A Validated Stability-Indicating HPLC Method for the Quality Control of Zolpidem in Pharmaceutical Dosage Forms

Saeed Nezami Rashid¹, Saeid Yaripour¹, Ali Mohammadi¹²*

¹Department of Drug and Food Control, Faculty of Pharmacy, Tehran University of Medical Sciences, Tehran, Iran
²Nanotechnology Research Centre, Faculty of Pharmacy, Tehran University of Medical Sciences, Tehran, Iran

Abstract: The purpose of our study was to develop and validate a stability-indicating RP-HPLC method for determination of Zolpidem in the presence of its degradation products in bulk and tablet dosage forms according to the ICH guidelines. Forced degradation studies were carried out on bulk samples and tablet dosage forms of Zolpidem using acid, base, H₂O₂, heat, and UV light as described by ICH for stress conditions to demonstrate the stability-indicating power of the method. The chromatographic separation was optimized on a Perfectsil® Target ODS column (3-5µm, 125 × 4 mm) using a mobile phase consisting of Methanol–50 mM ammonium acetate buffer (pH=3.7) (40:60, v/v) at a flow rate of 0.7 ml/min and UV detection at 254 nm. The present method linearity for Zolpidem was investigated in the range of 1–20 µg/ml (r = 0.9998). The LOD and LOQ were 400 and 1000 ng/ml respectively. The method specificity was evaluated by peak purity test using a PDA detector. There was no interference with detection of Zolpidem and its stressed degradation products. A simple, rapid, accurate, precise and cost benefit stability-indicating RP-HPLC method has been developed and validated for analysis of Zolpidem in bulk and tablet dosage forms. The results of stress testing, regarding to the ICH guidelines reveal that the method is selective and stability-indicating. Selectivity and specificity of the method were evaluated by peak purity test. The proposed method is able to separate and determine Zolpidem from its degradation products and can be applied for the quality control of Zolpidem and analysis of samples obtained during stability and shelf life studies.

Keyword: Zolpidem, Stability-indicating, HPLC, Forced degradation