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Degradation Behaviour of Brexpiprazole: Isolation, Characterization and Structural Elucidation of New Degradants

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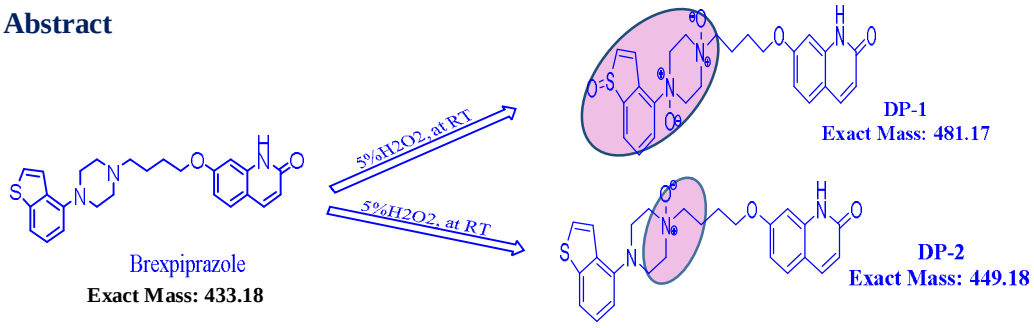
ABSTRACT

The aim of the present work is to study the stability of the Brexpiprazole (BREX) drug which is carried out under various stress conditions like acid, alkaline and oxidation according to International Conference on Harmonization (ICH) guidelines. BREX drug is stable under acidic and alkaline conditions where degradation is not observed, but when exposed to oxidation condition degradation occurs. Two degradation products are observed out of which DP-2 already reported in literature a DP-1is not reported anywhere in literature.LC-QTOF analysis is performed to separate the drug and its degradation impurities which were accomplished on C18 BEH UPLC column (50 mm X 2.1mm, 1.7 µm) using 0.05% Formic Acid in water and 0.05%Formic Acid in Acetonitrile as mobile phase. The flow rate is 0.6mL/min and detection is monitored at 215nm.The degradation product obtained is isolated by preparative HPLC. Characterization and structural elucidation of degradation product was studied by NMR, LCMS and HRMS.

Graphical Abstract



Keywords: Preparative HPLC, NMR, LCMS, HRMS, Brexpiprazole, Stability indicating method.