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Method Development and Validation of Reverse Phase HPLC for Quetiapine Fumarate in Pharmaceutical Dosage

Battula Sreenivasa Rao[1*] and K. Nagendra Rao[2]

1. Department of Chemistry, GITAM Institute of Technology, GITAM University, Visakhapatnam –530045, Andhra Pradesh, **INDIA**
2. Department of Chemistry, Acharya Nagarjuna University, Nagarjuna Nagar, AP, **INDIA**

Email: battula_sr@gitam.edu

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ABSTRACT

A rapid, specific and accurate isocratic HPLC method was developed and validated for the assay of Quetiapine Fumarate in pharmaceutical dosage forms. The assay involved an isocratic – elution of Quetiapine Fumarate in ODS - C18 column using mobile phase composition consists of (50:50, v/v) of acetonitrile and sodium acetate with 0.1 % ortho phosphoric acid respectively. The wavelength of detection is 294nm. The method showed good linearity in the range of 2.01 to 50.20 µg mL^{-1}. The runtime of the method is 8 min. The proposed method can be used for routine quality control samples in industry in bulk and in finished dosage forms. In present study, a rapid specific precise and validated HPLC method for the quantitative estimation of Quetiapine Fumarate in pharmaceutical dosage forms has been reported. The developed method can be applied to directly and easily to the analysis of the pharmaceutical tablet preparations. The percentage recoveries were near 100% for given methods. The method was completely validated and proven to be rugged. The excipients did not interfere in the analysis. The results showed that this method can be used for rapid determination of venlafaxine in pharmaceutical tablet with precision, accuracy and specificity.

Keywords: Quetiapine Fumarate, Assay, reverse phase, HPLC.