammonium dihydrogen phosphate 10 g/L was added to 5 mL of phosphoric acid): 11/15 (v/v)	280 nm	1.5 mL/min	about 4 min	DAD detector	[54]
30.	Lorata dine	Tablet	Inertsil ODS-3, C-8, (250×4.6 mm, 5µ) column	Mobile phase was composed of methanol andpottasiun0.02M dihydrogen phosphate Buffer (pH4) in the ratio of 80:20 v/v	247 nm	1.0 mL/min.	4.7 min	UV-VIS detector	[55]
31.	Lorata dine	Tablet	Symmetric C18 HPLC column, (4.6 x 250 mm; 5 mm bead size)	Mobile phase consisting of acetonitrile (HPLC grade): 0.01 M sodium salt of heptane sulphonic acid (58:42% v/v)	230 nm.	1.0 mL/min.	-	UV-VIS detector	[56]
32.	Deslor atadine	-	C18 column, 5µ (4.6 X 250 mm)	Mixture of Orthophosphoric acid (0.1%V/V), Acetonitrile and Methanol (50:35:15 V/V/V)	242 nm	1.0 mL/min	3.887 min	VWD detector	[57]
33.	Lorata dine	Tablet and Human Plasma	C18 ODS Hypersil column of 150 × 4.6 mm id with 5 µm particle size	Mobile phase of acetonitrile and 0.01N potassium dihydrogen phosphate (70:30)	269 nm	1.0 mL/min	5.6 min	UV visible detector	[58]
34.	Lorata dine and Deslor atadine	Human Plasma	Hypersil C18 column (5µm, 250 x 4.60 mm)	Mobile phase of MeOH: 0.025M KH2PO4 adjusted to pH 3.50 using orthophosphoric acid (85:15, v/v)	248 nm	1.0 mL/min	4.10 min and 5.08 min	PDA detector	[59]

35.	Loratadine (UPLC)	Human Urine and Human Plasma	BEH-C18 (carbon 17.7 %) and BEH-Shield RP18 (carbon 16.6 %) columns (100 x 2.1 mm, 1.7 µm particle size)	0.01 M KHPO4 and a mixture of methanol-acetonitrile (50:50)	254 nm	0.45 mL/min	2.24 min and 2.22 min	UPLC-PDA Detector	[60]

3.5. HPTLC Method

For the simultaneous assessment of ambroxol hydrochloride (AMB) and loratadine (LORA) in cough therapy, Magar, Samadhan, et al. devised a stability-indicating HPTLC approach. With Rf values of 0.36 and 0.68, respectively, AMB and LORA were well-separated using a silica gel 60 F254 TLC plate and a chloroform:methanol (9:1 v/v) mobile phase." The approach meets ICH requirements for robustness, accuracy, precision, and linearity with good results. The technology demonstrated its sensitivity and dependability when it was successfully implemented to a commercially available tablet formulation, with drug recovery rates that were almost 100%.[61]

A verified and selective high-performance thin-layer chromatography (HPTLC) approach for identifying loratadine (LOR) and desloratadine (DES) in pharmaceutical formulations is described by Youssef, Rasha M., et al. Using methanol-ammonia as the mobile phase, the procedure entails HPTLC separation followed by densitometric measurements at 254 nm. It demonstrates linearity in the ranges of 0.25–0.85 µg/band for LOR and 0.10–1.00 µg/band for DES. The procedure has been successfully used on commercial pills, capsules, and syrups. It is stable, accurate, exact, and specific—even when additional medications, such as pseudoephedrine, are present.[62]

Patel, Rashmin B. et al. provide a quick and reliable HPTLC technique for desloratadine quantification. The procedure separates the samples on silica gel 60F254 plates using a mobile phase consisting of methanol, chloroform, toluene, and ammonia. A linear range of 150-750 ng/mL with a correlation value of 0.9997 is revealed by densitometric analysis at 254 nm. The technique is sensitive, repeatable, exact, and accurate, with quantitation and detection limits of 65 ng/spot and 21 ng/spot, respectively. It works well with commercial tablet formulations as well as bulk medication formulations.[65]

Table 2: HPTLC method for analysis of Loratadine

Sr. No.	Drug	Dosage Form	Stationary Phase	Mobile Phase	Detection	Ret. factor	Linearity Range	Ref. No.
1.	Loratadine	Tablet, capsule, and syrups	Merck HPTLC plates (20 × 10 cm, aluminum plates with 250-µm thickness precoated with silica gel 60 F254)	Methanol–ammonia (10:0.3, v/v) as mobile phase.	254 nm	0.76	0.25–0.85 ng /spot	[61]
2.	Loratadine	Tablet	Silica gel 60 F254 HPTLC plate	Chloroform: Methanol (9:1 v/v)	216 nm	0.68	50-300 ng/band	[62]
3.	Loratadine	Tablet	Silica gel 60 F254 Premium Purity HPTLC glass plates (20 x 10 cm)	Ethyl acetate-methanol-concentrated ammonium hydroxide (24:3:1)	254 nm	0. 72 to 0. 85	-	[63]
4.	Loratadine	Tablet and Human Plasma	HPTLC aluminum plates, precoated with silica gel 60 F254 (20 × 20 cm), 0.2 mm thickness	Mobile phase consisted of acetone–hexane–ammonia (4:5:0.4, by volume)	254 nm	0.69	0.1–2 µg/band	[64]
5.	Desloratadine	API	Pre-coated silica gel 60 F254 HPTLC plates (10 × 10 cm, layer thickness 0.2 mm	Methanol: chloroform: toluene: ammonia (5.0+	254 nm	0.6	150 – 750 ng /spot	[65]

				5.0 + 1.0 + 0.3 v/v/v/v)				

Table 3: Liquid Chromatography/Mass Spectrometry method for analysis of Loratadine

Sr. No.	Drug	Dosage Form	Stationary Phase	Mobile Phase	Flow rate	Mass/charge ratio (m/z)	Ret. Time	Ref. No.
1.	Loratadine	Self-nanoemulsifying drug delivery systems in rat plasma	Gemini NX-Reverse Phase C18 (50 × 4.6 mm; 5µ), 110 Å analytical column	Mobile phase mixture of 5mM ammonium formate buffer in water (pH 3.5±0.1 with formic acid), and acetonitrile (20:80 v/v)	0.400 mL/min	383.3 → 337.4 m/z	2.62 min	[66]
2.	Loratadine	-	A ZORBAX RX-C8 analytical column (2.1×150mm, 5µm)	The mobile phase consisted of phase A (acetonitrile, containing 20% (V/V) tetrahydrofuran) and phase B (10 mM ammonium acetate, containing 0.2% (V/V) formic acid).	0.25 ml/min	0.5 m/z	-	[67]
3.	Loratadine	Human Plasma	Phenomenex Luna C (2) 5-mm, 15032.1-mm column	Mobile phase consisting of acetonitrile–0.1% formic acid using gradient elution (10 to 90% acetonitrile in 2 min)	0.3 ml/min	382.7 m/z	5.18 min	[68]
4.	Loratadine	Human plasma	Prepacked narrow-bore Zorbax SB-phenyl, 5 µm, 150 mm × 2.1 mm protected by a Phenomenex C18 guard column (4 mm × 2.0 mm i.d.)	Mobile phase, prepared by mixing acetonitrile:0.20% formic acid in the ratio of 68:32 (v/v)	0.20 ml/min	337 m/z	3.10 min	[69]

Table 4: Capillary Electrophoresis method for analysis of Armodafinil

Sr. No.	Drug	Matrix/ Dosage Form	Detection	Capillaries (Fused Silica Capillary)	Separation Voltage	Temp./ Pressure	Ref. No.
1.	Loratadine	-	200 nm	Uncoated fused silica capillary (57 cm x 50 mm ID)	20 kV	3.3 bar	[70]
2.	Loratadine	Tablet	240 nm	160 mm capillary tube with a 300 mm internal diameter, hydrodynamically (membrane) closed	6.2 kV	-	[71]
3.	Loratadine	API	205 nm	Fused silica capillary of 50.2 cm (40 cm effective length), 75 µm i.d	20 kV	3447.3 Pa/ at 25 ºC	[72]

4. Liquid Chromatography/Mass Spectrometry

Using loratadine-d5 as an internal standard, Samridhi Verma et al. devised a sensitive LC-ESI-MS/MS/MS technique for measuring loratadine in rat plasma. High sensitivity (1.0 ng/mL) and good linearity (1.0–405.41 ng/mL, r = 0.9998) were demonstrated by the technique. Applied to a self-nanoemulsifying drug delivery system filled with loratadine, it demonstrated notably higher bioavailability than LTD suspension. Strong in vitro-in vivo correlations were found using the Loo-Reigelman approach, and the in vivo-in silico prediction utilizing GastroPlusTM software demonstrated high accuracy.[66]

A sensitive high-performance liquid chromatography-tandem mass spectrometry (HPLC-MS/MS) process was proposed by Sutherland, F. C. W. et al. to determine loratadine and its active metabolite descarboethoxyloratadine in plasma concurrently. The procedure comprised chromatographic separation on a Phenomenex Luna C18 column, back-extraction into formic acid for DCL, and plasma extraction using toluene. Using a Perkin-Elmer API 2000 mass spectrometer, detection was accomplished. The technique demonstrated mean recoveries of 100% for DCL and 61% for LOR, with a quantification lower limit of 0.10 ng/mL for both. This assay is appropriate for pharmacokinetic research and is the first to measure DCL and LOR in plasma concurrently in a single run.[68]

Loratadine in human plasma may be identified and measured with a sensitive LC-ESI-IT-MS/MS approach that was developed and validated by Ismail Salem et al. With a Zorbax phenyl column for separation and isooctane:isoamyl alcohol for extraction, the technique demonstrated good accuracy (105.00–109.50%) and linearity (0.10–10.0 ng/mL, $r^2 = 0.9998$). With a precision of 9.84%, the lowest limit of quantification was 0.10 ng/mL. The procedure is appropriate for pharmacokinetic, bioavailability, or bioequivalency research and satisfies FDA bioanalytical validation requirements.[69]

4.1. Capillary electrophoresis

In addition to HPLC, Fernandez, H. et al. created a capillary electrophoresis (CE) approach to detect and measure seven contaminants in loratadine raw material. The approach achieved 0.1% impurity detection using an uncoated fused-silica capillary and a separation buffer of 100 mM H3PO4 (pH 2.5) with 10% acetonitrile. The technique proved to be sufficiently linear, accurate, and precise, indicating its suitability for long-term stability and purity investigations involving loratadine.[70]

A capillary zone electrophoresis (CZE) approach was created by Mikuš, P., et al. to identify loratadine in pharmaceutical preparations. The procedure optimized conditions using glycine, citric acid, and acetic acid at pH 3.2 using a 160 mm capillary tube. The validated approach completed the analysis in six minutes and shown great sensitivity, simplicity, and repeatability. With low rsd for peak area (1.1%) and migration time (0.6%), the detection limit was 1.96 µmol/L. For complicated biological materials, this CZE approach can be used with purification modes and is appropriate for loratadine analysis in tablets.[71]

A capillary zone electrophoresis technique for identifying loratadine (LOR) and rupatadine (RUP) in tablets is described by Mothé, Cintia Maria Alves, et al. Boric acid is employed as the background electrolyte in this approach, which employs a fused silica capillary to achieve separation at 1.8 and 2.8 minutes for RUP and LOR, respectively. In the range of 50.0 to 400.0 µg/mL, it is linear for both medications, with detection limits of 46.37 µg/mL for LOR and 29.60 µg/mL for RUP. High recovery (about 100%) and accuracy (less than 5.0%).[72]

4.2. Spectrophotometric overview

4.2.1. UV-Visible Spectroscopy Method

AUC approach was used by Ram S. Sakhare et al. to establish a stability-indicating UV-spectrophotometric method with a measuring range of 240-250 nm in methanol to quantify loratadine in bulk and tablet forms. With a correlation value of 0.998, the technique demonstrated linearity in the 1-6 µg/mL range. With %RSD values of 0.6159 for intra-day precision and 1.3696 for inter-day precision, the percent recovery values verified the correctness of the procedure. 1.6548 µg/mL was the LOQ and 0.6648 µg/mL was the LOD, respectively.[73]

Without requiring a lot of sample pre-treatment, Hassaninejad-Darzi et al. devised a method to resolve loratadine utilizing multivariate spectrophotometric calibration with PLS-1, PCR, and HLA methods. For calibration and validation, the models used data from UV-Vis spectra and central composite design, resulting in a minimum RMSEP of 0.251 mg/L and a detection limit of 0.05 mg/L. Despite spectrum overlap and sample variability, the approach was successfully used to pharmaceutical tablets and human plasma, displaying good recoveries.[74]

Using the ionic strength UV spectra of loratadine (LOR) and desloratadine (DES), Youssef, R., et al. established validated spectrophotometric techniques for identifying both compounds concurrently. At 339 nm, LOR and 306 nm, respectively, were measured. The techniques worked well with commercial tablets, capsules, and syrups and followed Beer's law. They also demonstrated good linearity, sensitivity, precision, accuracy, and stability. These attributes made the techniques appropriate for regular quality control analysis.[75]

Afreen, Syed Sara, et al. used 0.1 N HCl as a solvent and measured at 307 nm to create a first-order derivative UV

spectrophotometric technique for precisely quantifying loratadine in combination tablet forms. Excellent linearity, repeatability (%RSD < 2), and sensitivity were demonstrated by the technique, which was verified in accordance with ICH criteria. The LOD and LOQ values were 0.37 µg/mL and 1.15 µg/mL, respectively.[76]

A UV-spectrophotometric approach was developed by Prathap, B., et al. with an INFRADIGI IR-513C, 0.1 N HCl, and ethanol as solvents, and a detection wavelength of 276 nm for routine measurement of loratadine in APIs and dosage forms. The technique demonstrated good linearity, accuracy, and recovery rates when verified in accordance with ICH criteria. Its resilience for pharmaceutical quality control was further demonstrated by its assessment of deterioration under various stress settings.[77]

An accurate and dependable UV spectrophotometric stability-indicating technique for desloratadine tablet estimation at 242 nm was developed by Roge, A., et al. High precision, accuracy, and responsiveness were demonstrated by the technique, which was verified in accordance with ICH requirements and exhibited linear absorbance over 5–30 µg/mL with an R^2 value of 0.999. The LOD and LOQ of the procedure were, respectively, 0.121 µg/mL and 0.366 µg/mL. It was discovered that desloratadine was unstable in the presence of oxidative and hydrolytic stress.[78]

5. Conclusion

We have thoroughly examined the creation and verification of analytical techniques for the popular antihistamine loratadine in this study. The many methods covered, such as LC-MS, UV spectroscopy, and HPLC, show how reliable and accurate it is to measure and monitor the level of loratadine in pharmaceutical formulations. To guarantee adherence to legal requirements, the validation parameters—specificity, linearity, accuracy, precision, and robustness—were thoroughly assessed. In order to ensure the safety and efficacy of loratadine and, ultimately, improve treatment results and patient care, this review emphasizes the significance of careful method development and validation.

Numerous approaches may be used to examine the presence of loratadine in biological materials and pharmaceutical formulations. An analysis of the published data revealed that HPLC techniques were widely used to assess loratadine in various matrices, including serum and plasma. HPLC with UV detection is suitable since this technology produces accurate results and is less costly than more complex detection techniques.

This review provided a summary of the most cutting-edge analytical techniques available for identifying loratadine.

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None.

7. Conflict of Interest

None.

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