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NEW ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF CHLORPHENIRAMINE MALEATE BY USING UV-VISIBLE SPECTROPHOTOMETRY

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Abstract:
A simple UV-Visible Spectrophotometric method was developed for the determination of chlorpheniramine maleate in pure and its pharmaceutical formulations. chlorpheniramine maleate exhibited maximum absorption at 262nm in 0.1N HCl and obeyed linearity in the concentration range of 10-60 µg/ml. The proposed method was statistically validated.All the proposed methods are simple, selective, reproducible, sensitive and accurate with good precision. Some of the methods were proved to be superior to most of the reported methods. All these proposed methods for estimation of selected drugs such as chlorpheniramine maleate were successfully applied either in bulk or pharmaceutical formulations. The proposed methods can be used as alternative methods to the reported ones for the routine determination of selected drugs under the study in bulk and pharmaceutical dosage forms.
Keywords: chlorpheniramine maleate, UV-Visible Spectrophotometer, Hydrochloric acid.

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INTRODUCTION:

The UV-Visible Spectrophotometric methods which fall in the wavelength region 200-800 nm and fluorimetric methods (may fall in UV & Visible regions) are very simple, cheap & easy to carry out estimations of drugs in bulk form and their formulations. The limitations of many colorimetric or fluorimetric methods of analysis lie in the chemical reaction upon which the procedures are based rather than the instruments available. Many of the reactions involve color or fluorescence of a particular drug are quite selective or can be rendered selective through the introduction of masking agents, control of pH, use of solvent extraction technique, adjustment of oxidation states or by prior removal of interfering ingredients with the aid of chromatographic separate [1-3].

Chlorpheniramine maleate is an antibiotic useful for the treatment of a number ofbacterial infections [4,5]. This includes meningitis, plague, cholera, and typhoid fever. Its use is only recommended when safer antibiotics cannot be used. Monitoring both blood levels of the medication and blood cell levels every two days is recommended during treatment [6]. It is available intravenously, by mouth, and as an eye ointment [7-8].

MATERIALS AND METHODS:

Chlorpheniramine maleate was obtained as gift sample from Elite chemicals and all reagents were purchased from SD Chemicals Chennai. All materials and reagents used were in analytical grade.

Method Development

A simple UV-Visible Spectrophotometric method was developed for the determination of Chlorpheneramine Maleate in pure and its pharmaceutical formulation. Chlorpheneramine Maleate exhibiting maximum absorbance at 262nm in 0.1N HCl and obeyed linearity in the concentration range of 10-60 µg/ml. The proposed method was statistically validated.

Scanning and determination of maximum wavelength (λmax):

In order to ascertain the wavelengths of maximum absorption (**λmax**) of the drug, different solutions of the drug (10µg/ml and 20µg/ml) in 0.1N HCl were scanned using UV-Visible spectrophotometer within the wavelength region of 200–380nm against 0.1N HCl as blank. The resulting spectrum was presented in Fig.1. and the absorption curve showed characteristic absorption maximum at 262 nm for Chlorpheneramine Maleate.

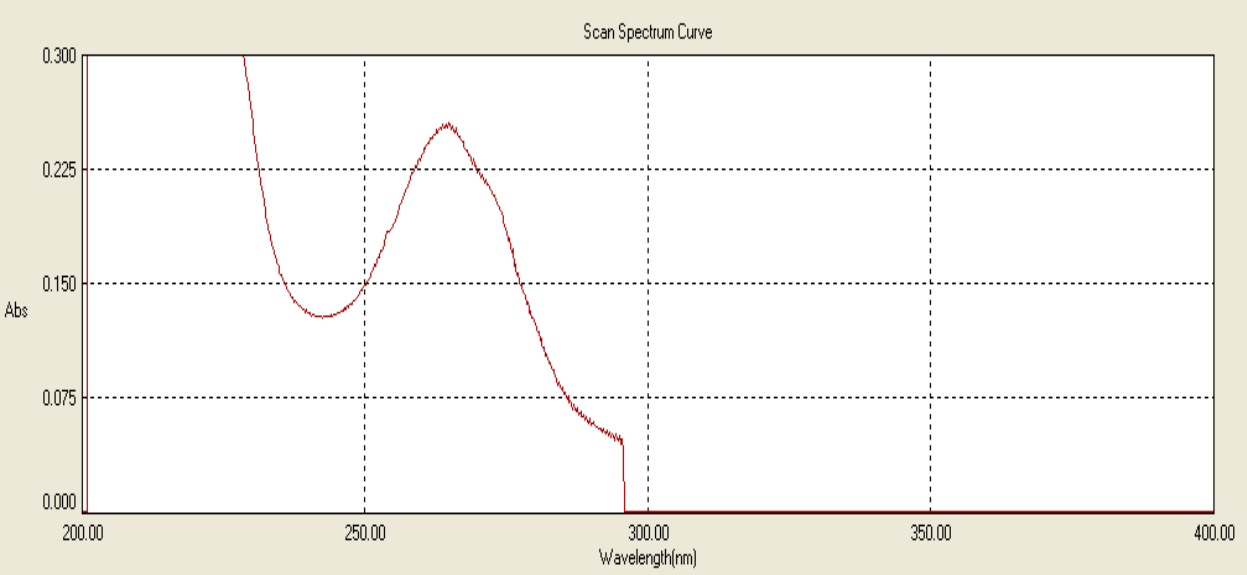

Fig 1: Absorption Curve for CPM in 0.1N HCl (λmax = 262nm)

Preparation of Stock Solution

Standard stock solution of Chlorpheniramine maleate was prepared by dissolving 10mg of Chlorpheneramine maleate drug in 10ml of 0.1N HCl in 10ml of volumetric flask to get a concentration of 1mg/ml (1000µg/ml) solutions.

Preparation of Working Standard Solutions and construction of standard graph

The prepared stock solution was further diluted with 0.1N HCl to get working standard solutions of 100µg/ml and 10µg/ml. To construct Beer's law plot for Chlorpheneramine maleate, different aliquots of Chlorpheneramine maleate were taken and diluted to 10 ml with 0.1N HCl to get the working standard solutions as shown in the table.1. The absorbance of each solution was measured at λmax 262 nm against 0.1N HCl as blank. The standard graph for Chlorpheneramine maleate was plotted by taking concentration of drug on x-axis and absorbance on y-axis. The results were shown in Fig.2 & Fig.3. The drug has obeyed Beer's law in the concentration range of 10-60 µg/ml.

Table 1: Linearity table of CPM (pure drug) in 0.1N HCl at 262 nm

Sl.no	Concentration (µg/ml) of Chlorpheniraminemaleate(CPM)	Absorbances(nm)
1	10	0.264
2	20	0.538
3	30	0.872
4	40	1.105
5	50	1.409
6	60	1.71

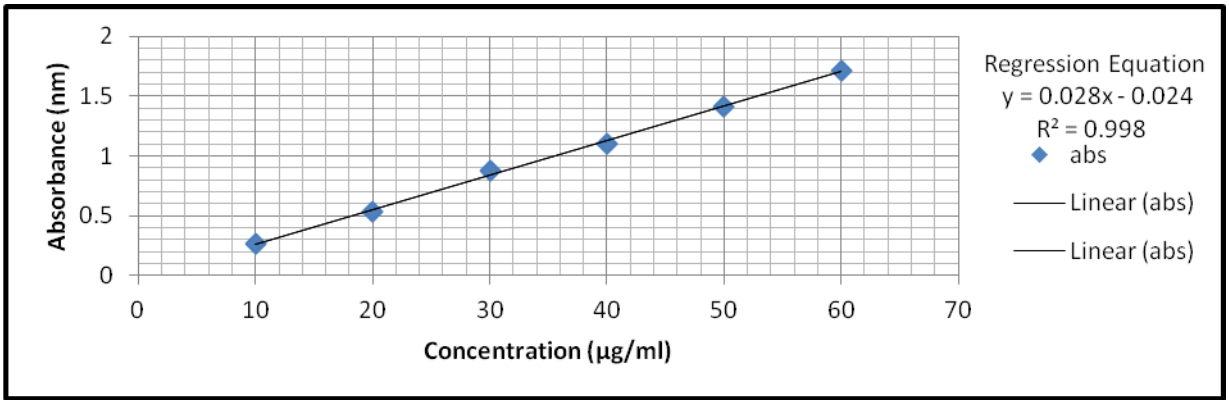

Fig 2: Linearity graph of CPM (pure drug) in 0.1N HCl at 262 nm

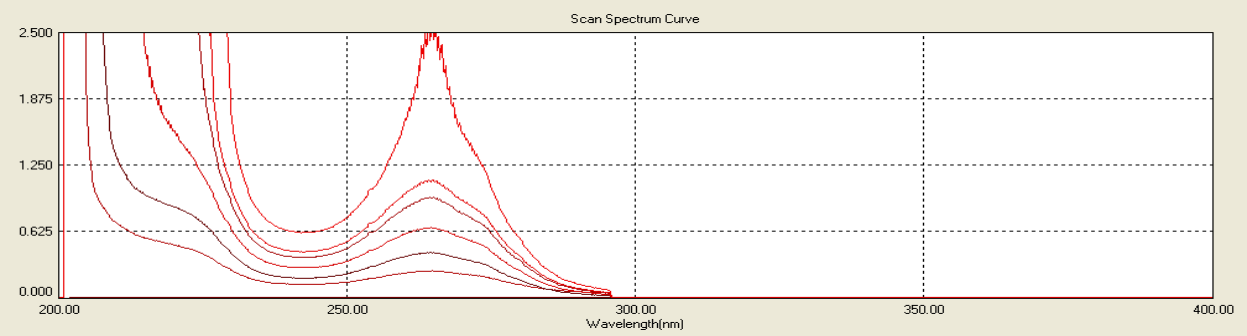

Fig 3: Linearity curve of CPM (pure drug) in 0.1N Hcl at 262 nm

Table 2: Optical characteristics of proposed method

Parameter	Chlorpheniraminemaleate
λmax (nm)	262
Beer's Law limit (µg/ml)	10-60
Sandell's sensitivity (µg/cm2/0.001absorbance unit)	0.0378µg/ml
Molar extinction coefficient ($lmole^{-1}.cm^{-1}$)	4.084×10^4
Regression equation (Y)	0.0288x-0.0246
Slope (a)	0.0998
Intercept (b)	0.0246
% Range of error 95% confidence limits 99% confidence limits	0.0021 0.0028
Correlation co-efficient	0.999

*Y= aX+b, where 'X' is concentration in µg/ml and Y is absorbance unit

Estimation of Chlorpheneramine maleate in commercial formulations

For analysis of commercial formulations, 10 tablets containing chlorpheniramine maleate were taken and powdered. The powder equivalent to 4mg of Chlorpheniramine maleate was taken in a 10ml volumetric flask, containing 7ml of HCl and sonicated for 30 minutes. The volume was made up to 10ml with HCl and filtered to get a solution of concentration 1000µg/ml.

This was further diluted with HCl to get a concentration within the linearity range and the absorbances were measured against the blank at 262nm. The results were shown in Table 3.

Table 3: Assay of Chlorpheniraminemaleate

Sl.No.	Formulation	Drug	Labeled Amount mg	Observed Amount mg Mean±SD	% Recovery
1.	Cadistin (Zydus cadila)	Chlorpheniraminemalate	4	4.902±0.0040	98.046

Validation

Table 4: Precision data

Sl.no	Concentration (µg/ml)	Absorbances (nm)
1	20	0.538
2	20	0.540
3	20	0.532
4	20	0.536
5	20	0.536
6	20	0.538
Mean		0.536667
sdv		0.002733
% rsd		0.509

Table 5: Accuracy data

Sl.no	Conc(bulk)	Conc(formln)	Abs(nm)	%rec	Mean	sdv	%rsd
1	8	10	0.462	16.89			
2	8	10	0.466	17.03	16.97	5.029826	41.67
3	8	10	0.465	17			
4	10	10	0.503	18.32			
5	10	10	0.501	18.25	18.30	5.483096	0.377
6	10	10	0.504	18.35			
7	12	10	0.578	20.92			
8	12	10	0.575	20.82	20.86	6.099674	0.369
9	12	10	0.576	20.85			

Precision

The precision of the proposed method was ascertained by actual determination of six replicates of fixed concentration of the drug within the Beer's range and finding out the absorbances by the proposed method. From these absorbance's, Mean, Standard deviations, %R.S.D were calculated. The readings were shown in Table 4.

Accuracy

To determine the accuracy of the proposed method, recovery studies were carried out by adding different amounts (80%, 100% and 120%) of bulk samples of Chlorpheniraminemaleate within the linearity range were taken and added to the pre-analyzed formulation of concentration 10µg/ml. From that percentage recovery values were calculated. The results were shown in Tab.5.

RESULTS AND DISCUSSION:

From the optical characteristics of the proposed method, it was found that Chlorpheniramine maleate obeys linearity within the concentration range of **10-60 µg/ml**. From the results shown in precision table, it was found that the % R.S.D is less than 2%, which indicates that the method has good reproducibility.

From the results shown in accuracy table, it was found that the percentage recovery values of pure drug from the pre-analyzed solution of formulation were in between **98.62-99.17%,** which indicates that the proposed method is accurate and also reveals that the commonly used excipients and additives in the pharmaceutical formulations were not interfering in the proposed method.

SUMMARY AND CONCLUSION:

A simple UV-spectrophotometric method was developed for the determination of chlorpheneramine maleate in pure and its pharmaceutical formulations. Chlorpheneramine maleate exhibited maximum absorption at **262nm** in 0.1N HCl and obeyed linearity in the concentration range of **10-60 µg/ml**. The proposed method was statistically validated.All the proposed methods are simple, selective, reproducible, sensitive and accurate with good precision. Some of the methods were proved to be superior to most of the reported methods. All these proposed methods for estimation of selected drugs such as chlorpheneramine maleate were successfully applied either in bulk or pharmaceutical formulations.The proposed methods can be used as alternative methods to the reported ones for the

routine determination of selected drugs under the study in bulk and pharmaceutical dosage forms.

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