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Review Article

Comprehensive Review On Analytical Methods For Determination Of Chlorpheniramine Maleate In Pharmaceutical Dosage Form And Bulk

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ABSTRACT

The specified paper presents a systematic review conduct on different methods for the analysis o the antihistamine drug. The focus of the article I to verify how the validation process of an analytical method I performed.Chlorpheniramine is approved by the U.S. Food and Drug administration is safe and effective when used to antihistamine and allergies. It is a prescription medication ues to preventing the release of histamine by acts on the brain and relieves symptoms of allergies. To provide relief form allergies symptoms such as sneezing,running nose, watery eyes, itching, swelling, and congestion or stiffness. Most recent analytical methods such as various spectroscopic methods (simultaneous estimation, Q absorption ratio) and chromatoghraphic methods (RP-HPLC, HPTLC, LC) are included in review. In different articles, the study is conducted on various analytical parameters such as mobile phase, the ratio of mobile phase, stationary phase, flow rate, wavelength ect. The observation are made based on Retention time, Area of peak, peak height, therotical plates, AUC, ect. From the data found in the literature, a comparison is made between different methods and observation having different base properties.

INTRODUCTION

Drug analysis plays a significant role in drug development, manufacturing, and its therapeutic use. Allergies are Immunological diseases caused by hypersensitivity reaction with external agents like allergens present in the environment. It works by blocking the action of histamine, a subtancein the body that causes allergic symptoms such as watery eyes, runny nose, sneezing. The psychomotor stimulant effects of chlorpheniramine involve action otherthan the blockade of histamine H1 and H2 receptors.H1 Receptor antagonist indicated for the management of symptoms associated with upper respiratory

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allergies. Chlorpheniramine maleate appears white crystalline solid or white powder with bitter taste.

Molecular weight	390.864 g/mol
State	Solid.
Taste	bitter
Chemical name	(Z)-but-2-enedioic acid ; 3-(4-chlorophenyl)-N,N-dimethylpyridin-2 Ylpropan-1-amine
Category	Antihistamine, Antiallergic
Solubility	Freely soluble in water, soluble in alcohol and in chloroform, slightly soluble in ether and benzene.
Description	Odorless, White crystalline solid or white powder, Bitter taste.
Ph	4.0 & 5.5
Storage	Store at room temperature , protected from light, Keep container
Melting point	266-2750C
Wavelength	262nm

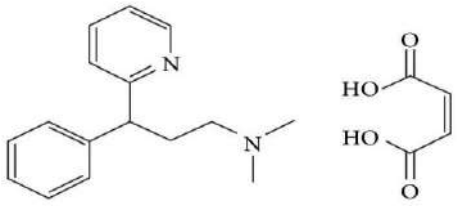

Fig 1: Chlorpheniramine Maleate

ANALYTICAL METHODS

The Analytical methods which are used for the determination of the chlorpheniramine maleate in the marketed formulation and in bulk are identified during the literature survey and reported. The present article describes the review on the analytical methods with specific conditions.

1. Chromatographic Methods

Various chromatographic methods are used for the determination of the chlorpheniramine maleate in combination with other drugs or alone in various marketed formulations. Chromatographic methods like Reverse phase High-performance liquid chromatography (RP-HPLC), High-performance thin-layer chromatography (HPTLC), and Ultra performance liquid chromatography (UPLC) are used for the determination of Chlorpheniramine maleate.

The given table describe the summary of the various chromatographic methods with the method description.

Table No. 1: Chromatographic methods of Chlorpheniramine maleate

Sr No.	Title	Method	Mobile Phase and Flow Rate	Column	Retention time and wavelength	Ref No.
1.	Development and Validation of RP-HPLC Method for simultaneous estimation of chlorpheniramine maleate and Diethylcarbamazine citrate in pharmaceutical dosage forms.	RP-HPLC	Acetronitrile:Potassium dihydrogen phosphate (80:20 v/v) Flow rate: 1.0ml/min	Kromasil C_{18} Column (250mmX4.6 mm) 5µm	RT: CPM:4.042min Diethylcrbamazine-2.808min 238nm	4
2.	RP-HPLC-DAD method for the determination of Phenylephrine, paracetamol, caffeine and chlorpheniramine in	RP-HPLC-DAD	Acetronitrile:Methanol:10 Mm phosphate buffer (16:22:62 v/v/v) Flow rate: 1.0ml/min	C_{18} Column (150mmX4.5 mm) 5µm	RT: CPM-10.9min PE-1.8min Para-3.1min Caffeine- 5.2min 280nm	5

	bulk and marketed formulation.					
3.	Validated RP-HPLC method for simultaneous determination and quantification of chlorpheniramine maleate, paracetamol, caffeine in tablet formulation.	RP-HPLC	Methanol: Phosphate buffer (30:70 v/v) Flow rate: 1.0ml/min	Phenomenex C_{18} Column (250 X 4.6mm) Luna 5µm	RT: CPM:2.4min Paracetamol:4.2min Caffeine:7.2min 215nm	6
4.	A chromatographic method for rapid and simultaneous analysis of codeine phosphate, ephedrine HCL and chlorpheniramine maleate in cough-cold syrup formulation.	HPLC	1.Methanol: glacial acetic acid: trimethylamine (980:15:6 v/v/v) 2.Water: glacial acetic acid: trimethylamine (980:15:6 v/v/v) Flow rate: 1.5ml/min	Zorbax XBD C_8 Column(150 X4.6mm) 5µm	RT: CPM:6.78min CP:2.27min EP: 3.23min 254nm	7
5.	Simultaneous determination of paracetamol, phenylephrine HCL, Oxalamide citrate and chlorpheniramine maleate by HPLC in pharmaceutical dosage forms.	HPLC	0.02M Phosphate buffer:Acetronitrile (85:15 v/v) Flow rate: 1.5ml/min	Zorbax SB-CN Column (150X4.6m) 5µm	RT: CPM:3.34 min Paracetamol:1.18 min Phenylephrine HCL:2.18min Oxolamine citrate:2.80min 365nm	8
6.	Stability-indicating High Performance liquid chromatography method for simultaneous determination of Aminophylline and chlorpheniramine maleate in pharmaceutical formulations.	RP-HPLC	Dilute H_2SO_4 :Methanol (60:40 v/v) Flow rate: 1.5ml/min	C_{18} Column (250 X 4.6mm) 5µm	RT: CPM:3.25 min Aminophylline:2.00min 264nm	10
7.	Simultaneous estimation of paracetamol, Guaiphenesin, phenylephrine HCL, chlorpheniramine maleate and bromhexine HCL in	RP-HPLC	Methanol:Acetronitrile (3:2 v/v) Flow rate: 1.0ml/min	Symmetry C_8 Column (150 X 4.6mm) 3.5µm	RT: CPM:21.78min Paracetamol:5.73 min Guaiphenesin:17.46min Phenylephrine HCL:18.29 min	11

	combined tablet dosage form by reverse phase High performance Liquid chromatography.				Bromhexine HCL:2355min 220nm	
8.	Validated stability-indicating RP-HPLC method for simultaneous Estimation of codeine phosphate and chlorpheniramine maleate from their combined liquid dosage form.	RP-HPLC	Water:Acetonitrile:Methanol (78:10:12 v/v/v) Flow rate: 1.0ml/min	Phenomenex C_{18} Column (250 X 4.6mm) 5µm	RT: CPM:9.45 min Codeine Phosphate:3.47 min 254nm	12
9.	Development and validation of RP-HPLC method for simultaneous estimation of Nimesulide, Phenylephrine HCL, chlorpheniramine maleate, Caffeine Anhydrous in pharmaceutical dosage form.	RP-HPLC	Methanol: Buffer (55.45 v/v) Flow rate: 1.0ml/min	Hypersil phenyl column (4.6mmX25 cm)	RT: CPM:17.15min NS:7.47min PE:3.944min CF:4.55min 214nm	13
10.	Development and validation of RP-HPLC method for simultaneous estimation of Diethylcarbamazine citrate and chlorpheniramine maleate in pharmaceutical preparation	RP-HPLC	Methanol: Buffer (55.45 v/v) Flow rate: 1.0ml/min	Hypersil ODS C_{18} (250 X4.6mm) 5µm	RT: CPM:2.091min Diethylcarbamazine citrate:4.74min 254nm	14
11.	A novel HPLC method for the simultaneous determination of chlorpheniramine maleate and Dextromethorphan in bulk and pharmaceutical formulation.	HPLC	Water: Acetonitrile (60:40 v/v) Flow rate: 1.0ml/min	Discovery C_{18} Column (250mmX4.6 mm) 5µm	RT: CPM:3.0min Dextromethorphan:3.6min 218nm	15
12.	Development and validation of an RP-HPLC method for	RP-HPLC	Acetronitrile:Methanol:Phosphat buffer (50:20:30 v/v/v)	Sunfire C_{18} Column	RT: CPM: 4.2min IBU:13.6min	16

	estimation of chlorpheniramine maleate, Ibuprofen, and phenylephrine hydrochloride in combined pharmaceutical dosage form.		Flow rate: 1.0ml/min	(250mmX4.6 mm) 5µm	PHE:2.7 min 220nm	
13.	Stability indicating RP-HPLC method development and validation of paracetamol, Guaifenesin, Ambroxol hydrochloride, phenylephrine hydrochloride and chlorpheniramine maleate in bulk and combined dosage form.	RP-HPLC	Buffer: Acetonitrile (50:50 v/v) Flow rate: 1.5ml/min	Zodiac C_{18} (50mmX4.6 mm) 5µm	RT: CPM: 7.319 min Paracetamol:3.993Mmin Phenylephrine HCL: 4.450 min Amroxol HCL:6.0min Guaifenesin:6.869 min 225nm	17
14.	Validated RP-HPLC method for determining the levels of bromhexine hydrochloride, chlorpheniramine maleate, dextromethorphan HBr and Guaiphenesin in their pharmaceutical dosage form	RP-HPLC	Methanol:Acetronitrile: Phosphate buffer (50:25:25 v/v/v) Flow rate: 1.0ml/min	Chromatopak C_{18} (25cm x 4.6mm) 5µm	RT: CPM:12.21 min Bromhexine Hcl:16.25 min Dextromethorphan HCL: 6.15 min Guaiphenesin: 9.43min 265nm	18
15.	Simultaneous High performance Liquid Chromatography determination of paracetamol, Phenylephrine hydrochloride and chlorpheniramine maleate in pharmaceutical dosage form	HPLC	Acetonitrile: Phosphate Buffer (78:22 v/v) Flow rate: 1.5ml/min	uBondapak CN RP Analytical Column (3.9 X 150mm) 10µm	RT: CPM: 3.44min Paracetamol:1.13 min Phenylephrine HCL:2.13min 265nm	3
16.	Development and validation of RP-HPLC method for the determination of chlorpheniramine maleate and phenylephrine in	RP-HPLC	Acetonitrile: Phosphate Buffer (55:45 v/v) Flow rate: 1.0ml/min	C_{18} Column (250mmX8mm) 10µm	RT: CPM: 3.13 min Phenylephrine: 4.58min	19

	pharmaceutical dosage form				255nm	
17.	Simultaneous determination of chlorpheniramine maleate and Dexamethasone in a tablet dosage form by liquid chromatography	LC	7.5Mm monobasic potassium phosphate in Methanol:water (62.5 + 37.5) Flow rate: 1.0ml/min	C_{18} Column (250 X 4.6mm) 10µm	RT: CPM:5min Dexamethaone:11 min 254nm	9
18.	Assessment of the greenness of micellar HPLC method for rapid separation and simultaneous estimation of chlorpheniramine maleate in presence of some co-administered drug (Levocloperatinefen dizoate, Dextromethorphan hydrobromide, Dexamethasone) in three pharmaceutical dosage forms using singal run.	HPLC	Orthophosphoricacid:ethanol (85:15 v/v) Flow rate: 1.0ml/min	Kinetex C_{18} Column (100 X 4.6mm) 2.6µm	RT: CPM:6.446 min LCF:4.749 min DXM: 3.374 min DEX: 2.135 min 230nm	20

1. UV Spectroscopic Method:

UV Spectroscopy is a commonly used analytical method for the quantitative analysis of compound. It is a powerful analytical technique for the determination of optical properties such as absorbance, reflectance, and transmittance. A simple, precise, and economical spectrophotometric method for the estimation of chlorpheniramine maleate in pharmaceutical bulk and tablet dosage form was developed and validated. Various methods like simultaneous estimation, Q-absorption ratio, dual wavelength and derivative methods are used for the determination of chlorpheniramine alone or in combination with other drugs in marketed formulation. The given table describes the different spectroscopic method with the method description and conditions which are reported on review literature.

Table No. 2 UV Spectroscopic Method of Chlorpheniramine maleate:

Sr No.	Title	Method	Wavelength for Chlorpheniramine Maleate	Wavelength for other drug	Solvents	Ref No.
1	Simultaneous estimation and validation of paracetamol, phenylephrine hydrochloride, and chlorpheniramine maleate	Simultaneous estimation and validation UV Spectrophotometric method	222.4nm	Paracetamol: 256.8nm	0.1N NaoH	1

	in tablet by spectrophotometric method			Phenylephrine HCL: 236.8nm		
2	Method development and validation of UV spectroscopic method for simultaneous estimation of chlorpheniramine maleate, and Diethylcarbamazine citrate in combined tablet Dosage forms	Development and validation of UV spectroscopic method	261nm	Diethylcarbamazine citrate:216nm	0.1N NaoH	2

CONCLUSION:

The review delineates the reported Spectroscopic and Chromatographic methods developed and validated for the estimation of Anti-Histamine drug Chlorpheniramine maleate. According to this review, it is concluded that different spectroscopic and chromatographic method are available for singal components as well as for combination UV and RP-HPLC method were found to be the most commonly used analytical methods.

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