Available online www.jocpr.com

Journal of Chemical and Pharmaceutical Research

ISSN No: 0975-7384
CODEN(USA): JCPRC5

J. Chem. Pharm. Res., 2011, 3(6):945-949

High Performance Liquid Chromatographic Analysis for Determination of Eprosartan Mesylate in Bulk Drug

G. Anantha Ram[a], M. N. K. Harish[c], Y. Arthob Naik[c], J. Keshavayya[c] and K. R. Venugopala Reddy [b*]

[a] *Central Drugs Testing Laboratory, G.M.S.D Compound, Belasis Road, Mumbai Central, Mumbai, Maharashtra, India*
[b]*Department of P.G. Studies and Research in Industrial Chemistry, Sahyadri Science College (Autonomous),University College, Shivamogga, Karnataka, India*
[c]*Department of Studies in Chemistry, Kuvempu University, Jana Sahyadri, Shankaragatta, Shimoga District, Karnataka, India*

ABSTRACT

A simple precise, accurate Reverse phase High performance liquid chromatographic method has been developed for the estimation of Eprosartan Mesylate in bulk. In this method a C18, 25 cm 5µ 4.6 mm ID (Oyster) column with mobile phase consisting of Sodium acetate buffer pH 3.0: Acetonitrile (70:30) was used. The detection wavelength is 235 nm and the flow rate is 1.0 ml/min. The linearity of Eprosartan shows regration coefficient of 0.9999. The proposed method is sufficiently selective to distinguish the parent drugs and the degradation products after hydrolysis photolysis or chemical oxidation.

Keywords: HPLC. Eprosartan Mesylate . Acetonitrile**.**

INTRODUCTION

Eprosartan Mesylate is a “Angiotension II receptor antagonist” used for the treatment of high blood pressure. As with other angiotensin II receptor antagonists, eprosartan is generally better tolerated than enalapril .

Literature survey reveals that the drug is not official in any pharmacopoeia. Very few chromatographic method has been described for the determination of Eprosartan Mesylate in

biological samples, which include determination of Eprosartan in human plasma by using solid phase extraction RP-HPLC method with photometric detector.

EXPERIMENTAL SECTION

2.1. Chemicals

HPLC-grade Acetonitrile(Merck),Triethylamnie, Sodium acetate ,Phosphoric acid , Mille Q water ,Eprosartan Mesylate and 0.45 micron filters

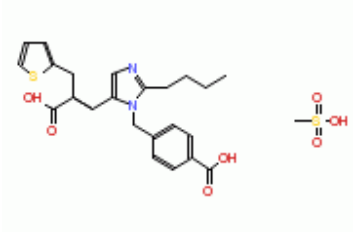

Fig 1. Chemical structure of Eprosartan Mesylate[1]

Molecular formula : C_{23} H_{24} N_2 O_4 S. CH_4 O_3 S
Molecular weight : 520.63 gm
IUPAC Name : 4-[[2-butyl-5-(2-carboxy-3-thiophen-2-yl-prop-1-enyl)-imidazol-1-yl] methyl] benzoic acid. Mesylate

2.2. Instruments:

The separation was carried out on E-Merck Hitachi High performance Liquid Chromatographic system equipped with isocratic solvent delivering pump L-7100, an automatic sample injection device L-7200, a variable wavelength UV-Visible detector L-7400 controlled by interface module with HSM software. A C18, 25 cm 5µ 4.6 mm ID (Oyster) column was selected and the flow rate of mobile phase is 1.0 ml/min, system was operated at room temperature (25 ± 2^0C)

2.3. Preparation of mobile phase:

A mobile phase was composed by 0.1 M Sodium acetate containing 0.4% Triethyl amine pH adjusted to 3.0 with phosphoric acid and Acetonitrile in the ratio of 70:30. The mobile phase was filtered with 0.45 micron filters and degased.

2.4. Standard and Sample solutions:

The reference standard, Eprosartan Mesylate stock solution (250mcg/mL) was prepared in mobile phase. From this stock solution 25 ,37.5 ,50 , 62.5 and 75 µg/mL concentration solutions prepared for linearity study (at 50,75 , 100,125 ,and150 % level).

The sample concentration 50 mcg/mL, for assay and 250 mcg/mL concentration for stability study was prepared.

2.5. Accuracy and Precision assay:

Three weight of sample taken in three volumetric flask injected each solution three times and standard solution six times within the same day to obtain the repeatability and six times over different days to obtain the intermediate precision. The percentage of relative standard deviations

(RSDs %) of the data obtained were calculated. The LOQ and the LOD were calculated according to USP [2].

A graph of concentration of Eprosartan Mesylate v/s absorbance was plotted, and coefficient of variation for Eprosartan Mesylate was found to be 0.999. The regration analysis of the calibration data carried out to determine the relationship between the absorbance concentration and detector response [6].

Table. I : Concentration and peak area

% level	mcg/mL	Average area
50	25	599903
75	37.5	904835
100	50	1204388
125	62.5	1508401
150	75	1796539

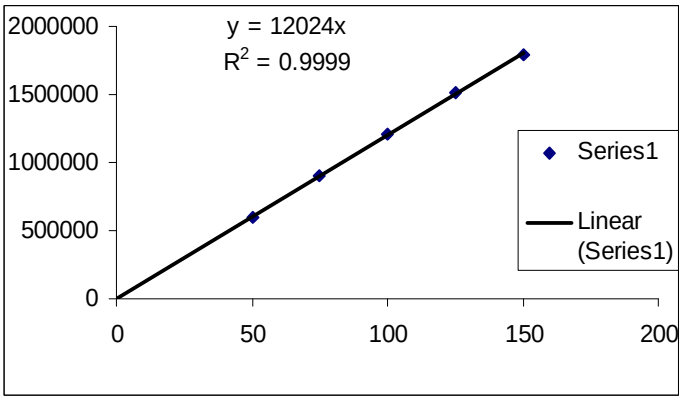

Fig .2 Linearity

RESULTS AND DISCUSSION

3.1. **Assay:**

The standard and sample solutions (20mcl) were injected in to Liquid chromatography. From the peak area of Eprosartan Mesylate the assay of sample is calculated. The values are in Table. II

Table. II

Experiment	% of Assay
I	99.53
II	99.35
III	99.68
Average	99.52
SD	0.165227
% of RSD	0.17

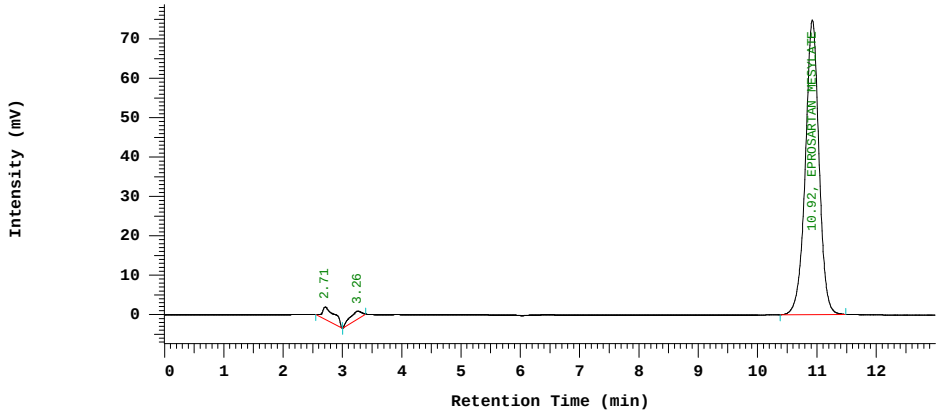

Fig.3 Chromatogram of Eprosartan Mesylate standard at RT 10.92 minutes.

3.2. Validation summary:

Table. III

System Suitability Test (SST)	Response
Theoretical plates (N) Tailing factor	8500 1.05
Linearity range Coefficient of variation(r 2)	25 to 75 mcg/mL 0.9999
Accuracy	99.45
Limit of quantitation(LOQ) (mcg/mL)	25 mcg/mL
Limit of detection (LOD) (mcg/mL)	5 mcg/mL

3.3. Stability in solution:

The stability Eprosartan Mesylate in solution containing mobile phase have been determined by keeping one sample in refrigerator and other in a tightly capped volumetric flask placed at ambient temperature under normal lighting conditions. The samples were checked for assay on two successive days of storage and compared with freshly prepared sample. The RSD values of experiments were found to be below 2.0% in both cases. This indicated that the Eprosartan Mesylate is stable in the solution [8].

3.4. Stability Study:

To check that the stability of the developed method the drug was subjected to stressed conditions like treatment with HCl, NaOH, Hydrogen peroxide, at ambient temperature for one hour. The solutions prepared after subjecting to the stressed conditions [7] was analyzed by the above developed chromatographic condition using Photo Diode Array Detector it was observed that the drug and degradation products were well resolved [4]**.**

3.5. Robustness of the method:

The robustness was evaluated by variation in the mobile phase constituents, flow rate and pH and found that the results were not adversely affected by these changes.

CONCLUSION

Precise, accurate method was developed and validated for the determination of Eprosartam Mesylate in bulk**.** The developed method was checked for selectivity and specificity by carrying out forced degradation studies [7]. Analytical data of the stability studies indicates that the developed method is selective and specific for monitoring degradation studies.

Acknowledgement
Authors are thankful to Directors & Officers of CDTL-Mumbai**.** Department of Studies in Industrial Chemistry, Kuvempu-University & Department of P.G. Studies and Research in Industrial Chemistry Sahyadri Science College Shimoga for providing all the facilities during research work.

REFERENCES

[1] The Merck Index. X111th edition (Monograph N0: 9209) Page No: 645
[2] US.Pharmacopeia/NF -30/25 **2007** Vol 1
[3] Quanitative estimation of Eprosartan in blood sample by Liquid chromatography (using SPE Catridge), Page no 225 .Lunn Willey Interscience.
[4] Validating Chromatographic methods By David M. Bliesner
[5] ICH, Q1A Stability Testing of New Drug Substances and products, in proceedings of International Conference on Harmonization Geneva **1993**.
[6] Hand book of Pharmaceutical Analysis by HPLC. By Satinder Abuja. Michel W. Dong
[7] ICH, Q2B Validation of Analytical Method procedure: Methodology, in proceedings of International Conference on Harmonization Geneva **1996**.
[8] Drug Stability: Principles and Practices, Edited by Carsensen, J., 3rd Ed., Marcel Dekker Inc **2000**,107 329.
[9] Rao, G R, Avadhanulu A B, Giridhar R. *Indian drugs*. July-**1998** 25(10) 418-220
[10] A.A. Gordus Theory & problems of Analytical Chemistry Schaums outline Series, McGraw Hill **1997** pp.22.30