ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

RP-HPLC method for the determination of ambroxol in pharmaceutical dosage forms

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ABSTRACT

A simple, rapid and reproducible high performance reverse phase liquid chromatography method has been developed for the estimation of Ambroxol in bulk drug sample and pharmaceutical dosage forms was developed using SS aokosil II C18, 250X4.6mm, 5µm column with mobile phase composition of acetonitrile methanol and 0.5% ammonium acetate 44:16:40 (PH 5). Flow rate of 0.8ml/min and uv detection at 295nm linearity was observed over concentration range of 20-100µg/ml. the accuracy of the proposed method was determined by recovery studies and found to be 95-105% . the proposed method was validated and results conformed with ICH parameters .

Keywords: Ambroxol, RP-HPLC

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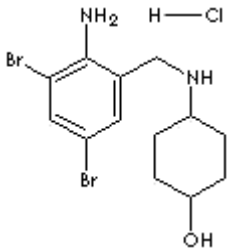
ISSN: 0975-8585

INTRODUCTION



Ambroxol Is chemically: trans-4-((2-Amino-3,5- dibromobenzyl)amino)cyclohexanol

Which is used as mucolytic agent and expectorant. It stimulates mucociliary action and liquefies the mucous and clears the air passages in the respiratory tract. A tablet formulation containing 30mg of Ambroxolis available (Ceftas-AL division of INTAS Ltd). a survey revealed that no official method is available for the estimation of Ambroxol by HPLC method. Present work describes the development of a simple, precise and accurate reverse phase HPLC method for estimation of Ambroxolin tablets. The drug sample of Ambroxol were obtained as a gift sample from intas

EXPERIMENTAL

Material and methods

Instrumentation

A isocratic high pressure liquid chromatography Shimadzu 10AT, SPD 10A detector was used for study .the column used was reverse phase. SS Wakosil II, C18, 250X4.6mm, 5mm i.d & partical size 5µm.the flow rate of mobile phase was maintained at 1ml/min and detection was carried out at 248nm at the room temp.

Chemical and regents

Water of HPLC grade was collected from milli-Q system acetonitrile R) methanol (Ranbaxy) and ammonium acetate AR (Ranbaxy).

Preparation of mobile phase

460ml of acetonitrile, 140ml of methanol was mixed with 400ml of ammonium acetate buffer the pH was adjusted to 5.5 with acetic acid, filtered & degassed through nylon membrane filter paper and sonicated for 10min.

Preparation of standard solution

Standard solutin of Ambroxol was prepared in mobile phase of concentration 500µg/ml. the stock solution were diluted to obtain working standard solution of

ISSN: 0975-8585

concentration of 5 µg/ml to 30 µg/ml. the resulting solution were sonicated for 10min . 100 µl of the standard solution was injected the retention time for Ambroxol was found to be 4.94min. The linearity ranges for Ambroxol was found to 5- 30 µg/ml.

Preparation of sample solution

Ceftas, tablets five in number were weighed an amount equivalent of 5mg of Ambroxol was transferred into 10ml volumetric flask . the powder as first dissolved with a few drops of mobile phase and the volume then made upto10ml with mobile phase . the solution was filtered through membrane filter with pore size of 0.45 micron. The sample stock solution was adequately dilute to obtain Ambroxol concentration of 5 µg/ml . the resulting solution was sonicated for 10min and 100 µl of the sample was injected . the peak area from the chromatogram was tabulated and amount of Ambroxol present in the tablet formulation was determined from the linearity curve.

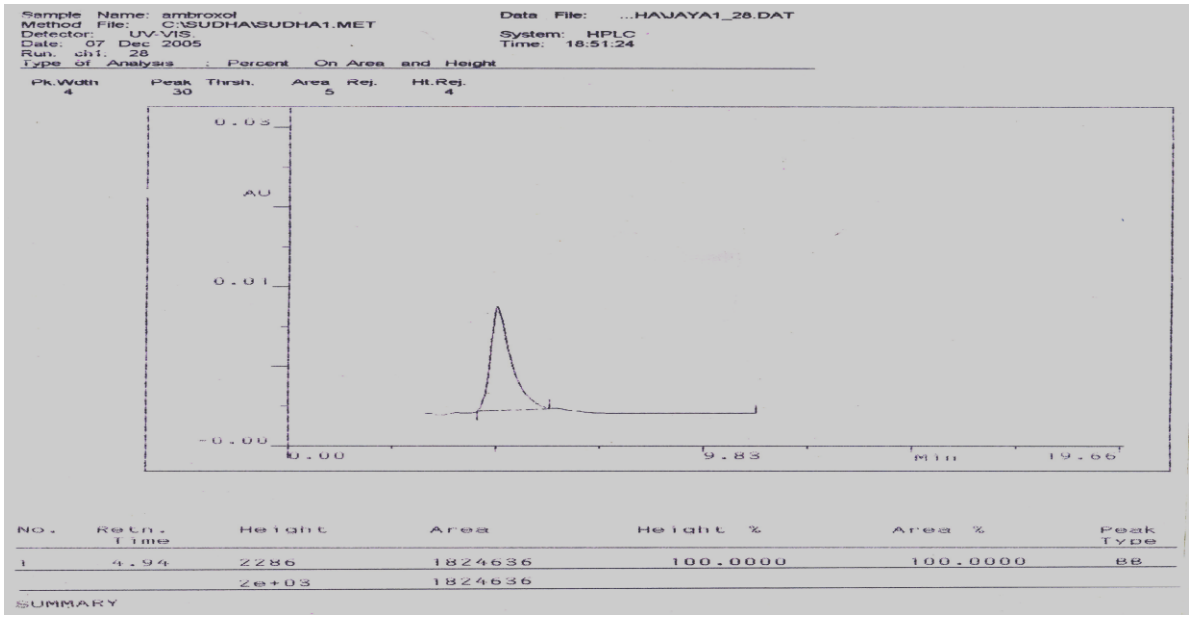
Table-1

Drug	Amount added	Amount recovered	Average recovery%
Ambroxol	13.5	13.3	98.5
	18	18.1	100.5
	22.5	22.7	100.8

Table -2

Parameter	Ambroxol
Theoretical plates	339325. per meter, 6786.5 per column for ambroxol
Tailing factor	1.0
Resolution	0.632
Calibration range	5 – 30 µg/ml

Chromatogram of sample solution



ISSN: 0975-8585

RESULTS AND DISCUSSION

The proposed method was validated as per ICH parameter precision of the proposed HPLC method was carried out by injecting replicate of six of concentration 10 µg/ml and the precision of the proposed HPLC method was found to be 0.79% for Ambroxol. The RSD values indicate that the proposed method had good precision. Accuracy of the method was also determined. The average recovery of Ambroxol was 98.5-100.8% respectively. The sample recovery in the formulation was in good agreement with the label claim. High percentage recovery showed that the method was free from interferences of the excipients used in the formulations ruggedness of the method was determined by carrying out the assay by different analysts on different days. The test results were found to be satisfactory with RSD for set of analysis on the same date being less than 0.23%. The percentage area on calculation was found to be 97.9 to 98.9% for Ambroxol. This shows that the result is reproducible. Robustness of the method was determined by carrying out the assay during which the mobile phase ratio and pH of mobile phase were altered slightly. The percentage recovery found to be 98.5 – 100.8% for Ambroxol is given in the table -1. Assay of the Ambroxol in tablet dosage form was found to 99.8% of Ambroxol [1-8].

CONCULUSION

The method was simple and had short run time of 4.94 min, which makes the method rapid. The results of the study indicate that the proposed HPLC method was simple, precise, highly accurate, specific and less time consuming

ACKNOWLEDGEMENTS

The authors are grateful to the Cipla (ltd) Mumbai for providing gift sample of bulk drug for research, principal Luqman College of Pharmacy, Gulbarga and Al-Ameen College of Pharmacy Bangalore for providing laboratory facilities.

REFERENCES

1. Perez Ruiz T, Martinez Lozano C, Sanz A, San Miguel MT. Talanta 1996 ; 43(7) : 1029-1034
2. lndrayanto G, Handajani R. J Pharm Biomed Anal 1993; 1 (8) : 781-784.
3. Narayana Reddy MKV, Kanna Rao, Swapna M. and Sankar DG. Indian J Pharm Sci 1998; 60 (4): 249 -252.
4. Narayana Reddy MKV, Kanna Rao, Swapna M, Sankar DG. East Pharm 1998; 41 (482): 125-128.
5. Flores Murrieta FJ, Hoyovadillo C, Hong E, Castanedahernandez G. J Chromatogr Biomed Appl 1989; 82 : 464-467.
6. Kitos M, Gandini C, Massonlini G, Delorenzi E, Caccialanza G. J Chromatogr 1991; 553 (1): 1-4.

ISSN: 0975-8585

7. Colombo L, Marcucci F, Marini MG, Pierfederici P, Mussini E. J Chromatogr Biomed Appl 1990; 95: 141-145.
8. Perez Ruiz T, Martinezlozano C, Sanz A, Bravo E. J Chromatogr Biomed Sci Appl 1997; 692 (1): 1999-2003.