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VALIDATED RP-HPLC METHOD AS A TOOL FOR THE ESTIMATION OF EPROSARTAN IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

A simple, specific, accurate, precise and sensitive Reverse phase high performance liquid chromatographic method has been developed for the quantitation of Eprosartan mesylate in both pure and pharmaceutical dosage forms. An Phenomenex Luna 5 µ C-18(2) 100A column having 250 x 4.6 mm internal diameter in isocratic mode with mobile phase containing Acetonitrile : 1% Diethyl amine : 1% Glacial acetic Acid (13 : 3 : 4 v/v/v). The flow rate was 0.6 mL/min and the effluents were monitored at 242 nm. The retention time was 4.757 min. The linearity was in the range of 5-20 µg/mL. This method was validated for linearity, precision, limit of detection, limit of quantitation and accuracy. Statistical analysis proves that the method is reproducible and selective for the estimation of the said drug.

Key words: RP-HPLC, Eprosartan Mesylate, Validation, Mobile phase.

INTRODUCTION

Eprosartan mesylate, an angiotensin II receptor antagonist (ARB), is used alone or with other antihypertensive agents to treat hypertension. Eprosartan mesylate competes with angiotensin II for binding at the AT1 receptor subtype. As with other angiotensin II receptor antagonists, Eprosartan mesylate is generally better tolerated than enalapril (an ACE inhibitor), especially among the elderly[1].

The chemical name of Eprosartan mesylate is 4-({2-butyl-5-[2-carboxy-2-(thiophen-2-ylmethyl) eth-1-en-1-yl]-1*H*-imidazol-1-yl} methyl) benzoic acid (Fig. 1). Several analytical methods that have been reported for the estimation of Eprosartan mesylate in

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biological fluids or pharmaceutical formulations which includes ESi/MS and NMR[2], LC/MS/MS[3], HPLC[4], spectrophotometric[5] and derivative spectrophotometry[6] methods. The objective of the work was to develope simple, accurate, precise and economic RP-HPLC method with lesser run time to estimate the eprosartan mesylate in bulk and pharmaceutical dosage forms.

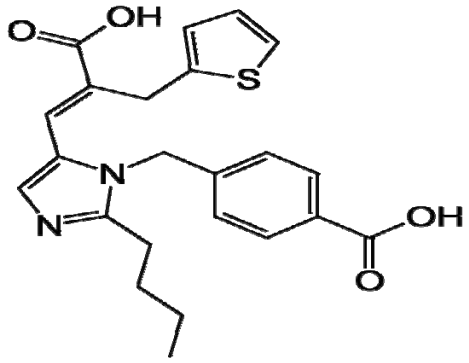

Fig. 1: Chemical Structure of Eprosartan Mesylate

EXPERIMENTAL

Material and methods

The liquid chromatographic system consisted of following components: A Shimadzu HPLC model containing LC-20AT (VP Series) Pump, variable wavelength PDA detector and Hamilton syringe (50 µL).

Chromatographic analysis was performed using empower software on a Phenomenex Luna 5 µ C-18 (2) 100A (250 x 4.6 mm, 5 µm) column. The mobile phase consisting of Acetonitrile: 1% Diethyl amine: 1% Glacial acetic Acid (13 : 3 : 4 V/V). The optimized chromatographic conditions are summarized in Table 1. The standard solution of Eprosartan mesylate was prepared by dissolving 10 mg of Eprosartan in 10 mL of diluent (50 mL of Acetonitrile mixed with 50 mL of 1% diethyl amine) and again 1 mL of above solution is diluted to 50 mL using the same diluent. The mobile phase and the drug solution were soinicated for 10 min and filtered using micropore filter paper of 0.45 µ size. The various dilutions of Eprosartan mesylate in the concentration of 5-20 µg/mL were prepared. The solutions were injected using a 20 µL fixed loop in to the chromatographic system at the flow rate of 0.6 mL/min and the effluents were monitored at 242 nm, chromatograms were recorded. The Eprosartan mesylate was eluted at 4.757 min as shown in Fig. 2 the method

was extended for determination of Eprosartan mesylate in pharmaceutical dosage form. The pharmaceutical dosage form containing 400 mg strength was taken.

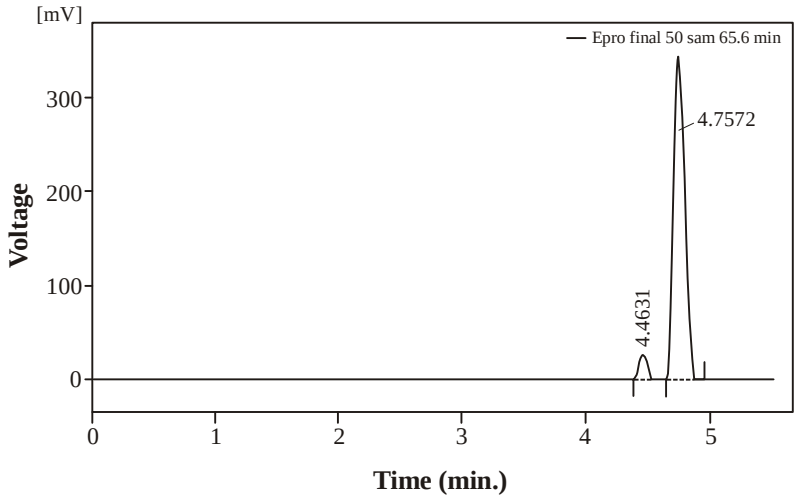

Fig. 2: Typical RP-HPLC Chromatogram of Eprosartan Mesylate by the proposed method

Table 1: Optimized chromatographic conditions for the proposed method

Parameters	Optimized condition
Column	Phenomenex Luna 5 µ C-18 (2) 100 A (250 x 4.6 mm, 5 µ)
Mobile phase	Acetonitrile : 1% Diethyl amine : 1% Glacial acetic acid (13 : 3: 4)
Flow rate	0.6 mL / min
Injection volume	20 µL
Detection	242 nm
Temperature	Ambient
Retention time	4.757 min

20 tablets of Eprosartan mesylate (containing 400 mg) were weighed and powdered in glass mortar and the powder equivalent to 25 mg of Eprosartan Mesylate was transferred into 25 mL volumetric flask and diluent was used to make up the volume to 25 mL. 2 mL of above solution was made up to 100 mL with diluent. Flask was soinicated for 10 min and the solution was filtered using micropore filter paper of 0.45 µ size. From this solution various dilutions were made with the diluent, which were analysed. The concentration of the drug in

tablet sample solution was calculated by comparing with peak area of standard. The proposed method was validated as per the ICH guidelines.

RESULTS AND DISCUSSION

A suitability test was applied to representative chromatograms for various parameters. The results obtained were within acceptable limits (Table 2). Thus, the system meets suitable criteria. The calibration curve was obtained for a series of concentration in the range of 5-20 µg/mL and it was found to be linear. The precision was measured in terms of repeatability, which was determined by sufficient number of aliquots of a homogenous sample. The % RSD was found and lying with in 2. This showed that the precision of the method was satisfactory. The accuracy of the method was inferred by establishing the precision and linearity studies of the standard. The % RSD was less than 2.0. This showed that the recoveries of Eprosartan mesylate by the proposed methods are satisfactory. The % RSD values were calculated from precision study was less than 2.0. Limit of Detection (LOD) and Limit of Quantitation (LOQ) were determined by the proposed methods. The results of validation parameters are summarized in Table 3. The results of recovery studies obtained by the proposed method were validated by statistical evaluation and are given in Table 4.

Table 2: System suitability test parameters for the proposed method

Parameters	Values	Required limits
Retention time	4.757	RSD ≤ 1%
Theoretical plates	10360.74	N > 2000
Tailing factor	1.2	T ≤ 2

Table 3: Summary of validation parameters for the proposed method

Parameters	Values
Limit of detection (µg/mL)	0.1358
Limit of quantitation (µg/mL)	0.4074
***Precision (% RSD)**	
Intra-day precision	0.9330
Inter-day precision	1.2776
*mean of 6 readings	

Table 4: Assay Results of Eprosartan Mesylate tablets using proposed method

Brand used	Labeled amount (mg)	Amount found (mg)	% Recovery
Tablet (eprozar 400)	400	399.50	99.88

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