Determination of lisinopril in dosage forms and spiked human plasma through derivatization with 7-chloro-4-nitrobenzo-2-oxa-1,3-diazole (NBD-Cl) followed by spectrophotometry or HPLC with fluorimetric detection

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Abstract

Two sensitive, simple and specific methods based on spectrophotometry and reversed-phase HPLC with fluorimetric detection are described for the determination of lisinopril in dosage forms as well as in spiked human plasma using solid phase extraction (SPE) procedures. Both methods are based on the derivatization of lisinopril with 7-chloro-4-nitrobenzo-2-oxa-1,3-diazole (NBD-Cl) in borate buffer of pH 9 to yield a yellow, fluorescent product. The spectrophotometric method depends on measuring the formed yellow color at 470 nm after optimization of the reaction conditions. The HPLC method is based on measurement of the derivatized product using fluorescence detection at 540 nm (excitation at 470 nm). The separation of the derivatized drug, the excess reagent and the internal standard (bumetamide) was performed on a reversed-phase ODS column using isocratic elution with methanol-0.02 M sodium dihydrogen phosphate, pH 3.0 (55:45, v/v) at a flow rate of 1.0 ml/min. The calibration graphs were linear over the concentration ranges 2–20 or 0.02–3.2 μg/ml of lisinopril with minimum detectability of 0.3 and 0.008 μg/ml (6.1 × 10⁻⁷ and 1.7 × 10⁻⁸ M) for the spectrophotometric and the HPLC methods, respectively. The proposed methods were applied without any interference from the tablet excipients for the determination of lisinopril in dosage forms, either alone or co-formulated with hydrochlorothiazide. Furthermore, the use of the HPLC method was extended to the in vitro determination of the drug in spiked human plasma. Interference from endogenous amino acids has been overcome by using the solid phase extraction technique, the percentage recovery (n = 6) was 101.6 ± 3.35.

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