Development and Validation of Stability Indicating RP-UPLC Method for Quantitative Estimation of Safinamide Mesylate in Bulk and its Tablet Dosage Form

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Abstract

Currently, there was an increasing interest on the development of a simple, rapid and sensitive method for safinamide mesylate due to its well- documented anti parkinsonism activity. This study aims to develop and validate a UPLC method for determination of the Safinamide mesylate in bulk and its tablet dosage forms. The chromatographic separation was achieved by using an ACQUITY BEH C18 column (50 mm × 2.1 mm, 1.7 μm; Waters), with an isocratic elution of 0.02 M diammonium hydrogen phosphate buffer pH 9.0 and Acetonitrile (80:20 v/v), at a flow rate of 0.25 ml/min with the help of UV detection at 272nm. The results of the analysis were validated statistically as per the International Conference on Harmonization (ICH) guidelines. Linearity studies were carried out in the range of 10 - 60 μg/ml and the linear response (r^2) was found to be 0.9999 with limits of detection and quantification being 0.081 and 0.271μg, respectively. The precision was performed by analysis of standard and sample solutions of SAF at working concentration level for six times. The % RSD values of the system and method precisions were found to be 0.527 and 0.324 respectively. Then, the precision of the method was confirmed by intra-day and inter-day analysis. The % RSD value of the intra-day and inter-day precisions were found to be 0.324, 0.531 respectively. Recovery studies were performed for determining accuracy of the method and the percentage recovery was found to be 99.48-100.85%. The Robustness were performed at different flow rates and different temperatures, and the % RSD value were found to be 0.5965, 0.6276 respectively. Thus, a highly sensitive, simple and the stability indicating method were developed for the estimation of SAF in bulk and tablet dosage forms.

Keywords: Safinamide Mesylate, ICH Guidelines, ACQUITY BEH C18 Column, Ultra Performance Liquid Chromatography, Diammonium Hydrogen Phosphate Buffer