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Validated New Spectrophotometric Methods for the Estimation of Eprosartan in pure and Pharmaceutical Dosage Forms

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ABSRACT

Two simple, precise and accurate spectrophotometric methods have been developed for the estimation of Eprosartan in pharmaceutical formulations. Eprosartan exhibits maximum absorbance (λ_{max}) at 233.0 nm (Method A). In Method B (D_1) is a first derivative method showing minima at 222.0 nm. The drug obeys the Beer-Lambert's law in the concentration range of 1-70 µg/ml in these two methods with an apparent molar absoptivity and sandell's sensitivity of 23.0 x $10^4$and 0.018 in the method A, 0.726 x 10^4 and 0.588 in the method B. The methods were validated according to the ICH guidelines and can be successfully applied to estimate Eprosartan in pharmaceutical dosage forms. Validation of the method yielded good results in the range (1-70ppm) with linearity (r^2=0.999 and 0.999), precision and accuracy.

Keywords: Eprosartan, Derivative spectroscopy and ICH.

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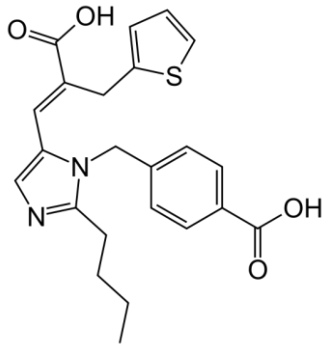
INTRODUCTION

Eprosartan (eprosartan; Fig. 1) is a highly selected, non peptide angiotensis-II antagonist. The compound has been shown to inhibit angiotensin-II included vasoconstriction in preclinical species and cause reductions in systolic and diastolic blood pressure at peak effect after dosing in clinical patients. It is currently being developed for the treatment of hypertension as other compounds of the angiotensin-II receptor antagonists (ARA-II) family. These are safe and effective agents for the treatment of hypertension and heart failure, either alone or in combination with diuretics. Therefore, they have been proposed as an alternative to the traditional angiotensin-converting enzyme (ACE) inhibitors [1].



4-({2-butyl-5-[2-carboxy-2-(thiophen-2-ylmethyl)eth-1-en-1-yl]-1*H*-imidazol-1-yl}methyl)benzoic acid

The literature survey revealed that there are so many methods for the estimation of Eprosartan in human plasma Ferreiroset al. [2,3] and Lundberg et al. [4] reported the limit of quantification of plasma eprosartan using SPE-HPLC-UV method to be 150 and 10 ng/mL, respectively. Hillaert et al. [5–7] reported the determination of eprosartan using a capillary zone electrophoretic method. [8] and determination of eprosartan in human plasma and urine by LC/MS/MS [9] But only one article have reported the determination of eprosartan by UV spectrophotometric determination by choosing solvent as methanol by UV in experimental tablets.[10] The purpose of this study was to improve the validated method with UV spectrophotometer for the determination of eprosartan in the pure and tablet dosage forms according to ICH guidelines[11].

MATERIALS AND METHODS

Chemicals and Reagents

Eprosartan gift sample was supplied by MSN Laboratories (India) and the commercial formulations were purchased from local market. Methanol was supplied by Merck chemicals.

Instrumentation

A double beam UV-VIS spectrophotometer (UV-1800, Shimadzu, Japan) connected to computer loaded with spectra manager software UV Probe was employed with spectral band-width of 1nm wavelength accuracy of ± 0.3 nm with a pair of 10 mm matched quartz cells. All weights were taken on electronic balance (Denver, Germany).

Methodology

Preparation of stock solution

The stock solution of EPS was prepared by dissolving accurately 10mg of drug in 0.1N methanol in a 10 ml volumetric flask to obtain a concentration of 1000 µg/ml. From this solution, 2.5 ml was taken and diluted with methanol in a 25 ml volumetric flask to prepare a working standard solution (100µg/ml).

Method A (Zero-derivative spectrometry)

Series dilutions of standard solutions were prepared in 10 ml volumetric flasks with methanol to get the concentration ranging from 1-70 µg/ml. The above solutions were scanned over the range of 400 nm to 200 nm against reagent blank. The λ_{max} was found to be 233.0 nm (Figure 1). The present study was carried out at 233.0 nm as the results were in good agreement with Beer-Lambert's law. The calibration curve was constructed by plotting concentration against absorbance at 233.0 nm (Figure. A). The absorbance characteristics were shown in Table 1.

Table 1. Optical characteristics of Eprosartan

Parameters	Method A	Method B
Beer-Lambert's range (µg/ml)	1-70	1-70
λ_{max} (nm)	233.0	222.0
Molar extinction coefficient (Litre/mol^{-1}.cm^{-1})	23.0 x 10^4	0.726 x 10^4
Sandell sensitivity (µg/cm^2/0.001 absorbance unit)	0.018	0.588
Slope	0.056	0.001
Intercept	0.023	0.001
Correlation coefficient	0.999	0.999

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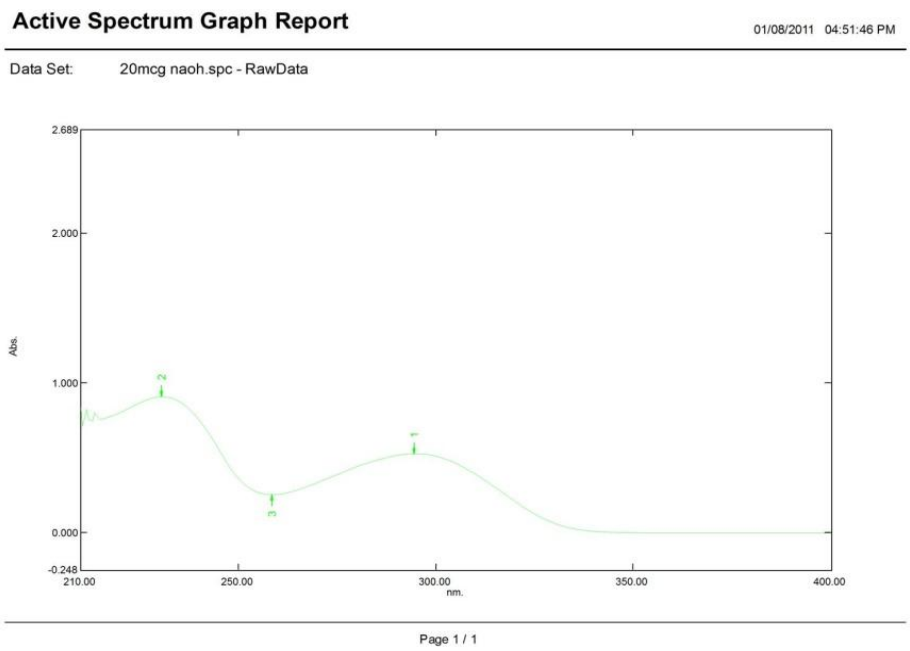
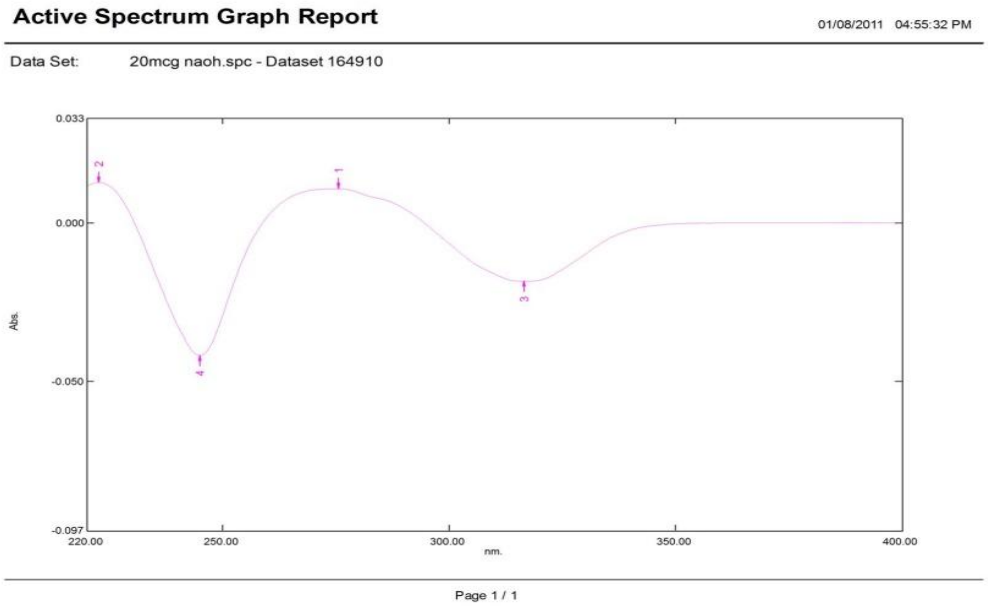


Figure 1: Zero-derivative Absorption spectrum of Eprosartan in Methanol (20 µg/ml)



[A]

Figure 2: First-derivative absorption spectrum of Eprosartan in Methanol (1-70 µg/ml).

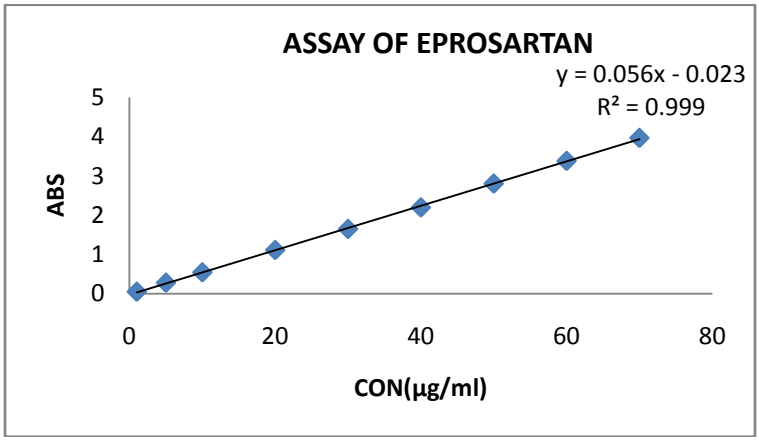
Method B (First-Derivative spectrometry)

All the above obtained zero-order spectrums were derivatised to get first-order derivative spectra (Figure. 2). The dA/dλ of the corresponding maxima and minima at 222 (max) nm were measured and plotted against concentration (Figure. B). The absorbance characteristics were shown in Table 1.

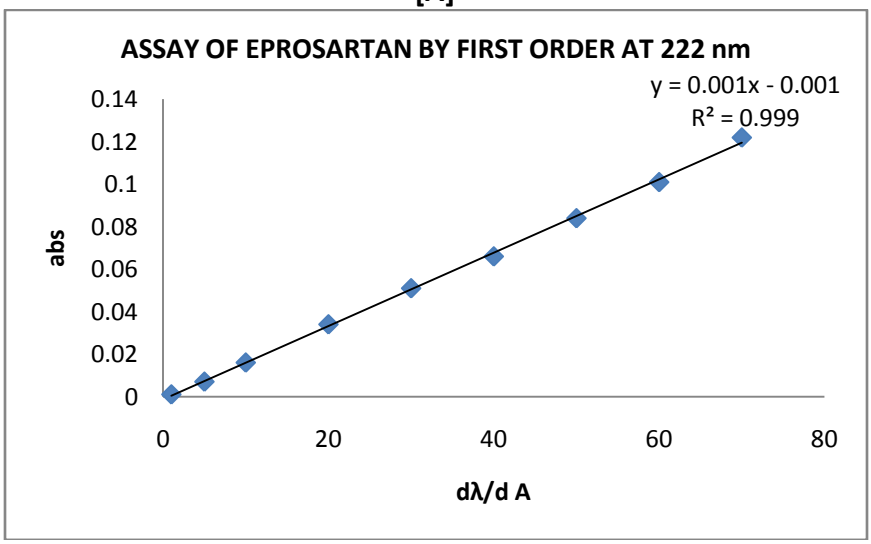
Estimation of Eprosartan in tablets

Table 2: Analysis of commercial formulation (Tablets)

Formulation	Labeled amount (mg)	Amount found (mg)	% Recovery
Brand I	20	21.477	107.385 ± 0.113



[A]



[B]

Figure Calibration curves of Eprosartan in Methanol (Method A and B)

Twenty tablets were weighed, finely powdered and powder equivalent to 25 mg of the drug was transferred to a 25 ml volumetric flask and dissolved in methanol, sonicated and filtered through 0.42 mm Wattmann filter paper. Different sample solutions were prepared and analyzed against blank (Table 2).

Method validation

Precision

The Inter-day precision was determined on three different days at three different levels (5, 10, 50 µg mL^{-1}) and the Intraday precision was determined at three different levels (5, 10, 50 µg mL^{-1}) by the same analyst. The %RSD values were found to be in the range 0.415-0.427 (Intraday) and 0.672-0.993 (Interday) which are less than 2% indicating that the mehtod is more precise.

Accuracy

Recovery studies were carried out by adding different amounts (80%, 100%, 120%) of bulk samples of EPS within the linearity range to pre-analyzed formulation as per ICH guidelines and the %RSD values were found to be less than 2% indicating that the method is more accurate.

RESULTS AND DISCUSSION

Eprosartan obeys Beer-Lambert's law in the concentration range of 1-70 µg/ml in all the two methods. The %RSD values in precision study were found to be less than 2% indicating that the mehtod is more precise. The %RSD values in accuracy study were found to be less than 2% indicating that the method is more accurate. Therefore the present methods can be employed for the estimation of Eprosartan in pharmaceutical formulations successfully.

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