

Determination of Enalapril maleate from tablets using a new HPLC method

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Abstract. For the determination of enalapril maleate in tablets a new, simple and economical HPLC method was developed and fully validated. Chromatographic separation was achieved on Hewlett Zorbax SB-C 18 (150 x 4.6 mm, 5 μ m) column and the mobile phase consisted of acetonitrile: 0.025 M phosphate buffer adjusted to pH 3 (70:30 v/v) pumped at a flow rate 0.8 mL/min and UV-detection was performed at 210 nm. The proposed method was validated according to ICH guidelines (linearity, limit of detection, limit of quantification, precision, accuracy, recovery and system suitability). The total run time was less than 3 min and the retention time for Enalapril maleate was 2.3 min. The calibration graph was linear in the concentration range between 10 – 100 μ g/mL with the correlation coefficient $r^2 = 0.9998$. The developed and validated method was successfully applied to determine the Enalapril maleate in tablets. Therefore, this method proved to be sensitive, specific and reproducible and can be applied for routine analysis of enalapril maleate from pharmaceutical formulation due to its simplicity of application.

Keywords: Enalapril maleate; HPLC; method validation; limit of detection.

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