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Development of new UV spectrophotometric method for the estimation of enalapril maleate in bulk and tablet dosage form

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ABSTRACT

A new, simple, specific, precise and accurate spectrophotometric method has been developed for determination of Enalapril in bulk and tablet dosage form. The drug shows absorption maxima at 226 nm. The method was statistically validated according to I.C.H.Guidelines. % Mean recovery obtained was 99.31%; coefficient of variance found to be less than 2% and linearity coefficient was 0.9985. Linear response obtained for Enalapril was in the concentration range of 10-90 µg/ml. The limit of detection and limit of quantification for Enalapril was found to be 0.224 µg/ml and 0.678 mg/ml, respectively.

Key words : Enalapril Maleate, Spectrophotometry, Validation.

Enalapril maleate is chemically N-[N-[(S)-1-ethoxycarbonyl-3-phenyproyl]-$_L$-anlanyl]-$_L$-proline hydrogen maleate[1]. It is angiotensin converting enzyme inhibitor[2] used in essential and renovascular hypertension, and in congestive heart failure. The drug is official in B.P.[3] and I.P.[1] Several methods such as High Performance Liquid Chromatography[1,3,4] and Spectrophotometric[5] have been reported for the estimation of enalapril maleate. In the recent communication, a new, simple, specific and accurate spectroscopic method is reported for the determination of enalapril maleate in bulk and tablet dosageform.

MATERIALS AND METHODS

Instrumentation:

Systronics UV-visible spectrophotometer with 1 cm matched quartz cells was used for all absorbance measurements.

Reagents:

Sodium hydroxide AR grade was procured from Loba Chemie Ltd., Mumbai. Double distilled water was used for preparing 1N sodium hydroxide solution. Enalapril Maleate used as API was gift sample from M/s Intas Pharmaceuticals Ltd., Matoda, Ahemdabad, India. Different brands of Enalapril Maleate were procured from the local market.

Preparation of stock solution, selection of analytical wavelength and plotting of calibration curve:

Enalapril maleate (10 mg) was accurately weighed and dissolved in 1N sodium hydroxide solution to prepare stock solution having concentration of 100 µg/ml. From this stock solution, working standard solution of drug was prepared by appropriate dilution.

Working standard solution was scanned in entire UV range to determine λ-max. The λ-max. for enalapril maleate was found to be 226 nm. Standard solutions were prepared having concentration 10, 20, 30, 40, 50, 60, 70, 80 and 90 µg/ml using working standard solution. The absorbance of these standard solutions were measured at 226 nm and calibration curve was plotted at this wavelength-using 1N sodium hydroxide solution as blank.

Estimation of drugs from pharmaceutical dosage forms:

Twenty tablets of three different pharmaceutical companies were accurately weighed and powdered. The powder equivalent to 10 mg of enalapril maleate was transferred into 100 ml volumetric flask, it was dissolved and diluted with 1N sodium hydroxide solution and filtered through Whatman Filter Paper No. 40. Further suitable dilutions were made with same solvent to get concentration within the range of Beer's law limits and the concentration of enalapril maleate present in dosage forms was determined from respective calibration curve.

Recovery studies and validation of the method according to I.C.H. guidelines:

Precision of the method was studied by carrying out Interday, Intraday analysis and expressed as % C.V. Specificity was determined by taking absorbance of a sample before adding excipients and after adding excipients and variation in concentration was observed. Limit of detection and limit of quantitation were studied based on standard deviation of the response and the slope.