

Sensitive Quantification of the PDE5 Inhibitors in Small Volumes of Biological Samples by High-Performance Liquid Chromatography with Fluorescence Detection

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Abstract

New, simple and sensitive high-performance liquid chromatography (HPLC) methods with fluorescence (and UV) detection were developed and validated for the determination of oral selective phosphodiesterase-5 (PDE5) inhibitors sildenafil, vardenafil, tadalafil in small volumes of biological samples. The absorbance and fluorescence characteristics of PDE5 inhibitors were studied and factors that affect the HPLC resolution and fluorescence intensity were examined and optimized. Separation of PDE5 inhibitors and the internal standards was achieved on a reverse phase C18 column at a flow rate of 1 ml/min. The calibration curves were linear over the operational ranges for plasma, bile and other biological samples. The intra- and inter-day imprecision did not exceed 20%, and the accuracy was within 20% deviation of the nominal concentration. Stability of PDE5 inhibitors in biological samples was excellent, with no evidence of degradation during sample processing and various storage conditions. The methods were used successfully to investigate the disposition and biliary excretion of PDE5 inhibitors in rats.

Keywords: Sildenafil, Vardenafil, Tadalafil, PDE5 inhibitor, HPLC