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Short Communication

Derivative Spectrophotometric validation of carbocisteine in pharmaceutical dosage form

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Abstract

The study involves developing a, third order derivative UV spectrophotometric method for assay of carbocisteine. The ICH guidelines were used for validation of carbocisteine. The study was carried out at 210 nm for derivative, in Ultra- violet region. At 1 to 12 µg / ml concentration range Beer's law was obeyed. The coefficient of correlation value and COV values was 0.1959 % observed for proposed method. Such method was easily applicable for the assay of carbocisteine in formulation. The analysis results were statistically validated. The Suggested method is useful in quality control laboratory.

Keywords: Third order derivative, UV spectrophotometry, Carbocisteine, Hydrochloric acid.

Introduction

Carbocisteine, (2R)-2-amino-3-[(carboxy-methyl)sulphanyl] propanoic acid, it has mucolytic category, it relieves mucus from body very easily. The COPD symptoms involve the excess secretion of mucus. The Carbocisteine is used for treatment of COPD. The COPD include airway inflammation and stress. The drug is assay methods were reported in BP[1] and EP[2]. The HPLC[3,4], UPLC[5] and Ion-Chromatography[6], Spectrophotometric[7-9] methods are suggested in literature. In literature also indicate Spectrophotometric[10,11] methods for assay of combined dosage form. The optimization and assay of method was carried out by ICH guidelines.

Materials and methods

Instrument and reagents: Shimadzu UV-spectrophotometer, model 1800 (Shimadzu, Japan) spectral band width of 0.5 n with UV-Probe 2.42 software, reference standards of carbocisteine.

Solution preparation: A 1000µg/ml. i.e. stock solution was prepared in 0.1N HCl and 100µg/ml i.e. working standard was prepared from 1000 µg /ml. i.e. stock solution with 0.1N HCl as solvent.

Preparation of sample solution: Average weight of each tablet was calculated from 20 tablets. They were powdered. A 10 mg of carbocisteine powdered sample was used for sample solution. It gave the concentration as 1000µg/ml of sample carbocisteine solution respectively. A working sample solution, 100µg/ml was prepared form above solution.

Method: A solution of standard (10µg/ml) was used for scanned at wavelength of 200-300nm for the selection analytical wavelength. With the help of software third order derivative spectrum was obtained hence the wavelength 210nm was used for analysis.

Preparation of calibration curves: For linearity study was observed with 1 -10µg/ml as concentration of carbocisteine. The series of solutions were scanned. The spectrum of various concentration range 1-10µg/ml and were recorded and by using UV Probe 2.42 software the amplitude of different concentration were calculated.

The spectra of various concentration carbocisteine were represented in Figure-1 respectively. The curve was plotted for amplitude of against µg/ml (Figure-2). The analysis evaluation was given in Table-1.

Estimation from dosages: Average weight of each tablet was calculated from 20 tablets. They were powdered. A 10 mg of carbocisteine powdered sample was used for sample solution. It gave the concentration as 1000µg /ml of sample carbocisteine solution respectively. A working sample solution, 100µg/ml was prepared form above solution. Software was used to conversion of absorbance spectra to third order derivative spectra. The amount of carbocisteine in tablet was calculated by linearity equations.

Equation is Y = 0.0013x - 0.0005.

Method Validation: This method validated was done as per ICH guidelines.

Accuracy: For the accuracy study 80%, 100% and 120% were used with standard addition method. The values percentage recovery for found as 99.88% to 100.41% (Table-2).

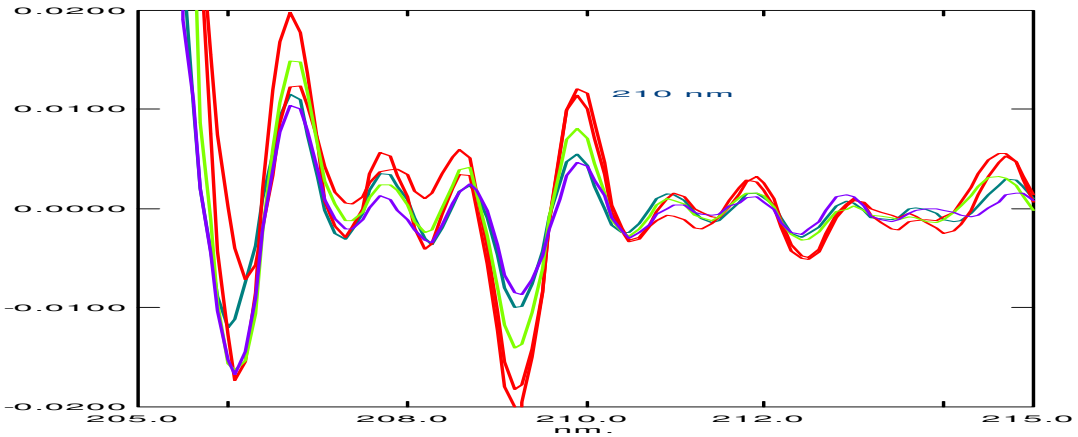

Figure-1: Overlain spectra of carbocisteine.

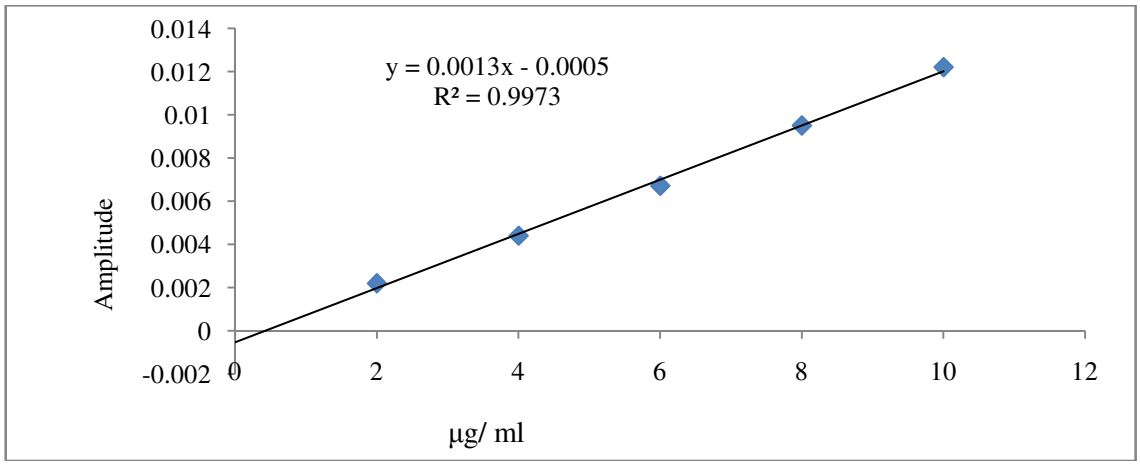

Figure-2: Linearity study.

Table-1: Optical and regression data.

Study of parameter	Wavelength of Detection in nm	Limit of Beer Law	Correlation coefficient (r^2)	Slope	Intercept
Values	210	1-10 µg/ml	0.9973	0.0013	-0.0005

Table-2: Standard addition method for Statistical evaluation (accuracy).

Steps	Standard Carbocisteine µg/ml	Sample Carbocisteine µg/ml	Recovered Carbocisteine µg/ml	Carbocisteine %	% recovery Mean
80%	15	12	26.964	99.87	99.88
	15	12	27.032	100.12	
	15	12	26.905	99.65	
100%	15	15	30.081	100.27	100.41
	15	15	30.321	101.07	
	15	15	29.952	100.65	
120%	15	18	32.940	99.82	100.07
	15	18	32.044	100.14	
	15	18	33.089	100.27	

Linearity: The linearity study was found in concentration of 1-10 µg/ml.

Precision: The precision study was established by using six replicates with relative standard deviation as 0.1959%. The Table-3 gives results of precision.

Table-3: Precision data for six replicates.

Replicate no.	Result of replicate analysis in %
1	99.86
2	100.18
3	99.95
4	100.12
5	100.29
6	99.79
Mean % assay	100.031
% R.S.D.	0.1959

The intra-day precision was carried in six replicates. Similarly inter-day precision was carried for 1st, 3rd and 5th days. For evaluation of statistical data mean of average was calculated. The data of precision in intra- day as well as inter-day was less in % RSD values. A table 4.reports precision data of intra and inter days.

Table-4: Study of intra-day and inter-day.

Study	Precision for	% C.O.V.
Intra-day	±100.12%±	0.1712
Inter-days	±99.55%	0.1814

Results and discussion

A newly proposed method for assay carbocisteine in tablet formulation was suitable for the quality control of drug. The Tables-1 to 4 indicated % RSD was found to be less than 1. The regression values was used for linearity at range. The value 0.9973, correlation coefficient indicated good linearity. The assay results obtained are in good agreement.

Conclusion

As per literature proposed methods the new method is much simpler hence the suggested method is found to be suitable for the determination of carbocisteine in bulk drug as well as formulation. The ratio of derivatives was not used like some literature method. In the proposed method amplitude of third order derivative was used directly for determination of purity of drug. This method has more benefits than the routine methods.

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