



Characterization of Paliperidone Palmitate Impurities Identification, Isolation and Structural Characterization of Process Related Impurities of Paliperidone Palmitate

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ABSTRACT

Paliperidone palmitate is a antipsychotic agent which is used for treatment of Schizophrenia and Schizoaffective disorders. Paliperidone palmitate is a long-acting injectable formulation of paliperidone palmitoyl ester. As per the regulatory authorities it is important to provide the complete information about the drug and the related impurities which are generated during the drug manufacturing process. To identify the paliperidone palmitate process related impurities here we are using reverse phase liquid chromatography coupled with mass spectrometry technique. Four impurities were separated by using X Select CSH C18 (150mm x3.0mm, 2.5µm) column in a gradient mixture of 0.05% TFA in water and 0.05% TFA in acetonitrile. Further the impurities were isolated by using preparative HPLC. Impurities were identified by using HRMS and structurally characterized by one dimensional (1D) (proton ¹H, Carbon ¹³C) and two dimensional (2D) (COSY, HSQC, HMBC) NMR spectroscopy. By using this highly advanced and sophisticated technique it is easier to characterize the structural elucidation of four impurities of Paliperidone palmitate.

High Lights

- LC-MS method was optimized and developed to determine the impurities present in Paliperidone palmitate.
- Characterization of impurities was not reported in any literature.
- In present paper all the four impurities were identified and characterized by using various high-end analytical techniques such as HRMS, NMR, and FT-IR.

Keywords: Paliperidone palmitate, process impurities, identification by LCMS, Isolation by Preparative HPLC, Characterization by HRMS and NMR.