Int J Pharm Bio Sci 2013 Apr; 4(2): (P) 847 - 851

Research Article **Analytical Chemistry**

International Journal of Pharma and Bio Sciences **ISSN 0975-6299**

ULTRA-VIOLET SPECTROPHOTOMETRIC METHOD FOR VALIDATION OF CARBOCISTEINE FROM BULK DRUG AND PHARMACEUTICAL FORMULATION

*** RELE RAJAN V. AND PATIL SACHIN S.**

CENTRAL RESEARCH LABORATORY,
D.G. RUPAREL COLLEGE, MAHIM , MUMBAI 400 016.

ABSTRACT

A simple, rapid, sensitive and precise UV spectrophotometric method have been developed for the estimation of carbocisteine from bulk drug and pharmaceutical formulation. In this method carbocisteine showed maximum absorbance at about 200.4 nm in 0.1N HCl. Beer's law was followed in the concentration range of 10 to 140 µg/ ml. Regression equation was found to be $y = 0.0067 x – 0.0015$ and coefficient of correlation was 0.9999 . The proposed method is accurate, sensitive, reproducible and useful for the estimation of carbocisteine from bulk drug and pharmaceutical formulation.

KEYWORDS: **Carbocisteine, 0.1N HCl**

RELE RAJAN
CENTRAL RESEARCH LABORATORY,
D.G. RUPAREL COLLEGE, MAHIM , MUMBAI 400 016.

INTRODUCTION

In this communication the present work proposes UV spectrophotometric method for assay of carbocisteine from bulk drug and pharmaceutical formulation. Its chemical name is (2R)-2-amino-3-[(carboxy-methyl) sulphanyl] propanoic acid. Carbocisteine is a mucolytic drug, which breaks down mucus in the body so that it can be more easily cleared from the body. In chronic obstructive pulmonary disease (COPD) symptoms involve the over secretion of mucus, mucolytic have great potential for treatment of this disease. Additional characteristics of COPD include airflow limitation oxidative, stress and airway inflammation. Carbocisteine is official in British Pharmacopoeia[1] and European Pharmacopoeia[2]. In literature survey HPLC[3-4], UPLC[5] and Ion-Chromatography[6] methods were reported. A rapid, simple and reliable UV spectrophotometric method is developed for the determination of carbocisteine. This method can be used for the routine analysis and research organization. In the proposed work optimization and validation of this method are reported.

MATERIALS AND METHODS

Shimadzu UV-1800 was used with 10 mm matched quartz cell to measure absorbance of solution. A Shimadzu analytical balance with 0.01 mg was used.

CHEMICAL AND REAGENTS

Reference standard of carbocisteine was obtained from reputed firm with certificate analysis. All spectral absorbance measurements were made on Shimadzu UV-1800 with 10 mm matched cell.

PREPARATION OF STANDARD SOLUTION

About 10 mg of standard carbocisteine was weighed accurately and transferred in 100 ml of volumetric flask. About 30 ml of 0.1N HCl was added and sonicated for 15 minutes. The volume was adjusted up to the mark with 0.1N HCl to give concentration as 100 µg /ml.

EXPERIMENTAL

Into a series of 10 ml graduated flask, varying amount of standard drug carbocisteine solutions were pipette out and volume was adjusted with 0.1N HCl. Absorbance of the resulting solutions was measured at 200.4 nm using 0.1N HCl as blank. (Fig.1)

Figure 1
(a)UV spectrum of standard carbocisteine (Pure drug)

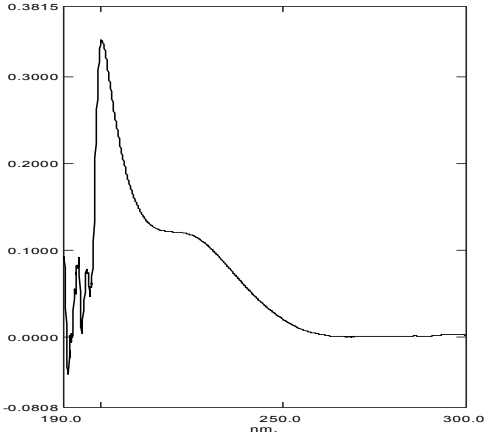
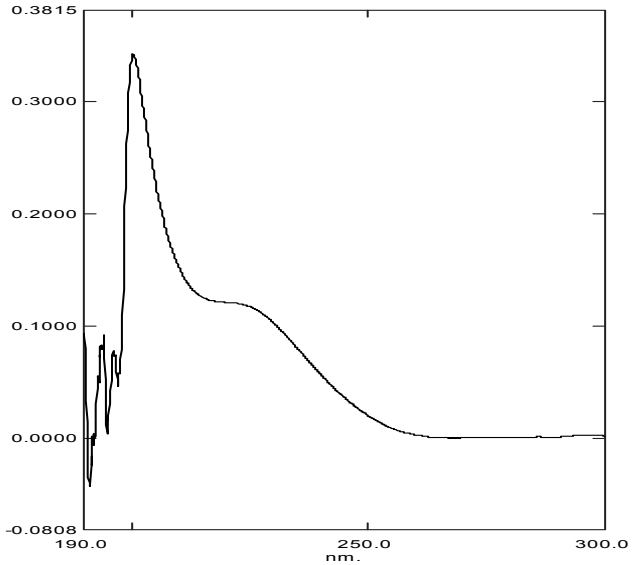


Figure 1
(b)UV spectrum of carbocisteine (Sample)



Estimation from tablets

Twenty tablets were weighed accurately and average weight of each tablet was determined. Powder equivalent to 10 mg of carbocisteine was weighed and transferred in 100 ml of volumetric flask. A 30 ml of 0.1N HCl was added and sonicated for 15 minutes and filtered. The filtrate and washing were diluted up to the mark with 0.1N HCl to give concentration as 100 µg /ml. Such solution was used for analysis. Into series of 10 ml graduated flask, varying amount of sample solutions of carbocisteine were pipette out and volume was adjusted with 0.1N HCl. Absorbance of the resulting solutions was measured at 200.4 nm using 0.1N HCl as blank. The concentration of the drug in the given sample was calculated using calibration curve. The results of analysis are given in table 1.

Table 1
Values of results of optical and regression of drug.

Parameter	Values
λ max (nm)	200.4
Beer Law Limits (µg/ml)	10-140
Molar absorptivity(L/mol.cm)	1.2005×10^3
Sandell's sensitivity	0.14925
Correlation coefficient(r^2)	0.9999
Regression equation (y=b+ac)	
Slope (a)	0.0067
Intercept	0.0015

VALIDATION

Accuracy

Accuracy of the proposed methods was carried as on the basis of recovery studies. It is performed by the standard addition method. Recovery studies were performed by adding standard drug at different

levels to the pre-analyzed tablets powder and the proposed method was followed. From the amount of the drug estimated, the percentage recovery was calculated. The results of the analysis are shown in table 2.

Table 2
Results of recovery of Carbocisteine in bulk drug

Amount of sample added (µg/ml)	Amount of standard added (µg/ml)	Total amount recovered	Percentage recovery(%)	Standard deviation	Percentage of relative standard deviation (C.O.V.)
10	0	9.9999	99.99	0.1493	1.4927
10	10	20.0852	100.426	0.1174	0.5846
10	20	30.0639	100.213	0.1456	0.4844
10	30	39.9999	99.99	0.1218	0.3046

Precision

The method precision was established by carrying out the analysis of homogenous powder blend of tablets. The assay was carried out of drug using proposed analytical method in six replicates. The value of relative standard deviation lie well within the limits indicated the sample repeatability of the method. The results obtained are tabulated in table 3.

Table 3
Precision- method precision

Experiment no.	Weight of carbocisteine taken in mg.	Content in mg. of carbocisteine
1.	10	10.1492
2.	10	10.010
3.	10	10.1492
4.	10	10.001
5.	10	9.7014
6.	10	10.001
Standard deviation = 0.16356		
%RSD = 1.6354		

Inter-day and intra-day precision

An accurately weighed quantity of tablets powder equivalent to 10 mg of carbocisteine was transferred to 100 ml of volumetric flask, sonicated for 15 minutes with 0.1N HCl and diluted up to mark with 0.1N HCl to get stock solution of concentration as 100 µg /ml. The contents were filtered through whatmann filter paper no. 41. Aliquots portions were further diluted with 0.1N HCl to get concentration of 10 µg /ml. of carbocisteine. The absorbance of final solutions was read after 0 hr., 3 hrs. and 6 hrs. in 10 mm cell at 200.4 nm. Similarly the absorbance of the same solution was read on 1^{st}, 2^{nd} and 5^{th} day. The amount of carbocisteine was estimated by comparison with standard at 200.4 nm. The results are recorded in table 4.

Table 4
Summary of validation parameter for intra-day and inter-day

Sr. no.	parameters	percentage
(A)	Intra-day precision (n=3)	99.60
	Amount found ± %RSD	0.5443
(B)	Inter-day precision (n=3)	98.484
	Amount found ± %RSD	0.8882
(C)	Ruggedness	100.12
	Analyst to analyst (n=3) %RSD	0.3845

RESULTS AND CONCLUSION

The proposed method was validated statistically and by recovery studies. The molar absorptivity and Sandell's sensitivity values show the sensitivity of methods while the precision was confirmed by the %RSD (relative standard deviation). Assay results of recovery studies are given in table 2. Results are in good agreement with labeled value. The reproducibility, repeatability and accuracy of this method were found to be good, which is evidenced by low standard deviation. The proposed method is simple, sensitive, accurate, precise and reproducible. Hence it can be successfully applied for the routine estimation of carbocisteine in bulk and pharmaceutical formulation even at very low concentration as 1 µg /ml. In conclusion the proposed method is simple, sensitive and accurate. It can be used for routine estimation of carbocisteine in bulk drug and pharmaceutical formulation.

REFERENCES

1. British Pharmacopoeia, Her Majesty's Stationary Office, London, volume I, II, and III, 1983,(2009).
2. European Pharmacopoeia 5.0, volume-2,(2005).
3. Rele R.V , Patil S.P, Reversed phase high pressure liquid chromatography technique for determination of carbocisteine from pharmaceutical formulation, J.Chem.Parm.Res. ,2(4):24- 30, (2010).
4. Archana Nadimintri, Ashwini Gunda, Karnaker Reddy Tupally, Abbaraju Prasanna Lakshmi, Kedarnath Jakka, Aravind Sai Nagubandi , Simultaneous estimation of amoxillcine trihydrate and carbocisteine drug present in formulation by RP-HPLC method and its validation, Journal of pharmacy research, 5(4), 1889-1895, (2012).
5. Ravindhar Burugu, G.Venkateshwarlu , A stability indicating ultra performance liquid chromatography (UPLC) method for the determination of assay of carbocisteine in various formulation products, International journal of pharmacy and pharmaceutical sciences, 4(4), 653-656, (2012).
6. Megoulas NC, Koupparis MA , Ion-chromatographic determination of carbocisteine in pharmaceuticals based on non-Suppressed conductometric detection , J.chromatography A, 1026 (1-2), 167-74, (2004).