HIGH-PERFORMANCE LIQUID CHROMATOGRAPHIC DETERMINATION OF LISINOPRIL IN PHARMACEUTICAL PREPARATIONS

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Lisinopril, a lysine analog of the nonsulfhydryl angiotensin-converting enzyme (ACE) inhibitor enalapril, is used for the treatment of hypertension and congestive heart failure in daily dosages of 10-80 mg. In this study, a high performance liquid chromatographic (HPLC) method was developed for the determination of this drug in tablets by means of the derivative formed with 5-(dimethylamino)naphthalene-1-sulfonyl chloride (dansyl chloride) which is a specific reagent in the analysis of primary and secondary aliphatic amines.

Optimum conditions of the reaction between lisinopril and dansyl chloride were investigated. It was found that the reaction proceeds quantitatively at pH 8.5 Borate buffer and 50 °C in 50 min. When the mole ratio of the reagent to lisinopril in 160. After completion of the reaction, the solvent was evaporated to dryness and the residue was dissolved in mobile phase. The liquid chromatographic analysis was performed using Phenomenex C18 column and methanol:phosphate buffer pH 3.2 (gradient) solvent system. The dansyl derivative was detected by a fluorescence detector at 520 nm (emission) (240 nm excitation).

The developed method was applied to the determination of lisinopril in tablets. The results were compared statistically with those obtained by the HPLC method using t- and F-tests. There was no significant difference between the two methods in the respect of mean values and standard deviations at 95 % confidence level.