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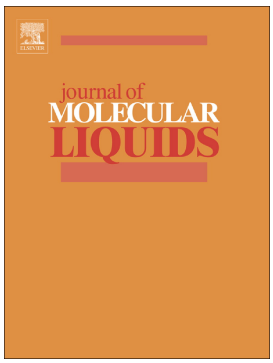

Spectrofluorimetric methods for the determination of lixivaptan and its hydrolysis product in human plasma and urine, with factors optimization study

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Spectrofluorimetric **methods** for the determination of lixivaptan and its hydrolysis product in human plasma and urine, with factors optimization study

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Abstract- Two simple and sensitive spectrofluorimetric methods for the determination of lixivaptan in spiked human plasma and urine were developed. Method (A) **is depend on** measuring the fluorescence intensity of lixivaptan at 307/273 nm in aqueous solution at pH 3 using phosphate buffer, whereas method (B) is based on measuring the fluorescence spectrum of the hydrolysis product of lixivaptan after leaving it for approximately 24 h at 25°C. The hydrolysis product was measured in phosphate buffer of pH 11. The fluorometric determination was performed at 483/280 nm. **Optimization of the factors** affecting on the fluorescence process of lixivaptan including the pH, diluting solvent and temperature were studied. The factors affecting the fluorescence intensity in case of the hydrolysis products was intensively studied using Box–Behnken design and optimized. The calibration curves were in the range of 57.9 - 500 and 50.1- 400 ng $mL.^{-1}$ for method (A) and (B), respectively. The analytical procedures were validated according to the ICH guidelines for validation. The limits of detection and limits of quantification of methods (A) and (B) were 19.11 and 16.56 ng mL^{-1} and 57.9 and 50.17 ng mL^{-1}, respectively. The developed methods were successfully applied for determination of lixivaptan using a back calculation formula in aqueous solution (100.90 ± 0.91%), spiked plasma

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