RJC
http://www.rasayanjournal.com

RASĀYAN ***J. Chem.***
Vol.2, No.2 (2009), 361-363
ISSN: 0974-1496
CODEN: RJCABP

DETERMINATION OF EPINASTINE HYDROBROMIDE ASSAY BY POTENTIOMETRIC METHOD

Mandava V. Basaveswara Rao*, B.C.K. Reddy, T. Srinivas Rao and P. Kalyani

Sadineni Chowdariah College of Arts and Science, Maddirala, Chilakaluripet, Guntur, Andhra Pradesh, India
* E-mail: vbrmandava@yahoo.com

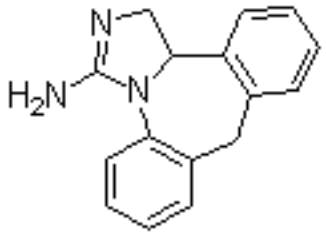
ABSTRACT

A Simple fast and precise potentiometric method has been developed for the determination of Epinastine Hydrobromide. Using calamol electrode [Lithium carbonate with ethanol bridge] and acetic anhydride: acetic acid [2:1] as medium.

Keywords: Epinastine hydrobromide, HPLC method, assay

INTRODUCTION

Epinastine Hydro bromide is a new antihistaminic drug. Chemically 3-Amino-9,13[b]-dihydro-1H-dibenz[c,f]imidazo[1,5-a]azepine. It is not reported in pharmacopoeias. Also there is no chemical method reported so far. *A* survey of literature reveals that HPLC methods[1,2,3]are reported for the determination of Epinastine hydrobromide in Quantitative determination of epinastine in plasma by high-performance liquid chromatography, Simultaneous multi response optimization applied to epinastine determination in human serum by using capillary electrophoresis, *Antiallergic drugs, azelastine hydrochloride and epinastine hydrochloride, inhibit ongoing IgE secretion of rat IgE-producing hybridoma FE-3 cells.*



HBr

Epinastine hydrobromide

EXPERIMENTAL

Instrument

MetroHM Auto titrater with calomel electrode, Tinet 2.4 Computer based data station.

Chemicals and Reagents

Epinastine Hydro bromide is procured from M/S Ranbaxy LTD. Acetic anhydride and acetic acid AR grade were purchased from SD fine chemicals.

Electrode

Calomol electrode [saturated lithium carbonate solution]

Preparation of medium

Acetic anhydride and acetic acid [2:1]

Sample solution preparation

Dissolve 0.250g in 50ml of *acetic anhydride and acetic acid [2:1]*. Carry out a potentiometric titration, using *0.1M perchloric acid*. Read the volume added between the two points of inflexion. 1ml of *0.1M perchloric acid* is equivalent to 33.02mg of $C_{16}H_{16}N_3Br$.

The results are tabulated as follows.

Table-1

S.NO	Wt taken in mg	Results in%	Limit	Mean	Standard deviation	Related standard deviation
1	250.8	100.41				
2	250.5	100.45				
3	250.9		Bet 99-101%			
4	250.7	100.43				
5	251.4			100.44%	0.02	0.0199
		100.45				
		100.46				

RESULTS AND DISCUSSION

The precision of the method is studied by making 5 standard and very low RSD values indicate good precision. The reproducibility and reliability of the method has been tested by performing recovery studies which showed good results.

Assay

The amount of epinastine hydrobromide calculated by formula (Fig.1).

```
>Start
Common variables
  Name              HCLO4_TITER
  Value                  0.1125
  Comment             NORMALITY
Method variables
  Name                 SmplSize
  Assign              &SmplSize
  Comment              SmplSize

>Calculations,     Calculations
Formulas
RS
  ASSAY
  'MET U.EP1'*'HCLO4_TITER'*100*33.022/(0.1*'SmplSize');8;2;1;
Statistic                    ON
Determinations n              2
```

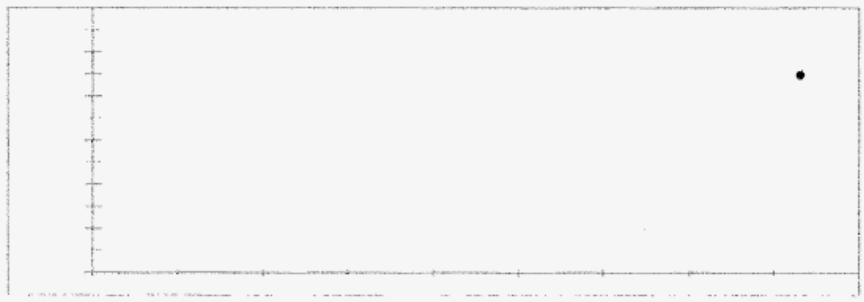


Fig.-1: Sample containing Epinastine hydromide.

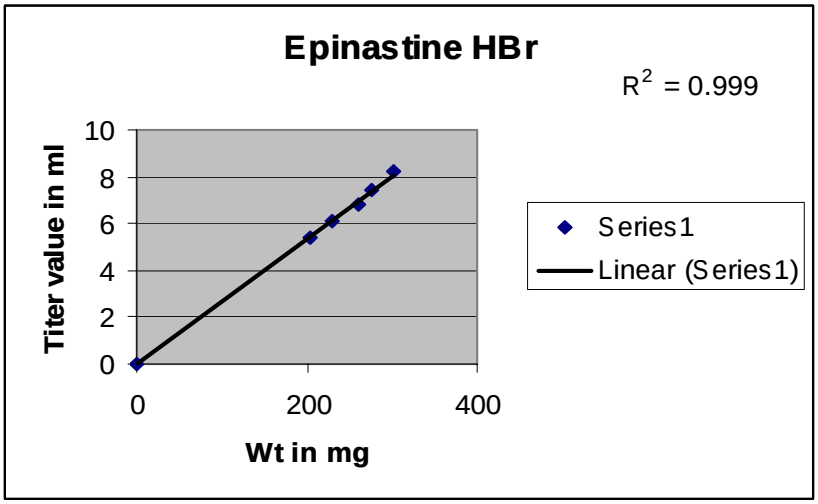
Recovery studies

To study the linearity, accuracy and precision of proposed method, recovery experiments were carried out. Known quantities of standard at two different levels were added to the pre-analyzed sample, the recovery was estimated to be more than 99%.

LINEARITY

The linearity of Epinastine hydrobromide is established by plotting a graph of peak area of standard solutions versus concentration. The linearity is found to be between 200-300mg/ml.

S.No	Wt in mg	Titer value in ml
1	0	0
2	203.8	5.4
3	228.5	6.1
4	259.9	6.8
5	276.9	7.4
6	301.5	8.2



CONCLUSION

The proposed method is very simple, therefore the method can be useful in routine quality control analysis.

REFERENCES

1. H. Ohtani, H. Kotaki, Y. Sawada and T. Iga, *J. Chromatogr B Biomed Appl*., **683**, 281 (1996).
2. K. Hanashiro, M.S.Y.T. Toshiyuki and N.O. Mariko et al., *Eur. J. Pharm*., **547**, 174 (2006).

(Received: 20 March 2009 Accepted: 3 July 2009 RJC-353)

Half of the modern drugs could well be thrown out of the window, except that the birds might eat them.

-Martin Henry Fischer