

A simple high-performance liquid chromatography method with fluorescence detection for zolpidem assay in human plasma: Application to a bioequivalency study.

S. Fateh Basharzad^{1,*}, D. Zamanehsazi¹, E. Sanati², M. Hamidi¹

¹Department of Pharmaceutics, School of Pharmacy, Zanjan University of Medical Sciences, Zanjan, Iran

²Department of Pharmacoeconomy, Faculty of Pharmacy, Tehran University of Medical Sciences, Tehran, Iran

Background and Aims: In the This present study a simple high-performance Liquid chromatography (HPLC) method with fluorescence detection was developing for Zolpidem assay in human plasma.

Methods: A reversed - phase HPLC method with Fluorescence detection at a wavelength of 320:388 nm (ex:em) was developed using liquid-liquid extraction and drug separation was achieved using a C18 analytical column. The mobile phase was consisted of KH₂PO₄ 0.05M (pH=3) - acetonitrile (45:55, v/v) running at a flow rate of 1 ml/min.

Results: The validation tests were carried out the developed metod. The method showed significant linear response-concentration relationship throughout the zolpidem concentration range of 10-250 ng/ml, with the average within-run and between-run variations of 5.1 and 11.85 percent throughout the linear concentration range with corresponding average accuracy values of 88.38 and 101.44 percent. The limits of detection (LOD) and quantitation (LOQ) of the method were 5 and 10 ng/ml, respectively. The practical applicability of the method was proven throughout a bioequivalence study.

Conclusions: An easy and simple HPLC method developed and validate for zolpidem assay in human plasma. The validation tests on the developed method indicated acceptable degree of sensitivity, linearity, precision and accuracy for the method. The method was used successfully for quantitation of zolpidem in human plasma samples of healthy volunteers throughout a bioequivalence study.

Keywords: Zolpidem; Zolpidem assay; Reversed-phase HPLC