UV Spectrometric Method for the Estimation of Eprosartan mesylate in Bulk and Pharmaceutical Formulation

Arpan Ramkrushna Ghule.[1*], Dattatraya Manohar Shinkar.[1], Ravindra Bhanudas Saudagar[2]

1. Department of pharmaceutics, KCT'S RGS College of pharmacy, Anjaneri, Nashik.422213.Maharashtra, India.
2. Department of pharmaceutical Chemistry, KCT'S RGS College of pharmacy, Anjaneri, Nashik.422213.Maharashtra, India.

E-mail: arpanghule21@gmail.com

ABSTRACT:

In this study, a simple, sensitive and highly accurate ultra-violate spectrophotometric method has been developed and validated for determination of Eprosartan mesylate in bulk and pharmaceutical formulation. The method is based on the measurement of the absorbance of Eprosartan mesylate solution in methanol: phosphate buffer PH 6.8(1:9) at 234nm in the wavelength range of 200-400nm.Beer's law was obeyed in the concentration range of 10-100 µg/ml.The slope, intercept and correlation coefficient were also calculated. Result of percentage recovery shows that the method was not affected by the presence of common excipients in tablets. The developed method was validated in terms of accuracy, precision, linearity, limit of detection, limit of quantification which proves suitability of proposed method for routine estimation of Eprosartan mesylate in bulk and pharmaceutical formulation.

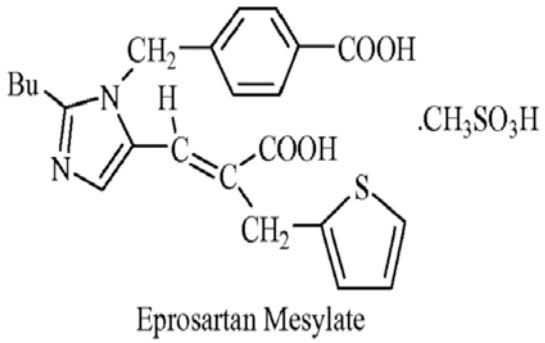
Keywords: Eprosartan mesylate, UV Spectrophotometer, Estimation, Tablet (TEVETEN).

INTRODUCTION:

Eprosartan antagonizes angiotensin II by blocking the angiotensin type I (AT_1) receptor. Angiotensin II is a potent vasoconstrictor, the primary vasoactive hormone of the rennin-angiotensin system and an important component in the pathophysiology of hypertension. It also stimulates aldosterone secretion by the adrenal cortex. Eprosartan blocks the vasoconstrictor and aldosterone-secreting effect of angiotensin II by selectively blocking the binding of angiotensin II to the AT_1 receptor found in many tissues (e.g., vascular smooth muscle, adrenal gland). Eprosartan mesylate is poorly absorbed after oral administration Peak plasma concentration is attained after 1-2 hours of oral administration in fasted state. Eprosartan is not metabolized by the cytochrome P450 system. Eprosartan is eliminated by biliary and renal excretion, primarily as unchanged compound. Less than 2% of an oral dose is excreted in the urine as a glucuronide. Terminal elimination half life of Eprosartan mesylate is 5 to 9 hrs. Eprosartan is Soluble in alcohol, Insoluble in water. Daily dose is 400-800 mg in single or two divided doses.

EPROSARTAN MESYLATE:

Structure:



Eprosartan Mesylate

Structure of Eprosartan Mesylate

Literature survey reveals that several spectrophotometric, LC-MS, HPTLC, HPLC, and methods have been reported for the estimation of Eprosartan mesylate in pure and tablet dosage form. The scope of present investigation was to develop and validate UV spectroscopic method for quantification of Eprosartan mesylate in bulk and pharmaceutical formulations.

MATERIALS AND METHOD:

Materials:

Eprosartan mesylate obtained as a gift sample from Milan pharmaceutical Ltd, Sinnar, and Nashik, India. All analytical grade chemicals and solvents were supplied by R G Sapkal College of pharmacy, Nashik, India. Distilled water and phosphate buffer 6.8 was used to prepare all solutions.

Equipment:

The UV-Visible spectrophotometer (Jasco-630) with data processing system was used. The sample solution was recorded in 1cm quartz cells against solvent blank over the range 200-400nm.A Citizen electronic analytical balance were used for weighing the sample. An ultrasonicator bath (PCI Analytics Pvt.Ltd.)Was used for sonicating the tablet powder.

Development of method:

Accurately weighed 10 mg of Eprosartan mesylate was solubilized by 1ml of methanol in a 10ml volumetric flask, and phosphate buffer PH 6.8 was added to make up the volume so as to give stock solution of concentration 100 µg/ml.The standard solution were diluted with phosphate buffer PH 6.8 to obtain various dilutions(10,20,30,40,50,60,70,80,90,100 µg/ml) in standard volumetric flasks(10ml).The dilution were scanned in the wavelength range of(200-400nm).The maximum of Eprosartan mesylate was found at 234nm.The linear relationship was observed over the range of 10-100 µg/ml.Absorbance were noted at 234nm against PH 6.8 phosphate buffer as a blank. A calibration graph of the absorbance versus drug concentration of the drug was plotted and represented in figure1.

Procedure for dosage form:

For analysis of commercial formulations, twenty tablets were taken and powdered. Tablet powder equivalent to 10 mg of Eprosartan mesylate was dissolved in small quantity of methanol into a 100 ml volumetric flask and final volume was made up to 100ml with PH 6.8 phosphate buffer and sonicated for 30 min.Then the absorbance of solution (after suitable dilution) was measured at 234nm using uv visible spectrophotometric (Jasco-V630) against PH 6.8 phosphate buffer as a blank. The % drug content was calibration calculated with the help of calibration curve (n=5).

VALIDATION OF THE PROPOSED METHOD:

The proposed method was validated according to the ICH guidelines:

Linearity :(calibration curve)

The developed method validates as per ICH guidelines. The plot of absorbance verses concentration is shown in figure. It can be seen that plot is linear in the concentration range of 10-100 µg/ml with correlation coefficient (R^2) of 0.988.

Precision :(repeatability)

Intraday and interday precision for was determined by measurement of the absorbance for three times on same day and on three different days. The relative standard deviation for replication of sample solution was less than 2% which meet the acceptance criteria for established method. The obtained results are presented in table 1.

Accuracy (recovery study)

Recovery studies were carried out by adding a known quantity of pure drug to the preanalysed formulations and the proposed method was followed. From the amount of drug found, percentage recovery was calculated as per ICH guidelines. The data were presented in table 2.

LOD and LOQ

The limit of detection (LOD) and limit of quantification (LOQ) of the drug were separately determined based on method of the intercept and the average value of slope. (i.e. 3.3 for LOD and 10 for LOQ) ratio using the followed equations designated by ICH guideline.

$$LOD = 3.3\ \sigma/s \qquad LOQ = 10\ \sigma/s$$

Where, σ = the standard deviation of the response, S = slope of the calibration curve.

RESULTS AND DISCUSSION

Beer's law is obeyed over the concentration range of 10-100 µg/ml, using regression analysis the linear equation y = 0.006x+0.055 with a correlation coefficient of 0.988. The limit of detection was found to be 0.4547µg/ml. The limit of quantification was found to be 1.5056 µg/ml.Precision was calculated with intra and interday variation. Recovery study was performed on formulation and %RSD was found. The optical parameter such as Beer's law limit, slope and intercept values were calculated and given in table3.Method was validated for accuracy and precision. The accuracy method was proved by performing recovery study in commercial available formulation. The result were given in table2 and shows relative standard deviation of less than 2% was observed

for analysis of replicate samples, indicating precision and reproducibility. The percentage recovery study indicating that there is no interference from excipients present in formulation. The result obtained were good agreement with the label claims of marketed preparation. The result of analysis of commercial tablet and the recovery study of the drug suggested that there is no interference from any excipients such as starch, lactose, magnesium stearate which are commonly present in tablet.

CONCLUSION:

The simple spectrophotometric method for determination of Eprosartan mesylate have been developed and validated as per ICH guidelines. The developed method is found to be sensitive, accurate and reproducible and can be used for the routine quality control analysis of Eprosartan mesylate in bulk and pharmaceutical formulation.

REFERENCES:

[1] http://www.drugbank Eprosartan (DB00876)
[2] Q2A: Text on; Validation of analytical procedures. In International Conference of Harmonization. Federal register.1995; 60(40):11260-11262.
[3] Q2B: Validation of analytical procedures: Methodology, Avaibility.In International conference on harmonization. Federal Register.1997; 62(96):27463-27467
[4] The Merck Index, Merck and Co.INC Whitehouse station, NJ.2001; 13th edition: pp.3635
[5] Shital Shridhar Gite et.al.UV spectroscopic method for estimation of Atenolol in bulk and pharmaceutical formulations.Am.J.PharmaTech Res.2013;3(6),2249-3387
[6] Shinkar Dattatraya Manohar et.al.Development of UV spectrophotometric method for estimation of Carvedilol in bulk and pharmaceutical formulations Asian.J.Reaserch Chem.6 (10); Oct 2013, 956-959.
[7] Ananadkumar K et.al.Development and validation of Eprosartan Mesylate and Hydrochlorothiazide in pure and fixed dose combination by UV spectrophotometry. Int.J.Pharma and Res.vol- 01,Issue-01,Jan-Mar-2011,22-27
[8] Vijaya Santhhi D.et al.A Novel Estimation of Eprosartan Mesylate in pure and in Tablet Formulations by simple UV Method.Research.J.Pharma.and Tech;4(7):July-2011,1069-1072
[9] M M Kamila, N Mondal et al.Spectrophotometric determination of Eprosartan mesylate in raw material and experimental tablets. Indian journal of chemical technology,vol.15,mar 2008, pp194-196
[10] Vinayak J.Dalvi et al.Analytical Methods For Estimation of Eprosartan mesylate ,An International J. of pharmaceutical sciences,vol.4,Issue 4,Jul-Sept 2013,371-387

Figure:

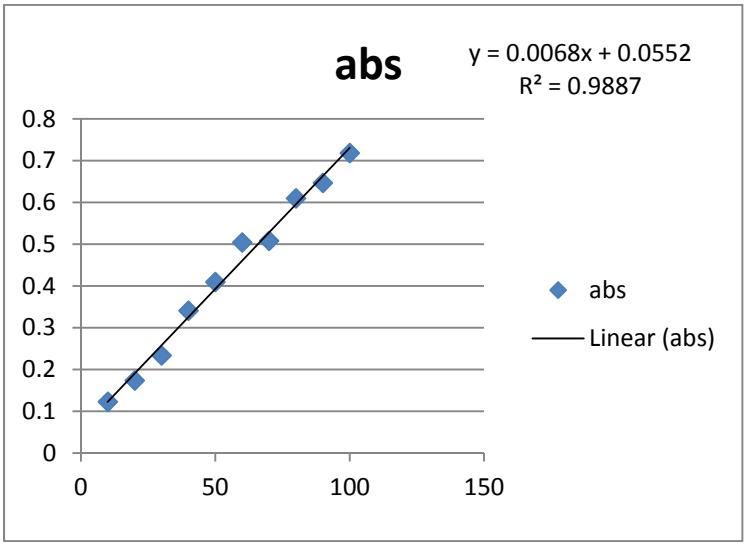


Figure1: Calibration curve of Eprosartan mesylate at 234nm

Tables:

Table 1: Precision study for proposed method

concentration µg/ml	Absorbance Mean	Standard deviation	% Relative standard deviation
Intraday Precision (n=3)			
20	**0.0868**	**0.00512**	**5.8**
40	**0.1023**	**0.00406**	**3.9**
60	**0.1163**	**0.00279**	**2.3**
80	**0.1559**	**0.00411**	**2.6**
100	**0.1830**	**0.0058**	**3.1**
Interday Precision(n=3)			
20	**0.0526**	**0.00551**	**1.04**
40	**0.0788**	**0.00375**	**4.7**
60	**0.0989**	**0.00122**	**1.2**
80	**0.1183**	**0.00325**	**2.7**
100	**0.1581**	**0.00595**	**3.7**

Table 2: Recovery study

Sr.No	Label claim, mg/ml(teveten)	Amount of standard added,mg	Total amount recovered,mg	% Recovery	Standard deviation	%Relative standard deviation
1	400	5	404.95	99.98 %	0.002645	0.6875
2	400	10	410.10	100 %	0.002647	0.3519
3	400	15	413.90	99.73 %	0.003214	0.6059
4	400	20	419.20	99.8%	0.003520	0.8610
5	400	25	424.10	99.7 %	0.003810	0.7210

Table 3: Optical parameter for determination of Eprosartan Mesylate

Sr.No	Parameter	Data
1	λ max	234nm
2	Beer's law limit	10-100 µg/ml
3	Regression equation	Y=0.006x+0.055
4	Correlation coefficient	R^2 =0.988
5	Slope	0.006
6	Intercept	0.055
7	Limit of detection	0.4547 µg/ml
8	Limit of qualification	1.5056 µg/ml