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Development and validation of rapid UHPLC method for determination of risperidone and its impurities in bulk powder and tablets

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The aim of this study was to develop a new, rapid and highly sensitive UHPLC method with UV detection for simultaneous determination of risperidone and four other related substances possibly present in tablets. The active substance, risperidone, is the most frequently used atypical antipsychotic drug for a treatment of schizophrenia, bipolar disease and behavioral disorders in young patients, up to 17 years of age. The study is based on main impurities specified in USP35 and Ph. Eur. 7 (Imp A, B, C, and E). Tablet sample preparation was very rapid and consisted of dissolution, sonication and filtration through a 0.22 μm membrane filter. The newly developed method is based on an innovative UHPLC that provides excellent separation efficiency within a very short analysis time. Binary gradient was optimized using RP-18 chromatographic column (100 mm×3.5 mm, 1.7 μm). Ammonium acetate buffer pH 6.8 and acetonitrile were used as mobile phases in gradient mode with the flow rate of 0.5 mL•min-1 and temperature equal to 40°C. The wavelength of UV detector was set to 260 nm. The developed method allows four times shorter analysis time and consumes twenty two times less solvents compared to conventional HPLC method used by USP35 for a determination of related substances of risperidone in tablets. This method was validated in accordance with ICH requirements included the linearity, precision, accuracy sensitivity, and specificity.

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