Available online at **www.joac.info**

ISSN: 2278-1862

Journal of Applicable Chemistry

2020, 9 (2): 259-268

(International Peer Reviewed Journal)

Isolation and Characterization of Quetiapine Degradation Products by NMR and HRMS: Development and Validation of Quetiapine by RP-UPLC

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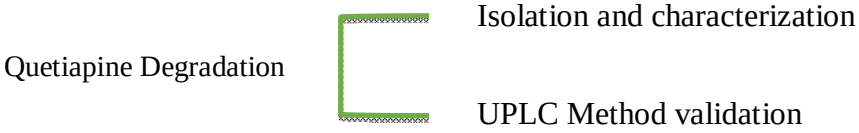
Accepted on 15th February, 2020

ABSTRACT

Quetiapine fumarate is an atypical antipsychotic drug and it was subjected to stress degradation under acidic, basic and peroxide mediated oxidation. The stress degradation was performed according to ICH guidelinesQ1A (R2), the drug was inert under basic hydrolysis, three degradants (referred as DP-Quet-1, DP-Quet-2, DP-Quet-3) were formed in peroxide mediated hydrolysis and one degradant (referred as DP-Quet-4) was formed in acid hydrolysis. These degradants were initially identified through Liquid Chromatography- Mass Spectrometry and isolated by automated purification system. The structures were established by substantial analysis of High Resolution Mass Spectrometry and 1D, 2D Nuclear Magnetic Resonance Spectroscopy. A stability indicating RP-UPLC method was developed and validated for assay determination of Quetiapine API drug. The Quetiapine RP-UPLC method was validated on Acuity BEH C-18 2.1X100mm, 1.7µm column with shorter runtime of 3 min. The method was validated as per regulatory guidelines in terms of specificity, accuracy, linearity, precision, limit of detection, limit of quantitation and the analysis time is faster than the traditional High performance liquid chromatography.

Graphical Abstract



Keywords: Quetiapine degradation products, HRMS, 1D and 2D NMR, UPLC method validation.