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November 12-13, 2018 | Rome, Italy

J Chem Tech App 2018, Volume 2

QBD DRIVEN STABILITY INDICATING RP-HPLC ASSAY METHOD FOR FLIBANSERIN: DEVELOPMENT, VALIDATION AND CHARACTERIZATION OF MAJOR DEGRADANTS BY LC/QTOF-MS/MS

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The inherent chemical stability of Flibanserin (FLB) was investigated by using Plackett Burman design for screening of independent variables. Box-Behnken design was used for optimization of high performance liquid chromatography (HPLC) stability indicating assay method. Forced degradation of FLB was carried out under hydrolysis (acidic, basic, and neutral), photolysis, oxidation and thermal stress conditions. The major oxidative degradation product was isolated by preparative HPLC. The degradation product was identified as 2-HBenz-imidazol-2-one,1, 3-dihydro-1-[2-[4-[3(trifluoro methyl) phenyl]-1-N-oxide-piperazinyl] ethyl] following characterization by UV, IR, HRMS and NMR techniques. The parent ion mass of the oxidative degradants was observed mass 407.1710 and major fragments (389.1582, 375.1422, 255.1100, 243.1103, 228.0866, 216.1127, and 200.0680) in LC-QTOF-MS when analysed in positive ionization mode. Oxidation and hydrolysis were found to be the primary degradation pathways for this molecule. The chromatographic separation was achieved on Cromasil C18 column (4.6mm×250mm, 5µm) using a mobile phase consisting of a mixture of ammonium acetate (pH 5.5) and acetonitrile in linear gradient elution mode. The method was found to be linear in the concentration range of LOQ (0.5 to 70 µg/mL). The method was validated as per ICH guideline Q2 (R1). Degradation of FLB followed first-order kinetics under all experimental conditions. A V-shaped pH-rate profile kinetics over the pH range 2–10 was observed with maximum stability at pH 6.8. In conclusion, a reverse phase high performance liquid chromatographic method has been developed and validated for quantitation of FLB in presence of their degradation products. The major degradation product has been identified and fully characterized that has not been reported till date. This is the first time to report a stability indicating assay method for FLB.