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A comprehensive review of the analytical methods used for the determination of selected antihistamines in pharmaceutical dosage forms and biological fluids

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ABSTRACT
Antihistaminic drugs are a group of therapeutic agents representing one of the most-widely prescribed medications for treating different diseases. They are often used to relieve symptoms of allergies, such as hay fever, conjunctivitis, and reactions to insect bites or stings. A comprehensive review with more than two hundred references reported on the analysis of selected antihistamines is explored. The selected drugs belong to different generations of antihistaminic drugs. These drugs include rupatadine, montelukast, desloratadine and fexofenadine.. The literature review covers most methods described for determining these drugs in bulk powder, pharmaceutical dosage forms, animal tissues and biological fluids. Different analytical techniques include UV and Visible spectrophotometry, spectrofluorometry, thin-layer liquid chromatography, high-pressure liquid chromatography, ultra-performance liquid chromatography, gas chromatography, capillary electrophoresis, and electrochemical methods.

Keywords:
Review; Determination; Antihistamines; Pharmaceutical dosage forms; Animal tissues; Biological fluids

1. Introduction

The peripheral effects of histamine are mainly mediated by two sets of receptors termed H1 and H2. The H1 receptors include the contraction of smooth muscle and the dilatation and increased permeability of the capillaries. The effects of histamine on vascular smooth muscle are mediated by H2 and H1 receptors. Other effects mediated by H2 receptors include cardiac accelerating effects and, in particular, the stimulating action of histamine on the secretion of gastric acid. An H3 receptor has also been identified in the CNS and peripheral nerves. The term ‘antihistamines’ is related to histamine H1-antagonists, H2-antagonists, and H3-antagonists. Antihistamines are classified according to their chemical structure into alkylamines, monoethanolamines, ethylene diamines, phenothiazines, piperazines, and piperidines.

The mechanism of action of antihistamines depends on the fact that histamine H1-antagonists diminish the significant actions of histamine in the body by competitive, reversible blocking of histamine H1-receptor sites on tissues; they do not inactivate histamine or prevent its synthesis, nor, in most cases, its release (although some are claimed to have mast-cell stabilizing properties). Histamine H1 receptors are responsible for vasodilatation, increased capillary permeability, flare and itch reactions in the skin, and to some extent, for smooth muscle contraction in the bronchi and gastrointestinal tract (Martindale, .2011).

2. Physical and chemical properties

Rupatadine fumarate (RUP) is chemically 8-Chloro-11-[1-[(5-methyl pyridine-3-yl)methyl]piperidin-4-ylidine]-6,11-dihydro-5H-benzo[5,6]cyclohepta[1,2-b]pyridine(2E)-but-2-enedioate (B. pharmacopeia, 2013) (Fig. 1). RUP is white or slightly pinkish powder. It is very slightly soluble in water, slightly soluble in anhydrous ethanol, and very slightly soluble in heptane. It is practically soluble in methanol and ethanol. It is log P is 0.8 while it is pKa is 7.19, which is strongly basic. It should be protected from light (B. pharmacopeia, 2013). This compound is officially in British pharmacopeia (BP) (B. pharmacopeia, 2013) and the United States pharmacopeia (USP) (U. S. Pharmacopeia, 2009).

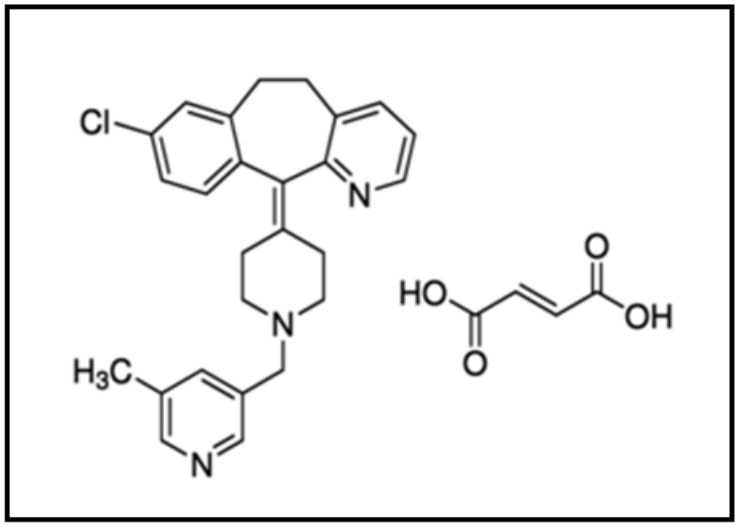

Fig. 1: Chemical structure of rupatadine fumarate

Montelukast sodium (MKT) is chemically [R-(E)]-1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methyl ethyl)phenyl]propyl]thio]methyl]cyclopropaneacetic acid, monosodium salt (B. pharmacopeia, 2013) (Fig. 2). MKT is a hygroscopic, optically active, white to off-white powder. Montelukast sodium is freely soluble in ethanol, methanol, and water and practically insoluble in acetonitrile (B. pharmacopeia, 2013). This drug is official in British pharmacopeia (B. pharmacopeia, 2013) and united states pharmacopeia (U. S. Pharmacopeia, 2009). Montelukast is a selective leukotriene receptor antagonist. It is used in managing chronic asthma and allergic rhinitis (see below). As prophylaxis for exercise-induced asthma, montelukast sodium is given in doses equivalent to 10 mg of montelukast once daily in the evening. It is used as the sodium salt, but doses are expressed in terms of the base; montelukast sodium 10.38 mg is equivalent to about 10 mg (Martindale, .2011).

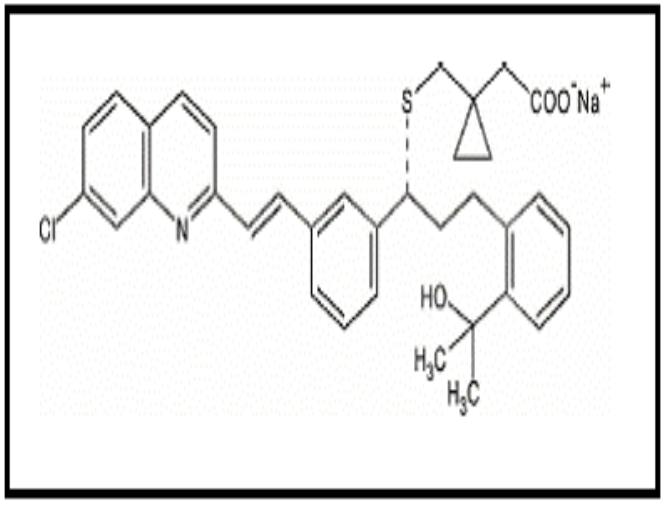

Fig. 2: Chemical structure of montelukast sodium

Fexofenadine (FEX) is chemically 2-[4-[(1RS)-1-Hydroxy-4-[4(hydroxydiphenylmethyl)piperidin-1-yl]butyl]phenyl]-2-methyl propanoic acid hydrochloride. FEX is a white or almost white powder and shows polymorphism. It is slightly soluble in water, freely soluble in methanol, and very slightly soluble in acetone (U. S. Pharmacopeia, 2009). It's log P values are 5.02 and 2.94.FEX is official in British Pharmacopeia (B. pharmacopeia, 2013) and United States Pharmacopeia (U. S. Pharmacopeia, 2009). Fexofenadine is an active metabolite of terfenadine, is a non-sedating antihistamine. It does not possess significant sedative or antimuscarinic actions. It is used as the hydrochloride in the symptomatic relief of allergic conditions, including seasonal allergic rhinitis and chronic urticaria. In the UK, a dose of FEX 120 mg once daily is given orally in treating seasonal allergic rhinitis; the recommended dose in chronic idiopathic urticaria is 180 mg once daily. FEX is also used with a decongestant such as pseudoephedrine hydrochloride (Martindale, .2011).

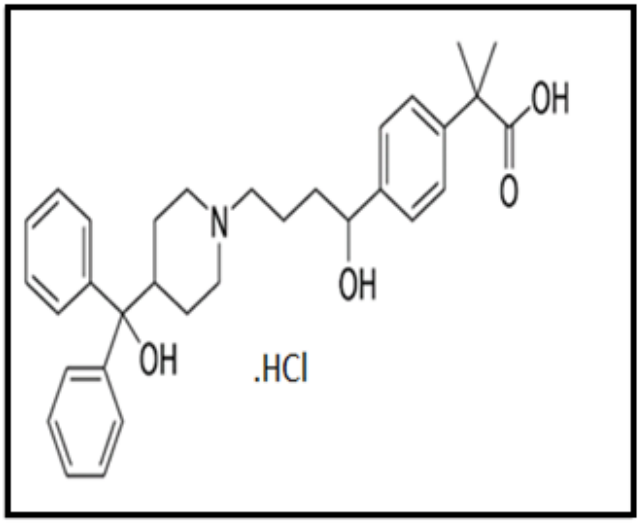

Fig. 3: Chemical structure of fexofenadine

Desloratadine (DES) is chemically 8-choloro-11-(piperidine-4-ylidene)-6,11-dihydro-5H-benzo[5,6] cyclohepta [1,2]pyridine (B. pharmacopeia, 2013). Its log P is 3.2. Its white or almost white powder. It is freely soluble in ethanol and methanol, insoluble in water, and slightly soluble in heptane, as it shows polymorphism (B. pharmacopeia, 2013). It is official in British pharmacopeia (B. pharmacopeia, 2013)and United states pharmacopeia(U. S. Pharmacopeia, 2009). Desloratadine is the major active metabolite of loratadine and is a non-sedating antihistamine. Desloratadine is used in the symptomatic relief of allergic conditions, including rhinitis and urticaria. Desloratadine is given in an oral dose of 5 mg daily (Martindale, .2011).

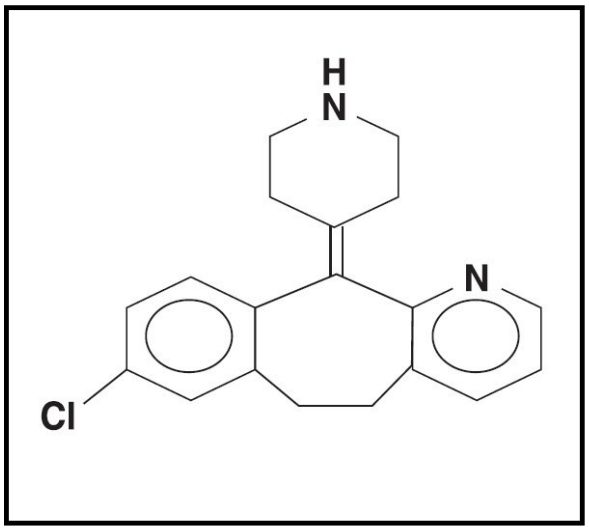

Fig. 4: Chemical structure of desloratadine

3. Literature review

Numerous analytical methods have been developed to determine the selected antihistamines in pure form, dosage forms, and biological fluids. A brief description of these methods can be outlined as follows:

3.1. Titrimetric methods:

The B.P (B. pharmacopeia, 2013) introduced the potentiometric titration method; by dissolving RUP in glacial acetic acid using 1mM perchloric acid as a titrant in addition to another aqueous potentiometric method using 0.1N sodium hydroxide as a standard for determination of rupatadine fumarate in the different pharmaceutical dosage forms (RV Rele, Mahimkar, & Sawant, 2009). A potentiometric titration method was developed and validated for MKT assay using HCl as a standard (Aslan, Erden, Canel, & Kilic, 2014). The method is based on the conductometric determination of 2.5-13.45 mg of FEX by titration with sodium tetraphenylborate (TPB) in an aqueous solution at 20°C (S Ashour, Khateeb, & Mahrouseh, 2013) FEX is treated with a known excess amount of bromate-bromide mixture in acid medium followed by the determination of unreacted bromine iodometrically (Raghu, Shantharam, & Yogesh Kumar, 2018). Another method is based on the formation of an ion association complex of cations coming from the cited drugs with tetraphenylborate anions, and the conductance of the solution is measured as a function of the volume of titrant (Safwan Ashour & Khateeb, 2013).

Discussion

3.2. Spectroscopic method

3.2.1. UV and Visible Spectrophotometric Methods

Table 1: UV/Visible spectrophotometric methods for RUP determination

Matrix	Technique/derivatizing agent	λ_{max} (nm)	Ref.no.
Pharmaceutical dosage forms	Forming colored complexes using three reagents: bromocresol green, eriochrome black-T, and solochrome dark blue in an acidic medium.	416 nm, 511 nm, and 527 nm, respectively	(Rajan Rele & Patil, 2012)
Pharmaceutical dosage forms	single point standardization method	246 nm	(Basha, Manikanta, & Jahnavi, 2019)
Pharmaceutical dosage forms	Forming colored complexes using three reagents: bromothymol blue, bromophenol blue, and methyl orange in an acidic medium	416, 418, and 422 nm, respectively	(RV Rele, Desai, & Sawant, 2010)
Pharmaceutical dosage forms	1. first-order derivative UV-spectrophotometric method 2. area under the curve (AUC), the zero-order spectrum	1. 214 nm. 2. from 245 to 255 nm	(R. V. Rele & P. P. J. D. P. L. Tiwatane, 2014)
Pharmaceutical dosage forms	second-order derivative UV-spectrophotometric method	220.5 nm	(R. V. Rele & P. P. J. A. J. R. C. Tiwatane, 2014)
Bulk powder	Stability indicating method	232 nm	(Gandi et al., 2020)
pharmaceutical dosage forms	1. Direct spectrophotometry 2. First-order derivative	1. 273.5 nm 2. 261.5 nm	(*DEVELOPMENT AND ITS VALIDATION FOR DETERMINATION OF RUPATADINE HCL IN BULK AND FORMULATION BY U . V . SPECTROMETRIC METHOD Daswadkar*, 2017)
RUP and MKT in tablets.	first-order derivative UV spectroscopy method	273.46 and 297.27 nm, respectively	(P. Patel, Vaghela, Rathi, Rajgor, & Bhaskar, 2009)

Table 2: UV/Visible spectrophotometric methods for MKT determination

Matrix	Technique/derivatizing agent	λ_{max} (nm)	Ref.no.
MKT/FEX in bulk and tablets	Direct spectrophotometry	344.5 nm, 259 nm	(Sowjania & Sastri, 2018)
FEX, MKT, and Ambroxol in tablets	zero order and first derivative method	220.20, 283.42, and 245.84 nm in zero order; 221, 287.52, and 262.25 nm in first order derivative method, respectively	(Sharma et al., 2018)
Doxofylline, MKT, and Levocetirizine in bulk powder and pharmaceutical formulations	Vierordt's method and first-order derivative method	273.3, 283.1, and 231.05 nm in vierordt's method and 287.93, 292.57, and 242.45 in the first-order derivative method, respectively.	(Nitish Kumar, Anghore, Rawal, & Pandey, 2018)
MKT and bilastine in their combined pharmaceutical dosage forms	Based on a risk-based analytical quality-by-design approach using statistical analysis and chemometric methods		(Prajapati, Tamboli, Surati, & Mishra, 2021)
MKT	A: Reduction of FE(V) to FE(II) by MKT.B: MTK coupling with MBTH C: MTK reaction with 2,2'-Bipyridy	A: 510 B: 610 C: 430	(Felice)
MKT in bulk, pharmaceuticals, and human serum	Spectrophotometric Method	283 nm	(Saeed Arayne, Sultana, & Hussain, 2009)
MKT and Theophylline	Ratio method Simultaneous Equation and Q-Absorbance	287 (Ratio),271 (Simultaneous), and 280 (Iso absorptive point)	(R. Patel, Parmar, Patel, Shah, & Sciences, 2012)
MKT and DES	Q-Absorbance Ratio Method and Dual Wavelength Method	283(MKT),345 (MKT), (iso absorptive point) 265.6 and 294 (DES)263.6	(Bankar & Patel, 2013b)
MKT and DES	Ratio Spectra Derivative Spectrophotometric Method	first derivative amplitudes:218.6(MKT),262(DES)	(Bankar & Patel, 2013a)

Table 2: (Continued)

Theophylline, MKT and Loratadine	Multivariate Spectrophotometric Calibration-partial least squares, principal component regression and hybrid linear analysis.	275 (THEO), 276(MKT), 251 (LORA)	(Hassaninejad-Darzi, Samadi-Maybodi, & Nikou, 2016)
MKT, Levocetirizine and Dihydrochloride	Derivative and Absorption Factor Spectrophotometric Method	232 (MKT),279 (LEV).FD amplitudes:340(MKT),331 (LEV)	(Choudhari et al., 2011)
RUP and MKT	Q Analysis method	260 MKT (Iso absorptive point) 244(RUP)	(R. L. Choudekar, M. P. Mahajan, & S. Sawant, 2012)
Acebrophylline and MKT	Simultaneous Equation Method	313 (ACBR),344.5 (MKT)	(Kumar Naraharisetti, 2014)
MKT and FEX in bulk and pharmaceutical preparation	Chemometric method. Non-parametric linear regression analysis (Theil's method). (Hybrid chemometric method)		(Ragab & Youssef, 2013)

Table 3: UV/Visible spectrophotometric methods for FEX determination

Matrix	Technique/derivatizing agent	λ_{max} (nm)	Ref. No.
FEX in bulk and pharmaceuticals	a pale yellow color complex formed by the reaction of FEX with bromothymol blue at pH 2.6	412 nm	(K. S. Kumar, Ravich, Raja, Thyagu, & Dharamsi, 2006)
FEX and pseudoephedrine (PSE) in their combined tablet formulation	partial least squares (PLS) chemometry	The UV spectra of the samples were acquired between 235 and 275 nm within the next two hr and processed employing the PLS algorithm	(Maggio, Castellano, Vignaduzzo, Kaufman, & Analysis, 2007)
(FEX) in bulk sample and pharmaceutical formulations	formation of ion-association complex involving the carboxylic acid group of FEX and the basic dyes, Safranin-O and methylene blue	Safranin-O AT 520 and methylene blue at 650 nm	(Srinivas, Kumar, & Sastry, 2005)
FEX in the presence of Its Degradation Product	Derivative spectrophotometry (First and second)	The first derivative: in the presence of alkaline or acidic degradation products at interval Δλ of 6 nm, at 223 nm. A wavelength interval Δλ of 8 nm at 211 nm in the presence of its oxidative degradation product. The second derivative is at Δλ of 8 nm, at 217 nm, in the presence of its alkaline or acidic degradation products. Under oxidative degradation conditions at 215 nm, Δλ of 10 nm. The second derivative was used in the presence of its UV degradation product at a wavelength interval Δλ of 6 nm and at 211nm	(El-Din, Ibrahim, Eid, & Wahba, 2011)
FEX in bulk and pharmaceutical preparations	The first method is based on the formation of colored chloroform extractable ion-association complexes (1:1) of fexofenadine with bromocresol purple (BCP) and bromophenol blue (BPB) dyes in aqueous acidic buffer pH 3.0	bromocresol purple= 411 nm bromophenol blue (BPB) dyes= 415 nm	(S Ashour et al., 2013)
FEX in Pharmaceuticals	Direct spectrophotometry	220 nm	(Breier, Steppe, & Schapoval, 2007)
FEX	The formation of extractable ion pair complex of drug with bromophenol blue, bromocresol purple, and bromocresol green dyes in an acidic medium	416 nm, 412 nm, and 419 nm, respectively.	(Polawar, Shivhare, Bhusari, Mathur, & Technology, 2008)
FEX and Cyanocobalamin in Separate Ophthalmological Dosage Forms	Direct spectrophotometry	At 228 nm	(Zhilyakova, Mohamad, Bakri, Naplekov, & Martseva, 2019)

MKT and FEX in Bulk & Combined tablets	Direct spectrophotometry.	at 259.60nm for Fexofenadine Hydrochloride and 283.00 nm for Montelukast Sodium	(Patle, Nagar, & Pharmacy, 2017)

Table 3: (Continued)

Sensitive Extractional Colorimetric Analysis of FEX and Irbesartan Bases Through Acid-Dye complex	the reaction of the above-cited drugs with naphthol blue-black (NBB) dye in solutions containing Britton buffer to form ion-pair complexes extractable with chloroform	At 625 nm	(Safwan Ashour & Bayram, 2017)
Charge-transfer interaction between antiallergic antihistamine drugs, diphenhydramine, FEX, cetirizine, and two π-acceptors in pharmaceutical forms	charge-transfer complex formation between FEX, diphenhydramine, and cetirizine with 2,3-dichloro-5,6-dicyano-1,4-benzoquinone (DDQ) and 7,7,8,8-tetracyanoquinodimethan (TCNQ) reagents.	460 and 840 nm for DDQ and TCNQ	(El-Didamony & Ramadan, 2020)
Q analysis of MKT and FEX in Tablets	first-order derivative spectroscopy	340 nm and 212.6 nm of the first derivative spectrum	(P. R. Kumar & Kumar, 2017)
Spectrophotometric Determination of Some NonSedatingAntihistamines Using Erythrosine B	ion-pair complex formation with erythrosine B	550 nm	(El-Kommos, El-Gizawy, Atia, & Hosny, 2013)

Table 4: UV/Visible spectrophotometric methods for DES determination

Matrix	Technique/derivatizing agent	λ_{max} (nm)	Ref. no.
DES in Pharmaceutical Formulations	formation of ferric chloride and potassium ferricyanide, which forms a colored chromogen	710 nm	(Sekhar, Prasad, & Kumar, 2012)
DES in Tablet Formulation	ionic association complex formed with bromocresol green	407 nm	(Zagorodny, Buhaiova, & Vasyuk, 2018)
DES in tablets formulation	Measurement of uncertainties associated with UV spectrophotometric method.	282 nm	(Takano, de Souza Reis, Singh, & Lourenço, 2017)
DES in tablets	Based on the deep-blue colored TCNQ*- radical anion formed by the interaction of the drug (n-donor) with 7,7,8,8-tetracyanoquinodimethane (TCNQ, pi-acceptor)	843 nm	(Caglar Andac & Oztunç, 2007)
DES in pharmaceutical dosage form	Formation of colored complexes by the drug with reagents like eriochrome black T, methyl orange, and picric acid in an acidic medium	500 nm, 420 nm, and 414 nm, respectively	(RV RELE, SAWANT, & MALI)
DES in Dosage Forms and Human Plasma	1. DES coupled with 4-chloro-7-nitrobenzo-2-oxa-1,3-diazole (NBD-Cl) in borate buffer of pH 7.6 where a yellow-colored reaction product, derivatization of DSL with 2,4-dinitrofluorobenzene (DNFB) in borate buffer of pH 9.0 producing a yellow-colored product	1.485 nm 2.375 nm	(El-Enany, El-Sherbiny, Belal, & Bulletin, 2007)
DES in tablets	Direct spectrophotometry	242 nm	(Bondili, Reddy, & Research, 2011)
DES	1. Single wavelength 2. Multiple component equations 3.Multivariate analysis consists of PLS and PCA, a chemo-metric based, assisted the model selection and model calibration	1.290 nm 2. 273 nm and 283 nm	(Ainurofiq & Choiri, 2020)
DES in Pharmaceutical Formulations	formation of colored product between DES and sodium 1,2-naphthoquinone-4-sulphonate (NQS)	485 nm	(Safwan Ashour & Khateeb, 2015)
DES and pseudoephedrine sulfate in tablets	First derivative spectrophotometric method	280 and 244 nm for DES and pseudoephedrine, respectively	(Çağlar & Toker, 2011)
DES in tablets and the presence of its parent drug.	Depend on the interaction of the secondary amino group in DSL with acetaldehyde to give N-vinylpiperidyl product. The formed N-vinylpiperidyl compound was reacted with 2,3,5,6-tetrachloro-l,4-benzoquinone (chloranil) to create a colored product	672 nm	(Sayed Mohamed Sayed, 2014)

Table 4: (Continued)

DES + Loratadine + RUP	Formation of colored ion pair complexes by the drugs with thiocyanate ions	618 nm, 614 nm, and 616 nm, respectively	(Pankaj & sciences, 2012)
DES, FEX, Etodolac, Moexipril and Thiocolchicoside in Pure and Pharmaceuticals	The method depends on the oxidation of each of the studied drugs with alkaline potassium permanganate, where a green color peaking is produced	607 nm	(S. S. Abd El-Hay, M. Y. El-Mammli, & A. A. J. B. B. R. A. Shalaby, 2016)
Loratadine and DES in the presence of Pseudoephedrine	differential derivative spectrophotometric procedure	OR at 339 nm DES at 306 nm	(Youssef, Khamis, El-Sayed, Mohamed, & Moneim, 2017)
Clemastine fumarate, DES II, losartan V and moexipril IV	binary complex formation with eosin	552, 549 nm for (I), (II) while was measured at 540 nm for (V) and (IV)	(S. S. Abd El-Hay, M. Y. El-Mammli, & A. A. J. A. J. o. C. Shalaby, 2016)

3.2.2. Spectrofluorometric methods:

The native fluorescence of RUP was examined at 455 nm after excitation at 277 nm and synchronized with MKT determined via first order derivative technique (Ghonim, El-Awady, Tolba, & Ibrahim, 2021). RUP was derivatized using erythrosine B via Resonance Rayleigh scattering and spectrofluorometric approaches (Almahri, Abdel-Lateef, Samir, Derayea, & El Hamd, 2021).

The native fluorescence of MKT was scanned at 390 nm using 340 nm for excitation dosage forms and spiked human plasma. (Alsarra, Khalil, Sultan, Al-Ashban, & Belal, 2005).

The native fluorescence of FEX was examined after protonation in an acidic medium at 290 nm after excitation at 230 nm (El-Kommos, El-Gizawy, Atia, & Hosny, 2015). Synchronous Spectrofluorimetry (FDSFS) was used to measure FEX in its alkaline or acidic degradation products at 406 nm and 367 nm in the presence of its oxidative or UV degradation products. In comparison, FEX was determined at 225 nm in the presence of all degradation products (El-Din et al., 2011). Derivatization of FEX with some Π acceptors namely p-chloranilic acid (CLA), tetracyanoethylene (TCNE), and 2,3-dichloro-5,6-dicyano-*p*-benzoquinone (DDQ) to give highly fluorescent derivatives (Sharaf El-Din, Ibrahim, Eid, & Wahba, 2012) and with AgNPs gives quenching product (Alothman, Bukhari, Haider, Wabaidur, & Alwarthan, 2010) and also by sensitization of terbium (Tb^{3+}) by complex formation with FEX (Al-Kindy, Al-Shamalani, Suliman, & Al-Lawati, 2019).

The native fluorescence of DES was exhibited at 438 nm after excitation at 290 nm (Walash, Belal, El-Enany, Eid, & El-Shaheny, 2011) and determined with MKT through second derivative fluorescence technique at $\Delta\lambda$=160 at 288 nm (Ibrahim, El-Enany, El-Shaheny, & Mikhail, 2015). Derivatization of DES with NBD-Cl produced yellow colored product measured at 538 nm after excitation at 480 nm (El-Enany et al., 2007).

3.2.3. Miscellaneous spectroscopic methods:

Complexation of fexofenadine with α-cyclodextrin in an aqueous medium was studied, so the inclusion complex was determined by 1H NMR titration data and 2D ROESY data (Ali, Khan, & Crowyn, 2012).

Simple, environment-friendly, rapid, accurate, and cost-effective Fourier Transform Infrared Spectrophotometric (FT-IR) methods have been developed to quantify some drugs including DES (Balusani, 2022).

3.3. Chromatographic methods:

3.3.1. Thin layer chromatography:

Simultaneous estimation of RUP and MKT using TLC aluminum plates precoated with silica gel 60F-254 as a stationary phase with Toluene: Ethyl acetate: methanol (5:3: 2v/v) as a mobile phase at room temperature (M.T.Patil & Ankalgi, 2013) also RUP and FEX were determined densitometrically using Silica gel 60 F_{254} HPTLC plates were used as stationary phase, while mixtures of acetonitrile-water - 25% ammonia (90: 10: 1, v/v/v) and acetonitrile - methanol -acetate buffer at pH 5.5 (3: 2: 5, v/v/v) were used as mobile phases (Czerwinska, Wyszomirska, Kublin, Malanowic, & Mazurek, 2016).

Two reported methods for FEX determination using HPTLC technique with MKT using C aluminum plates of silica gel G60 F254, (20×10 cm) with 250 µm thickness using toluene: ethyl acetate: methanol: ammonia (30%) (0.5: 7: 2: 0.5, v/v/v/v) as mobile phase with the densitometric measurement at 220 nm (Tandulwadkar et al., 2012)and the other method is stability indicating method with its degradation products (Pallavi, 2015).

Analysis of DES using the HPTLC technique in combination with densitometry using a mixture of ethyl acetate, n-butanol, ammonia, and methanol as a mobile phase and HPTLC plates precoated with silica gel as a stationary phase, then

Spectrodensitometric analysis was then performed to determine the optimal wavelength for the quantitative determination (λ=276 nm).DES was aged by exposure to UV irradiation producing new products determined by the GC-MS technique (Bober, Płonka, Miszczyk, & Sciences, 2015). TLC-Densitometric method for the simultaneous estimation of Ambroxol hydrochloride (AMB), Pseudoephedrine hydrochloride (PSE), and Desloratadine (DES) in pure form and pharmaceutical dosage form obtained by the use of mobile phase (Ethyl acetate: methanol: ammonia), (14: 0.8: 0.5, *v/v/v*), the scanning of spots was performed at 254 nm (Morsi, 2022).

Table 5: HPTLC methods for MKT determination

Analyte and Matrix	Stationary phase	Mobile Phase	Detector	Ref. No.
MKT and febuxostat	TLC aluminum plates precoated with silica gel G $60F_{254}$	chloroform : methanol (9 : 1, v/v)	Fluorometric detection Febuxostat (Ex= 322, Em= 388 nm) while MKT (Ex= 283, 327, 346, and 359 nm, Em= 392 nm)	(Hosny, Atia, El-Gizawy, Badary, & Hareedy, 2018)
MKT and Bambuterol with its pharmacopeial-related substance Terbutaline	silica gel aluminum plates 60 F254	ethyl acetate, ethanol, and ammonia (78.9: 12: 9.1)	Densitometrically at 210 nm	(El-Kafrawy, Abo-Gharam, Abdel-Khalek, & Belal, 2022)
MKT and Levocetirizine	silica gel $60F_{254}$ aluminum plate	ethyl acetate: methanol: triethylamine (5:5:0.02 v/v/v)	UV at 240 nm	(Rote, Niphade, & technologies, 2011)
MKT and bilastine	aluminum plates pre-coated with silica gel $60F_{254}$	acetonitrile–ethyl acetate–ammonia (4:6:0.1, *V/V*)	Densitometric detection was carried out at 282 nm	(D. A. Shah, Patel, & Chhalotiya, 2021)
MKT and Theophylline in bulk and tablet	aluminum plates pre-coated with silica gel $60F_{254}$	Ethyl acetate: Chloroform: Ethanol: Ammonia (6:4:3:1v/v/v)	UV AT 254 nm	(K. A. Shah & Parmar, 2019)
MKT and Cetirizine	aluminum plates pre-coated with silica gel $60F_{254}$	Ethyl Acetate: Methanol: Ammonia solution (25%) (14: 3 :2 v/v/v)	UV AT 230 nm	(Haghighi, Shapouri, Amoli-Diva, Pourghazi, & Afruzi, 2013)
MKT in bulk and tablet	aluminum plates pre-coated with silica gel $60F_{254}$	Toluene: Ethyl Acetate: Glacial acetic acid (6.0:3.4:0.1 v/v/v)	UV AT 344 nm	(Sane, Menezes, Mote, Moghe, & Gundi, 2004)
MKT and FEX in their combined dosage form	aluminum plates of silica gel G60 F254	ethyl acetate: methanol: ammonia (30%) (7: 3: 0.5, v/v/v/v	densitometric measurement in the absorbance mode at 215 nm	(Vekaria, Muralikrishna, & Sorathiya, 2012)

1.3.2. High Pressure Liquid Chromatography (HPLC) and Ultra Performance Liquid Chromatography (UPLC).

1.3.3. Table 6: HPLC and UPLC methods for RUP determination

Material	Column	Mobile phase	Detection	Technique	Ref. no.
RUP in bulk and pharmaceutical dosage forms	C18 column	Acetonitrile: Methanol:Water in the ratio of 40:50:10 (v/v/v) ,flow rate of 1.0 mL min−	UV detector at 244 nm	RP-HPLC	(R. L. Choudekar, M. Mahajan, & S. J. P. C. Sawant, 2012)
RUP in tablets	cyano column	the mixture of Phosphate buffer pH 4.4 and acetonitrile in the ratio of 40:60	PDA detector at 242 nm	RP-HPLC	(Farooqui, Ahmed, Sangshetti, & Zaheer, 2014)
RUP and its Degradation Products in Solid Oral Dosage Form	Hypersil BDS column	gradient mixture of a buffer (acetate buffer pH-6.0) and solvent (methanol)	UV detector at 264 nm	RP-HPLC	(Trivedi & Patel, 2012)
RUP Impurities in Solid Dosage Form	C18 column	Buffer containing 0.3 M sodium acetate pH 4.4 ± 0.05 and methanol in the ratio of 80:20 %	UV detector at 245 nm	RP-HPLC	(R. Rele & R. J. D. P. L. Mali, 2016)
RUP and its related substances: 3-dibromomethyl-5methylpyridine; desloratadine and 3,5di(desloratadinyl) methylpyridine	XTerra-C18 column	acetate buffer solution (pH 40)-methanol (25:75)	UV detection at 244 nm	RP-HPLC	(WANG, GE, ZHAO, HANG, & LI, 2009)
RUP and MKT in bulk and tablets	Hypersil BDS C 8 column	methanol: acetonitrile: buffer (40: 30: 30), (pH 3 with H 3 PO 4)	UV detection at 270 nm	RP-HPLC	(Redasani, Kothawade, & Surana, 2014)
RUP and MKT in bulk and tablets	C-18 Column	Acetonitrile and 0.05% OPA (60:40, v/v)	UV detection at 242 nm	RP-HPLC	(Bangale G, 2018)
RUP and MKT	C-18 Column	Acetonitrile: Phosphate buffer (75: 25) v/v with pH adjusted to 4.0	UV detection at 246 nm	RP-HPLC	(S Sutar & S Magdum, 2021)
Antihistaminic parent molecules and their active metabolites in human serum and urine	Cyano column	acetonitrile–methanol–ammonium acetate buffer (40 mm; pH 3.8 adjusted with acetic acid): 18:36:46%	UV detection at 222 nm	RP-HPLC	(Kanthiah & Kannappan, 2017)
RUP	C_{18} column	ammonium acetate buffer (0.01 M, pH 3.0) with 0.05% of 1-heptane sulfonic	PDA detector at 242 nm	RP-HPLC	(Dalmora, Nogueira, Calegari, Bergamo, &

	acid/acetonitrile (71.5:28.5, v/v)	Stamm, 2010)

Table 6: (Continued)

RUP and MKT	C8 column	gradient mixture of solvent A (0.02 M KH2PO4, pH 3.0) and B (90:10 v/v mixture of acetonitrile and water)	UV detection 240 nm	RP-UPLC Stability indicating	(Navneet Kumar, Sangeetha , & Sunil Reddy, 2013)
RUP in Bulk and Tablet Dosage Form	Hypersil ODS column	0.02 M phosphate buffer (pH 3.0, pH was adjusted with orthophosphoric acid), HPLC grade methanol and acetonitrile at the ratio of (45:30:25%)	UV detection 242 nm	RP-HPLC	(Khatun)
RUP and its two active metabolites: desloratadine and 3-hydroxydesloratadine	C18 column	ethanol and 10mM ammonium acetate containing 0.1% (v/v) formic acid	Tandem mass spectroscopy	LC-MS	(Sun et al., 2015)
RUP	C18 column	ammonium acetate buffer (pH 3.0; 0.01 M) with 0.05% of 1-heptane sulfonic acid–acetonitrile (71.5:28.5, *v/v*)	photodiode array (PDA) detection at 242 nm	LC	(Nogueira , D'Avila, Rolim, & Dalmora, 2007)
RUP in human plasma and its pharmacokinetics	C18 column	methanol–ammonium acetate (pH 2.2; 5 mM) (50:50, v/v)	a triple-quadrupole mass spectrometer in the positive ion	LC-MS	(Tian et al., 2008)
RUP and MKT in combined tablet dosage form	C18 column	Methanol: Water (90:10v/v) with 0.1% Tri ethyl amine pH 3.41	UV detection at 260 nm	RP-HPLC stability indicating	(Jani, 2014)
RUP impurities in Solid Dosage Form Supported By Forced Degradation Studies	C18 column	Buffer containing 0.3 M sodium acetate pH 4.4 ± 0.05 (adjusted with glacial acetic acid) and methanol in the ratio of 80:20 % (v/v), respectively	UV detection at 245 nm	RP-HPLC	(R. V. Rele & R. N. Mali, 2016)

Table 7: HPLC and UPLC methods for MKT determination

Material	Mobile phase	Column	Technique	Detection	Ref. No.
MKT in Rat Plasma using liquid-liquid extraction	Gradient mobile phase program between 5 mmol/L of an aqueous ammonium formate solution and methanoL	C18 column	LC-MS/MS	Tandem mass spectrometry	(Kim et al., 2020)
MKT and its impurities from bulk	Gradient elution: solution A (0.1% OPA), solution B (water:acetonitrile, 5:95 v/v)	C18 column	RP-HPLC	PDA 225 nm	(Rashmitha et al., 2010)
MKT from bulk and tablet	Acetonitrile: 1 mM sodium acetate buffer (pH 6.3 adjusted with acetic acid), 90:10v/v	C 18 column	RP-HPLC	UV 285	(Singh, Saini, Mathur, Singh, & Lal, 2010)
MKT and Theophylline in tablet	Methanol	C18 column	RP-HPLC	UV 210	(Jain, Rajoriya, & Kashaw, 2015)
MKT and Doxofylline in tablet	Methanol: sodium phosphate buffer (pH 6.5 adjusted with orthophosphoric acid), 75:25 v/v	C8 column	RP-HPLC	UV 230	(Ethiraj, Revathi, Thenmozhi, Saravanan, & Ganesan, 2011)
MKT and its degradation products in tablet	Acetonitrile: 0.01M potassium dihydrogen phosphate buffer (pH 4.0), 3:7 v/v	C18 column	RP-HPLC	PDA 355 nm	(Eldin, Shalaby, & El-Tohamy, 2011)
MKT in oral granules	0.05M Potassium dihydrogen phosphate buffer (pH 3.5): acetonitrile, (30:70 v/v)	C18 Column	RP-HPLC	PDA 225	(Garg et al., 2013)
MKT in tablet	Methanol: 0.02 M sodium phosphate buffer (pH 3.5 adjusted by 0.01 M Phosphoric acid), 15:85v/v	C8 column	RP-HPLC	SPD-20 A VP 218	(J. Kumar, Ramachandran, Saradhi, & Pharmacy, 2010)
MKT in tablet	Methanol: TFA, 90:10 v/v.	C18 column	RP-HPLC	UV 350	(Kanakadurga Devi, Prameela, Madhavi, & Mrudula, 2010)
MKT and Levocetirizine Dil HCl in bulk and tablet	0.02M Disodium hydrogen phosphate buffer: Methanol (7.0 pH adjusted ortho- phosphoric acid, 25:75 v/v	C18 column	RP-HPLC	UV/Vis 231	(Rathore, Sathiyanarayanan, & Mahadik, 2010)
MKT and FEX HCl in tablet	50 mM Sodium acetate buffer: acetonitrile: methanol (8.2 pH adjusted with 5% o-phosphoric acid, 25:35:40 v/v	C18 column	RP-HPLC	UV/Vis 210	(Vekaria, Limbasiya, & Patel, 2013)
MKT and Bambuterol HCl in tablet	Gradient elution: Solution A (0.025 M sodium phosphate buffer: methanol, 85:15v/v); Solution B (Acetonitrile: methanol 85:15v/v)	C18 column	RP-HPLC	UV/Vis 218	(Patil, Pore, Kuchekar, Mane, & Khire, 2009)
MKT and DES in tablet	Orthophosphoric acid: water, 20:80v/v	C18 column	RP-HPLC	UV/Visible 280	(Gandhi, Rao, & Rao, 2015)

Table 7: (Continued)

MKT and RUP fumarate in tablet	Methanol: Potassium di hydrogen phosphate buffer: Acetonitrile (3.0 pH Adjusted with 1% orthophosphoric acid), 50:30:20v/v/v	C18 column	RP-HPLC	PDA 226	(Gandla, Spandana, Kumar, Surekha, & SheshgiriRao, 2012)
MKT and FEX HCl in tablet	0.1M potassium dihydrogen orthophosphate buffer (5.0 pH): methanol, 60:40 v/v	C18 column	RP-HPLC	UV-Visible detector 220	(K. P. Kumar et al., 2012)
MKT in tablet	Water: acetonitrile (modified with 0.2% TFA), 50:50v/v	Phenyl column	RP-HPLC	variable wave length UV detector389	(Hoang, Farkas, Wells, McClintock, & Di Maso, 2002)
MKT and Ebastine in bulk and tablet	Methanol: acetonitrile: ammonium acetate (80: 10: 10, % v/v/v), pH of mobile phase was adjusted 5.5	C18 column	RP-HPLC	UV detector 244	(Rana et al., 2013)
MKT in tablet	Acetonitrile: 0.2% TFA, 50:50	Phenyl column	RP-HPLC	UV Detector 389	(Okumu, DiMaso, & Löbenberg, 2008)
MKT and Loratadine in tablet	Sodium phosphate buffer (3.7 pH adjusted): Acetonitrile, 20:80 v/v	C18 column	RP-HPLC	PDA 225	(Radhakrishna, Narasaraju, Ramakrishna, Satyanarayana, & analysis, 2003)
MKT in tablet	Acetonitrile:Methanol:Water (pH 3.8), 75:10:15 v/v/v	C18 column	RP-HPLC	PDA 280	(Roman, Breier, & Steppe, 2011)
MKT in bulk and tablet	n-hexane: ethanol: 1,4-dioxane: TFA: diethylamine, 65:25:10:0.3:0.05 v/v	Cellulose coated on silica-gel column	RP-HPLC	PDA 280	(Radhakrishnanand, Subba Rao, Surendranath, Subrahmanyam, & Himabindu, 2008)
MKT in human plasma	Methanol: Acetonitrile:0.0 4M disodium hydrogen orthophosphate (4.9 pH), 22:22:56 v/v	C8 column	RP-HPLC	Fluorescence detector, em= 350nm ex=450nm	(Sripalakit, Kongthong, & Saraphanchotiwitthaya, 2008)
MKT in human plasma	10mM Ammonium formate (pH 4.0): Acetonitrile, 20:80 v/v	C18 column	ESI–MS	ESI–MS/MS	(B. R. Challa, B. Z. Awen, B. R. Chandu, M. Khagga, & C. B. J. S. p. Kotthapalli, 2010)
MKT in human plasma	Gradient elution: Acetonitrile:0.1 MAmmonium acetate	C18 column	RP-HPLC	Fluorescence detector, em= 350nm ex=400nm	(Ochiai et al., 1998)
MKT in human plasma	Acetonitrile:0.02 M Ammonium phosphate (3.5 pH), 65:35 v/v	C18	RP-HPLC	Fluorescence detector, em= 350nm,ex=400nm	(Kitchen et al., 2003)
MKT in human plasma	Acetonitrile: Methanol: Water (containing 0.05% (v/v) formic acid),70:20:10	C8 column	LC-MS/MS	LC-MS/MS- ESI	(N. K. Patel et al., 2009)
MKT in human plasma	10mMAmmonium acetate buffer (3.0 pH) : Acetonitrile, 35:65 v/v	C8 column	RP-HPLC	Fluorescence detector, em=350nm, ex=400nm	(Chauhan, Rani, Nivsarkar, & Padh, 2006)

Table 7 : (Continued)

MKT in human plasma	10Mm Ammonium acetate (6.4 pH): acetonitrile 15:85 v/v	C18 column	MS	MS (ESI)	(B. R. Challa, B. Z. Awen, B. R. Chandu, M. Khagga, & C. B. Kotthapalli, 2010)
MKT in human plasma	Acetonitrile: 0.1% Formic acid, 84:16 v/v	C18 column	MS	MS	(Ezzeldin, Abo-Talib, Tammam, & Shahat, 2014)
MKT and FEX in human plasma	20 mM Ammonium formate: Acetonitrile, 20:80 v/v	C18 column	LC-MS/MS	LC-MS/MS- ESI	(Muppavarapu, Guttikar, Rajappan, Kamarajan, & Mullangi, 2014)
MKT in human plasma	Acetonitrile:5mM Ammonium acetate, 80:20	Phenyl column	LC-MS/MS	LC-MS/MS- ESI	(Katteboina, Pilli, & Salta, 2015)
MKT in sheep plasma	mobile phase A (0.5% Formic acid: water) Mobile Phase B (0.5% Formic acid: Acetonitrile)	C18 column	LC-MS/MS	LC-MS/MS- ESI	(Papp, Luk, Mullett, & Kwong, 2007)
MKT in human plasma	Acetonitrile:0.05 M Ammonium phosphate buffer (pH 3.5), 62:38 v/v	C18 column	RP-HPLC	Fluorescence detector, em=350nm ex=400nm	(Amin, Cheng, Rogers, & analysis, 1995)
MKT in human plasma	Solution 1: Methanol: 10mM Ammonium acetate (3.6 pH), 10:100 v/v. Solution 2: Acetonitrile- 10mM Ammonium acetate (5.8 pH),32.5:100 v/v	Chiral AGP column	RP-HPLC	Fluorescence detector, em= 350nm ex=400nm	(Lida Liu, Cheng, Zhao, Rogers, & analysis, 1997)
MKT in human plasma	0.025 M Sodium acetate (4.0 pH): Acetonitrile, with 50 ml triethylamine (20:80% v/v)	C8 column	RP-HPLC	Fluorescence detector, em= 350nm ex=400nm	(Al-Rawithi et al., 2001)

Table 8: HPLC and UPLC methods for DES determination

Material	technique	Column	Mobile phase	Detection	Ref. No.
DES and pseudoephedrine sulfate in tablets	RP-HPLC	C18 column	10 mm ortho-phosphoric acid: acetonitrile (77:23).	UV at 262 nm	(Çağlar & Toker, 2011)
Ambroxol, Pseudoephedrine, Levocetirizine, and DES, in Pure forms and Pharmaceuticals	RP-HPLC	C8 column	acetonitrile: 0.01 M phosphate buffer (PH 5.5) (50:50, v/v) in an isocratic mode t	UV at 215 nm	(Morsi, 2022)
DES in dog plasma/tablets/ tablets dogs	RP-HPLC	Hypersil CN column	methanol, acetonitrile and phosphate buffer (pH 5.5; 0.01 mol/l) (35:35:30, v/v/v)	UV at 241 nm	(Lihe Liu, Qi, Wang, Li, & analysis, 2004)
DES in tablets	RP-HPLC	BDS C18 column	methanol, 0.03 mol/l heptane sulphonic acid sodium, and glacial acetic acid (70:30:4, v/v)	UV at 247 nm	(Qi, Wang, Geng, & analysis, 2005)
DESe Tablet	RP-HPLC	C18 column	Methanol: Water (70:30, v/v)	UV at 242 nm	(Parmar, Tandel, & Rabari, 2015)
dDES and related compounds: desloratadine 3,4-dehydropiperidine derivative	RP-HPLC gradient ion-pair chromatography	C (18) column	A contains 3 mM sodium dodecylsulfate (SDS), 15 mM sodium citrate buffer at pH 6.2-, and 40 mM sodium sulfate, while the mobile phase B is acetonitrile in gradient elution	UV at 267 nm	(Zheng & Rustum, 2010)
loratadine and DES in pharmaceutical preparations	RP-HPLC	cyano column	Microemulsion mobile phase consisted of 0.1M sodium dodecyl sulphate, 1% octanol, 10% n-propanol and 0.3% triethylamine in 0.02 M phosphoric acid, pH 3.0	UV at 247 nm	(El-Sherbiny, El-Enany, Belal, & Hansen, 2007)
Pseudoephedrine, Ambroxol, and DES in Bulk and Their Tablet Dosage Forms	RP-HPLC	C8 Column	The mobile phase is composed of 0.01 M potassium dihydrogen phosphate and acetonitrile in the ratio of 50:50 v/v	UV at 220 nm	(Nagasarapu & Sankar, 2016)
ambroxol hydrochloride and DES	RP-HPLC	C18 column,	acetonitrile: potassium dihydrogen orthophosphate buffer in the ratio 25: 75 and pH adjusted to 3.9	UV at 270 nm	(Babu, Shirin, & Rajapandi, 2013)
Loratadine and its metabolite DES	RP-HPLC	BDS C18 column	MeOH: 0.025M KH2PO4 adjusted to pH 3.50	PDA t 248 nm	(Sebaiy & Ziedan, 2019)
DES and Montelukast	RP-HPLC	BDS C18	orthophosphoric acid and water in the ratio of 20:80 v/v	UV at 280 nm	(Bonthu, Atmakuri, & Rao, 2015)
DES and pseudoephedrine in human plasma	normal-phase liquid chromatography/tandem mass spectrometry	Thermo Electron Corp., silica column	15:85 (v/v) mixture of 25 mM ammonium acetate in 1% formic acid: 25 mM ammonium acetate in methanol	the mass spectrometer was operated in the multiple reaction monitoring (MRM) mode	(Shen et al., 2007)
DES and its active metabolite 3- hydroxy desloratadine in human plasma	LC/MS/MS	C18 column	5 mM ammonium formate in water, methanol, and acetonitrile (50:30:20).	Detection was by positive ion electrospray tandem mass spectrometry	(Xu, Li, Chen, Chu, & analysis, 2007)
DES in Dosage Forms and Human Plasma	RP-HPLC	Cyano column	Acetonitrile–water (60: 40)	UV at 375 nm	(El-Enany et al., 2007)

Table 9: HPLC and UPLC for FEX determination

Material	technique	Column	Mobile phase	Detection	Ref. NO.
FEX in human plasma	RP-HPLC	ODS-80A column	The mobile phases were: (A) 0.05 M KH_2PO_4 buffer/acetonitrile/methanol (60:35:10, v/v/v) (B)0.05 M KH_2PO_4 buffer/acetonitrile (40:60, v/v) using a linear gradient from A to B in 10 min	fluorescence detector set at Ex 220 nm and Em 290 nm.	(Uno et al., 2004)
FEX and its related compounds A (keto acid) and B(meta isomer)	RP- HPLC	Eclipse XDB C8 column	1% triethylamine phosphate (pH 3.7), acetonitrile and methanol in the ratio 60:20:20 (v/v/v)	UV detection set at a wavelength of 210	(Radhakrishna, Reddy, & analysis, 2002)
FEX in human plasma and urine by liquid chromatography-mass spectrometry	HPLC–electrospray mass spectrometry	1.C18 solid-phase extraction cartridges. 2. LUNA CN column	1. (A) 12 m*M* ammonium acetate in water and (B) acetonitrile. 2. linear gradient from 40% B to 60% B in 10 min	mass spectrometry: the selected ion monitoring mode using the respective MH^+ ions, *m*/*z* 502.3 for FEX	(Hofmann, Seiler, Drescher, & Fromm, 2002)
FEX enantiomers in human plasma	RP-HPLC	Chiral CD-Ph column	0.5% KH_2PO_4–acetonitrile (65:35, v/v)	UV detection at 220 nm	(Miura, Uno, Tateishi, Suzuki, & analysis, 2007)
FEX in coated tablets and human serum	RP-HPLC	C-18 column.	Phosphate buffer pH 7.4 and methanol (methanol–phosphate buffer, 35:65, v/v)	1. UV at 220 nm.	(Arayne, Sultana, Shehnaz, & Haider, 2011)
FEX in human plasma	LC/ESI-MS/MS	XBridge C18 column	acetonitrile/2 mM ammonium acetate (91:9, v/v)	mass spectrometer by multiple reaction monitoring	(Yamane et al., 2007)
FEX in Human Plasma	HPLC-MS	LC-MS system was operated under the positive electrospray ionization mode (ESI) with c18 column	mobile phase of acetonitrile: 10 mM ammonium acetate: formic acid, 70:30:0.1 (*v/v/v*)		(İşleyen, Özden, Özilhan, & Toptan, 2007)
FEX and its related impurities in pharmaceutical tablets	HPLC-DAD	Hypersil BDS C-18 analytical column	The mobile phase consisted of a mixture of phosphate buffer containing 0.1 gm% of 1-octane sulphonic acid sodium salt monohydrate and 1% (*v/v*) of triethylamine, pH 2.7 and methanol (60:40, *v/v*)	DAD detector at 215 nm	(Maher, Sultan, & Olah, 2011)

Table 9: (Continued)

FEX determination in tablet formulations	RP-HPLC	C18 column	acetonitrile5mM ammonium ace tate buffer [50:50, v/v]	UV at 254 nm	(Malothu, Paladugu, & Katamanen i, 2018)
MKT and FEX: stability indicating	RP-HPLC	RP-18e column	methanol:0.1% *o*-phosphoric acid (90:10 v/v), pH 6.8	PDA detector UV at 226 nm	(Pankhaniy a, Patel, & Shah, 2013)
cetirizine or FEX with pseudoephedrine in binary pharmaceutical dosage forms	RP-HPLC	Zorbax C8	The optimized mobile phase was consisted of TEA solution (0.5%, pH 4.5)–methanol–acetonitrile (50:20:30, v/v/v)	UV detection at 218 and 222 n	(Karakuş, Küçükgüze l, Küçükgüze l, & analysis, 2008)
FEX in Hank's balanced salt solution	RP-HPLC	Lichrospher® C_{18}	phosphate buffer (pH 3.2) containing 10 m m of sodium octanosulphonate and acetonitrile (60:40)	UV detection at 218 nm	(Júnior et al., 2015)
Photodegradation Kinetics of FEX	RP-HPLC	RP-18 octadecyl silane column	The mobile phase was prepared by mixing 50 mM ammonium acetate buffer and acetonitrile (50:50, *v/v*)—pH 3.2 (adjusted with hydrochloric acid 0.1 N)	UV detection at 220 nm	(Breier, Steppe, & Schapoval, 2006)
Force Degradation Studies of FEX in Pharmaceutical Dosage Form	RP-HPLC	C18 column	The mobile phase consists of 5Mm acetate buffer: acetonitrile (50:50; v/v) with pH 9.4 adjusted with acetic acid	UV detection at 220 nm	(Sanam, Nahar, Saqueeb, & Rahman, 2018)
analysis of FEX enantiomers in plasma and urine	LC-MS/MS	C8 column	methanol: ammonium acetate 7 mM, pH 4.25 (97:3, *v/v*),	Xevo TQ-S® triple quadrupole mass spectrometer	(Pinto et al., 2020)
FEX and MKT	RP-HPLC using Derringer's Desirability Function	Intek chromasol column	75:25 mixture of acetonitrile and phosphate buffer (pH 6.5, pressure 49 mM)	UV at 240 nm	(Jayaseelan , Kannappan , & Ganesan, 2021)
pravastatin, FEX, rosuvastatin, and methotrexate in a hepatic uptake model	UPLC–MS/MS	SB-C18 column	gradient conditions with a mobile phase consisting of 0.03% acetic acid (v/v) and methanol	triple-quadrupole hybrid mass spectrometer with linear ion trap functionality (AB SCIEX, Framingham, MA, USA) equipped with a TurboIonSpray ESI (electrospray ionization) source	(Wu, Cheng, Jiang, Zhang, & Huang, 2021)

3.3.3. Gas Chromatography

To determine the content of residual solvents in RUP like cyclohexane, ethyl acetate, methanol, methylene chloride, and trichloromethane using headspace gas chromatographic conditions: DB-WAXETRR capillary column (30 m × 0. 32 mm,0. 25 μm) was used, and the carrier gas was nitrogen. The detector was an FID and the inlet temperature was 200°C (Shi, Liu, WU, Fang, & Song, 2016). Another method depends on some antihistamines including RUP were excreted in milk in small quantities so they were determined via gas chromatography. The antihistamines were solid-phase extracted and derivatized with acetic anhydride and *n*-propanol. Diazepam-d_5, hydroxyzine-d_4, and cetirizine-d_8 were internal standards (Katselou et al., 2018).

1.3.4. Capillary Electromigration Separation Techniques

Simultaneous determination of montelukast enantiomeric and diastereomeric forms (Flor, Huala Juan, Tripodi, & Lucangioli, 2016).

It was demonstrated that FEX could be effectively analyzed in free solution cationic CE at low pH. Another analytical approach was based on cyclodextrin (CD) modified CE, where highly charged CD derivatives served as analyte carriers. In this way, the separation range was spread to the physiological pH region, and a CE analysis of FEX, present actually in its zwitterionic form, could be accomplished (Mikuš, Valášková, Havránek, & pharmacy, 2005). A reversed-polarity capillary electrophoretic method based on application of sodium dodecyl sulfate (SDS) micelles as the carriers was developed for the separation and determination of Fexofenadine (FEX) hydrochloride and its three major structural impurities in bulk and a tablet dosage form (Javid, Shafaati, Zarghi, & Technologies, 2014).

3.4. Electrochemical methods:

Graphene-modified glassy carbon electrode in Britton-Robinson buffer (pH 6.5) by square wave voltammetry was used to study the electrochemical behavior of rupatadine fumarate (Devnani, Singh, Saxena, Satsangee, & Research, 2014).

The electrochemical behavior of MKT was studied at zinc oxide nanoparticles modified carbon paste electrodes were investigated by cyclic and square wave voltammetry(Çölkesen, Öztürk, & Erden, 2016). Also, the voltammetric behavior of MKT was noticed through direct current (DC t), differential pulse polarography (DPP), and alternating current (AC t) polarography (Alsarra, Al-Omar, Gadkariem, & Belal, 2005). Adsorptive stripping voltammetry was used for prospecting the adsorption property of montelukast sodium (MKST) on the hanging mercury drop electrode (HMDE) (Alghamdi, 2014). Three new graphite electrodes coated with a polymeric membrane were constructed to simultaneously determine fexofenadine hydrochloride and montelukast sodium (D. Nashed, I. Noureldin, & A. A. Sakur, 2020).

A sensitive and selective sensor; was constructed based on the modification of a pencil graphite electrode (PGE) by nitrogen-doped graphene (NDG) and molecularly imprinted polymer (MIP) for the determination of FEX (Oghli & Soleymanpour, 2021). Another method depends on the electrochemical oxidation of FEX was investigated by cyclic, linear sweep, differential pulse (DPV), and square wave (SWV) voltammetry using glassy carbon electrode (Golcu, Dogan, & Ozkan, 2005). The construction and general performance of thirteen new polymeric membrane sensors based on their ion exchange with reineckate, tetraphenylborate and tetraiodomercurate have been studied for the determination of FEX (Abbas, Fattah, & Zahran, 2004). Other electrochemical methods for preparing three new electrodes of Fexofenadine hydrochloride in a polymeric membrane. The first electrode was prepared from ion pair: molybdophosphoric acid reagent and fexofenadine cation with Di-n-butyl phthalate (DBPH), the subsequent electrode was prepared with O-Nitro phenyl octyl ether (NPOE), and the third electrode was set up by Tri-n-butyl phthalate (TBP), respectively as a plasticizer for determination of FEX (Abass, Hassan, Rikabi, Salim, & Ahmed, 2021). This one introduces the first electrochemical approach for the determination of Fexofenadine hydrochloride and Montelukast sodium as a combined form by constructing three new graphite electrodes coated with a polymeric membrane. The first electrode was made using ammonium molybdate reagent as an ion pair with fexofenadine cation for the determination of Fexofenadine drug, the second electrode was constructed using cobalt nitrate as an ion pair with montelukast anion for the determination of Montelukast drug, the third electrode was prepared by incorporating the two previously mentioned ion pairs in the same graphite sensor, which makes this sensor sensitive to each Fexofenadine and Montelukast drug (D. Nashed, I. Noureldin, & A. A. J. B. c. Sakur, 2020).

The Current study describes the construction of three carbon paste electrodes for the quantitative measurement of the third-generation antihistamines fexofenadine (FEX), Desloratadine (DES), and Levocetirizine (LEV) (Sakur, Nashed, & Noureldin, 2022), DES and MKT was also estimated in their pure and binary dosage form by fabricating three pencil graphite sensors (Sakur, Nashed, & Noureldin, 2021). Another voltammetric method depends on the examination of the electrochemical behavior of desloratadine (DLOR), and its derivative 3-hydroxydesloratadine (3OH-DLOR) was investigated by direct current (DCP) polarography, cyclic (CV), differential pulse (DPV) and square-wave (SWV) voltammetry (Aleksić, Radulović, Kapetanović, & Savić, 2010).

Conclusion

The analytical methods published over the last two decades for determining seven widely prescribed antihistaminic drugs from the first and second generations have been covered by this comprehensive review. The selected drugs include rupatadine, montelukast, desloratadine, fexofenadine, dimenhydrinate, orphenadrine, and cinnarizine. Different analytical techniques were explored, including spectroscopic, chromatographic, capillary electrophoretic and electrochemical methods. The present review represents an excellent guide to the work reported on the selected antihistamines that saves the efforts that many researchers perform to get up-to-date knowledge about this category of therapeutic agents.

Disclosure

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this review article.

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