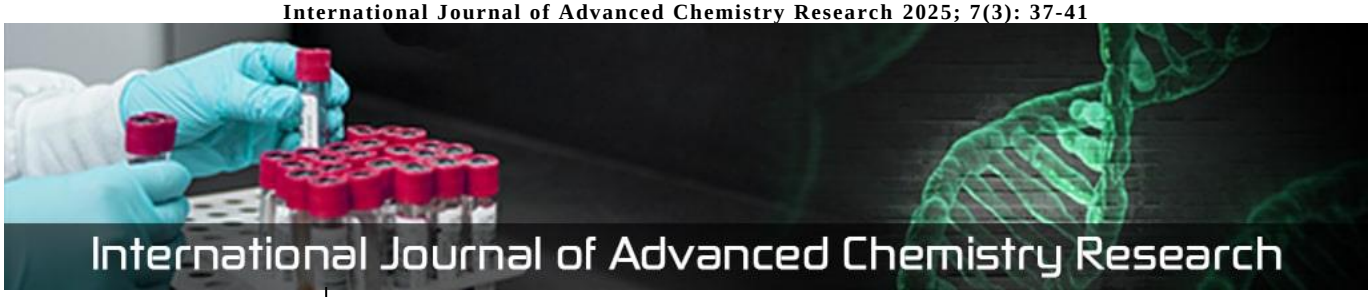

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Dr. Gayatri Barabde
The Institute of Science,
Mumbai, Maharashtra, India

Priyanka Raju Pataskar
The Institute of Science,
Mumbai, Maharashtra, India

Vijay Bagul
The Institute of Science,
Mumbai, Maharashtra, India

Corresponding Author:
Dr. Gayatri Barabde
The Institute of Science,
Mumbai, Maharashtra, India

Sustainable UV spectrophotometric assay method development and validation of chlorpheniramine hydrochloride in tablet dosage form

Gayatri Barabde, Priyanka Raju Pataskar and Vijay Bagul

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Abstract
With growing attention to environmental sustainability in analytical sciences, this study presents an eco-friendly UV spectrophotometric method for Chlorpheniramine maleate. This method is simple, precise, accurate, reproducible, eco-friendly as well as sensitive. The method has been optimized and validated using Water as a diluent, shows no interference. UV-Visible model 1800 was used for the analysis and maximum absorbance (λ_{max}) measured at 223 nm against blank solution. Important validation parameters validated. Results show high accuracy with recovery between 95% to 105% and precision with an RSD below 1.0% across multiple trials. The linearity noticed between the concentration range i.e. 8-24 µg/ml with correlation coefficient in limit. This eco-friendly method demonstrates reliability for routine regular analysis in pharmaceutical industries in Quality Control, stability while reducing environmental impact.

Keywords: Chlorpheniramine Maleate, Eco-friendly method, UV Visible spectrophotometer, Analytical method validation

Introduction
Spectroscopy is nothing but the interaction of light with matter [1]. When light is absorbed by matter [2], the energy content of the atom or molecule increases. When electromagnetic radiation is passed through the subject, it gets absorbed or transmitted or scattered [3]. UV Spectroscopy is a type of absorption spectroscopy where light is immersed by a compound in the range of 200-400nm (ultra-violet region) which results in excitation of electron from ground level to higher level.

Introduction to Chlorpheniramine maleate
Chlorpheniramine maleate (CPM) chemically named as 3- (4-chlorophenyl) -N, N-dimethyl-3-pyridine-2-ylpropan-1-amine [4] is a synthetic alkyl amine used in pharmaceutical industry for supportive care of cough and cold, allergic reaction [5] for example urticarial and Rhinitis. Chlorpheniramine is present in multiple dosage forms in the market. A handful analytical techniques have been mentioned for estimation of Chlorpheniramine [6], HPLC [7], Polarography [8] and Colorimetry [9]. As with allergies, CPM reverses histamine reactivity. Chlorpheniramine maleate, or CPM, was first introduced in medical practice in 1951 and may be administered orally or by intravenous, intramuscular, or subcutaneous injection. Several bacterial diseases can be treated efficiently using Chlorpheniramine maleate. This includes cholera [9], typhoid fever, plague, and meningitis. This drug should only be used when safer antibiotics cannot be employed [8]. During treatment, it should be monitored by checking blood cell levels and drug levels every two days [10]. It can be administered orally, intravenously, or as an eye ointment.

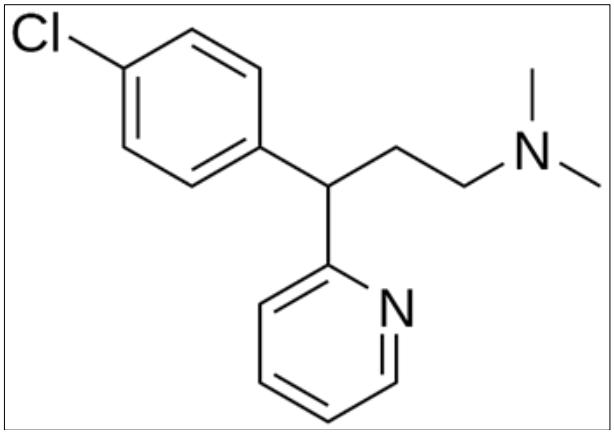

Fig 1: Chlorpheniramine Maleate

Aim of Present Work

The analysis of formed procedure and validate it for Chlorpheniramine maleate is the focus of the study. Therefore, regular quality control analysis and stability may be performed using this approach.

Materials used

Chlorpheniramine maleate standard.

Chlorpheniramine maleate tablets enclosing 4 mg Chlorpheniramine and the placebo that is an inactive ingredient used were obtained from stores.

Diluent

Water

Standard preparation

20 mg of CPM standard was solubilized into 30 ml water and blended neatly. Then in that diluent added to it to 50 ml. From that 4 ml taken and volume made to 100 ml with water.

Test preparation

1 tablet having label claim 4mg shifted to 50 ml flask then 30ml diluent was added. Sonicated in sonicator for about 15 min. shaken well to dissolve. Then diluent was added and made up to volume 50 ml (80 PPM). Further dilute 2 ml to 10 ml in 10 ml volumetric flask with diluent (16 PPM).

Instrument Used

Shimadzu corporation UV-Visible Spectrophotometer 1800 single beam with quartz cell (1cm) was used for the analysis.

Development of Spectrophotometric method

The main two aspects while developing spectrophotometric methods are Selection of Wavelength and Diluent.

Selection of Wavelength depends on the sample nature and also solubility. Trials were taken by using different solvents to completely dissolve Chlorpheniramine Maleate. Solvents such as 0.1N NaOH, 0.1N HCl, Ethanol, Methanol, but Water showed best results and degassed in an ultrasonic bath. Even to develop sustainable method water is the best diluent as it is non-toxic, non-flammable, and does not produce harmful residues. It reduces environmental pollution as many organic solvents. Water is one of the most readily available natural resources on Earth.

Results and Discussion

Chlorpheniramine maleate standard and water (diluent) scanned in UV spectrophotometer in the range of UV spectrum. Refer figure II and figure III. Chlorpheniramine Maleate showed maximum absorbance λ_{max} at 223nm. This developed method is simple, faultless and consistent.

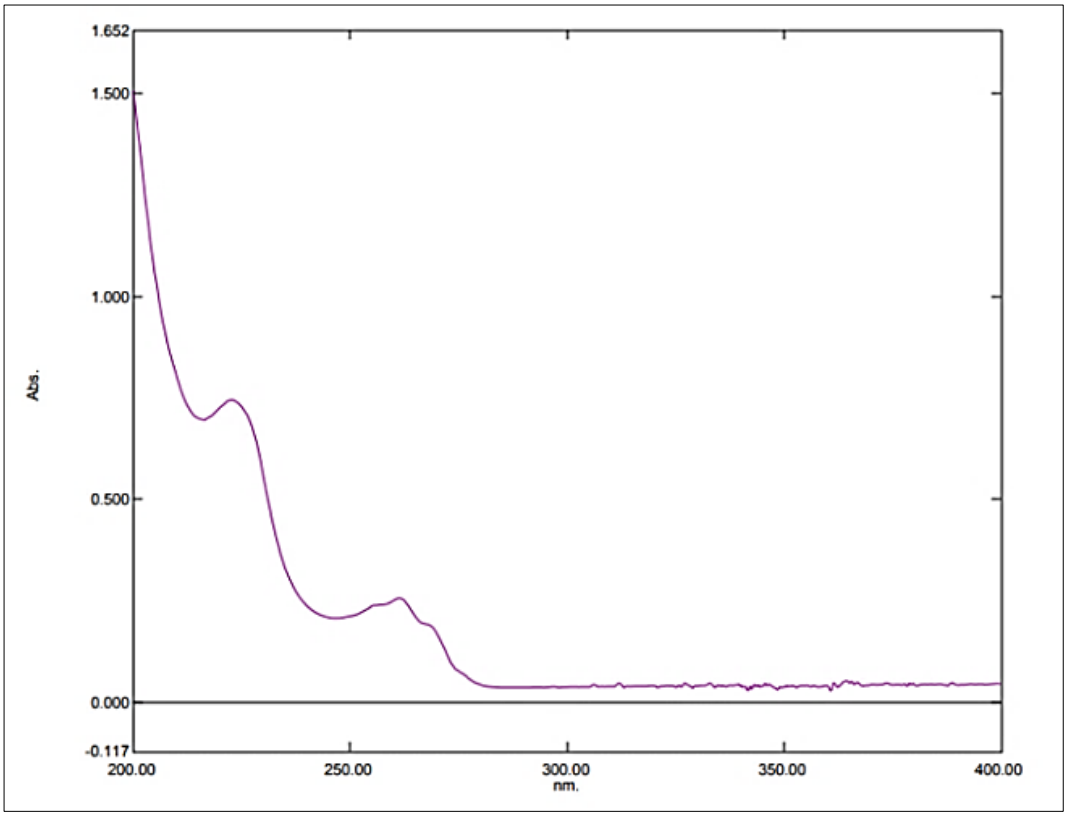

Fig 2: Scan of Chlorpheniramine standard

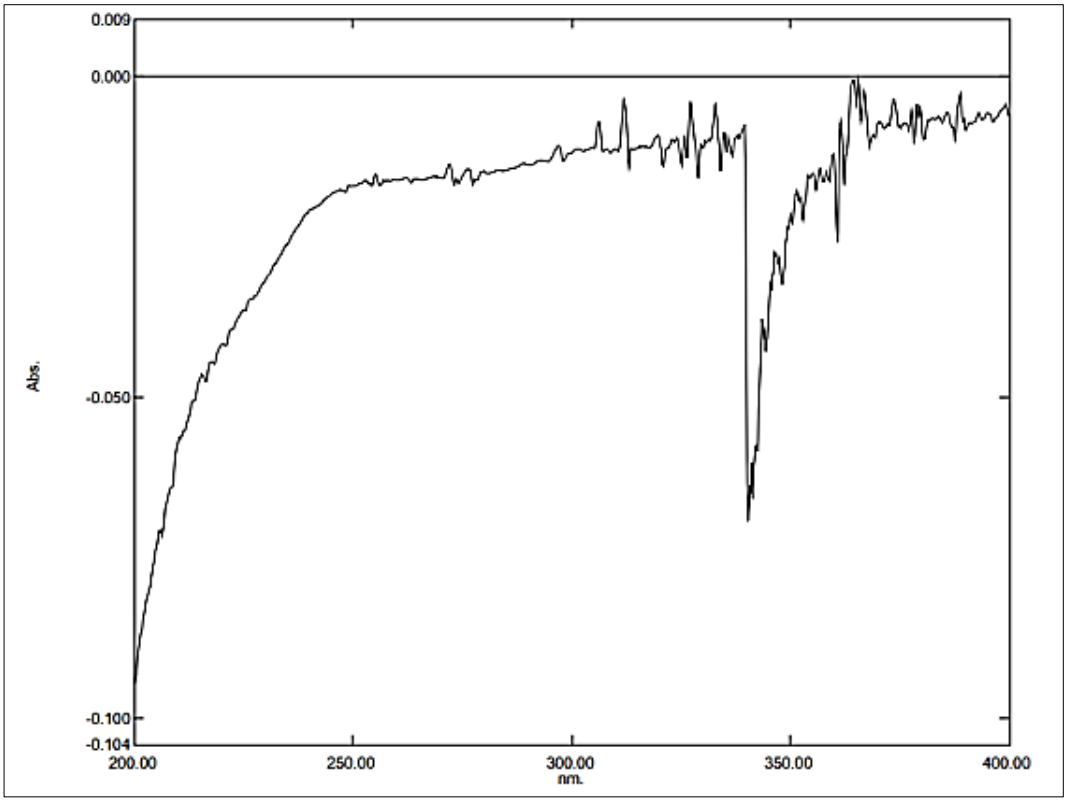

Fig 3: Scan of Blank

Methods validation

Linearity

A calibration curve obtained by plotting absorbance against concentration using a range from 8-24 ppm for Chlorpheniramine Maleate. A linear response was found in the investigation with the linear regression equation value was y = 0.0461x - 0.0176 with correlation coefficient value 0.9975.

Table 1: Linearity study

Sr. Num	Concentration	λ_{max} at 223 nm
1	8	0.338
2	12.8	0.578
3	16	0.741
5	19.2	0.866
6	24	1.078

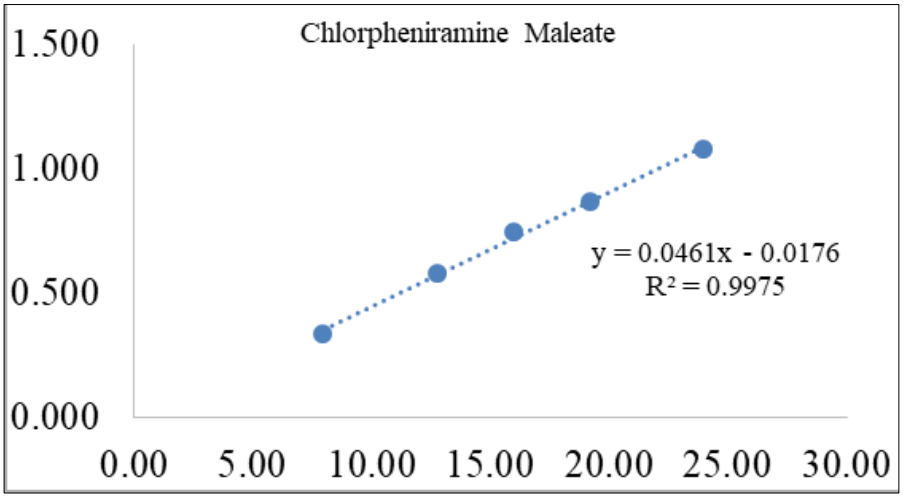

Fig 4: Linearity Curve for Chlorpheniramine Maleate

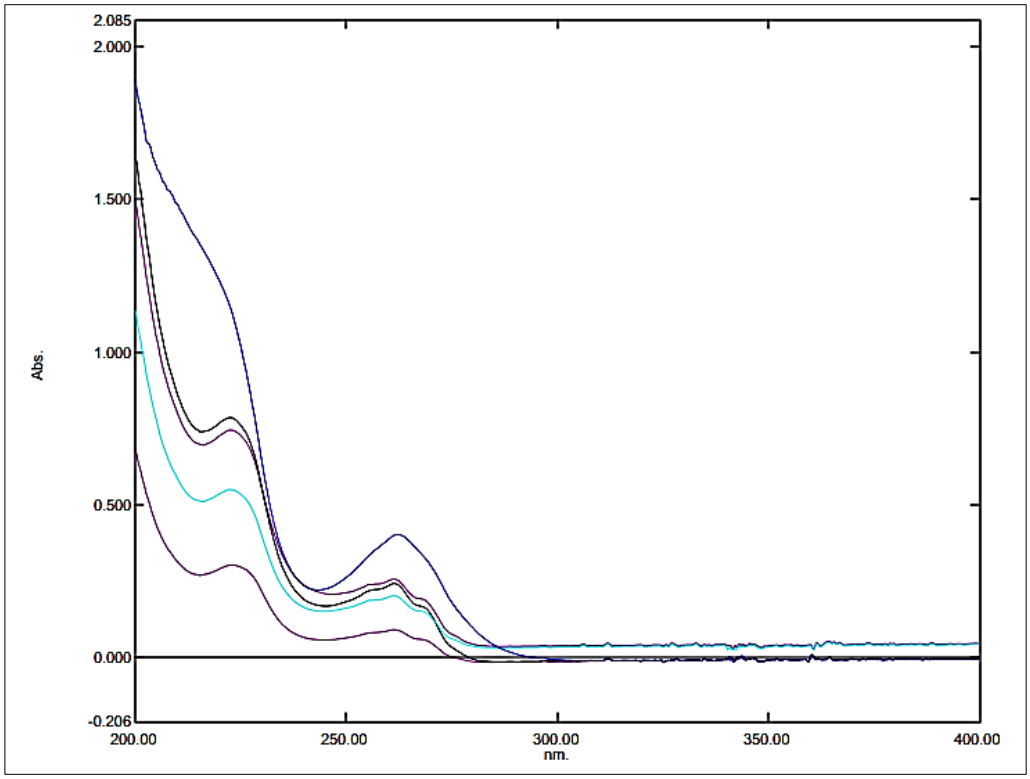

Fig 5: Scan of Linearity spectrum

Table 2: Result noticed for Linearity of Chlorpheniramine Maleate

Parameter	Values	Acceptance Value
Correlation coefficient R	0.99	≧ 0.99
Slope	0.0461	To be mentioned
Regression coefficient	0.99753	To be mentioned
Y Intercept	-0.02	To be mentioned
% Y Intercept	-2.3685	≤ ±5%
λ max	223nm	To be reported

Table 3: Linearity conc of Chlorpheniramine Maleate

% Level	Stock solution	Mixed to (ml)	Final concentration
50%	2 ml	100	8
80%	3.2 ml	100	12.8
100%	4 ml	100	16
120%	4.8 ml	100	19.2
150%	6 ml	100	24

The method stays in line for the area of 8-24 µg/ml for Chlorpheniramine maleate since the Correlation coefficient number fits within acceptable restrictions.

Accuracy

The % recovery of Chlorpheniramine Maleate in Table 4 showed that the method is accurate. The recovery percentages for each case were between 97-103%, and the average recovery percentage was 98-102%, which shows that the method is good for quantitative analysis.

Table 4: Recovery Levels

Accuracy Level	Chlorpheniramine Maleate (%)
50%	98.53
	97.72
	97.99
100%	99.60
	99.87
	99.33
150%	99.96
	100.76
	100.76
Mean recovery	99.39
Min. recovery	97.72
Max. recovery	100.76

Precision

Because the Relative standard deviation (RSD) from six tests was much less than the allowed limit of ≤ 2 %, the method showed precision as per the definition of precision. See Table 5.

Table 5: Method Precision

Test No.	% Assay of Chlorpheniramine Maleate
Test 01	99.43
Test 02	99.83
Test 03	100.10
Test 04	100.10
Test 05	99.97
Test 06	99.97
Mean	99.898
STD Dev	0.25
% RSD	0.25

Intermediate Precision (IP)

The intermediate precision (IP) measures two independent test on separate days and preparation with different analyst. Refer table 6 for IP Results.

Table 6: Intermediate Precision

Test Num.	% Assay of Chlorpheniramine Maleate
Test 01	99.81
Test 02	99.94
Test 03	99.94
Test 04	99.68
Test 05	99.68
Test 06	99.94
Mean	99.833
STD Dev	0.13
% RSD	0.13

Robustness

Robustness is the capacity of an assay method to maintain its integrity when certain parameters are purposefully changed. The wavelength changes to 221 and 225. It showed that no change was found refer Table 7. Also, Sonication time of sample increases and decreases to check robustness. The results showed that no change recorded Refer Table 8.

Table 7: Robustness (Wavelength)

Sr. No.	Concentration	Wavelength	Absorbance	% Recovery
1	16	221	0.716	100.19
			0.717	
2	16	225	0.704	99.96
			0.703	

Table 8: Robustness (Sonication time)

Sr. No.	Concentration	Sonication Time	λ_{max}	% Recovery
1	16	10 min	0.724	100.28
			0.726	
2	16	20 min	0.719	99.45
			0.719	

Solution Stability

Solution was preserved for 24 hrs. After 24 hrs absorbance was noted and it shows no critical change in % Assay.

Table 9: Solution Stability of Chlorpheniramine Maleate

Sr. No.	Time	Absorbance	% Recovery
1	24 Hrs	0.724	100.31
		0.725	

Conclusion

The current analytical technique satisfies all the parameters in accordance with guideline ICH (Q2(R1). The analytical approach was found to be specific, accurate, linear, precise. The current analytical approach is suitable for its intended usage.

Acknowledgement

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