

Identification of stress degradation products of bupropion using LC-PDA, LC-MS-TOF and MSⁿ techniques

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Stress degradation studies on bupropion were conducted under the ICH guidelines recommended conditions of hydrolysis (acid, base and water), oxidation, dry heat and photolysis (acid, base and water). Seven degradation products were formed under alkaline hydrolysis which were resolved isocratically on a C₁₈ column (250 mm x 4.6 mm; 5µm, XTerra) with mobile phase comprising of ammonium formate (20mM, pH 4.0), methanol and acetonitrile (75:10:15 v/v) taking 252 nm as detection wavelength. The drug was found stable in all other stress conditions. The degradation products were characterized through LC-PDA, MSⁿ and LC-MS-TOF studies. The products (III, IV, V and VII) were characterized as 2-hydroxy-2-(3'-chlorophenyl)-3,5,5-trimethylmorpholine, (2,4,4-trimethyl-1,3-oxazolidin-2-yl)(3-chlorophenyl)-methanone, 1-hydroxy-1-(3-chlorophenyl)propan-2-one and 2-(3'-chlorophenyl)-3,5,5-trimethylmorphol-2-ene, respectively. The products II and VI were not characterized due to their trace levels (0.5% of the total peak area) while product I was not characterized due to its inherent weak ionizability. Based on the chemical reactivities of the functional groups in the drug, the most probable degradation mechanisms were proposed. The HPLC method was found to be stability indicating and linear in the range of 0.1-100 µg/ml. The method was found accurate, precise, robust, sensitive, specific and rugged for quantification of the drug with in the linearity range. The method was also applied to stability testing of the commercially available bupropion tablets successfully.

Biography

Rohit Bansal has completed his M.Pharmacy from Punjabi University, Patiala and pursuing PhD from the same university under the supervision of Dr. Gulshan Bansal. His areas of interest include characterization of impurities/degradation products in drug substances through chromatographic and spectral techniques. He is proficient in HPLC method development and validation and in interpretation of mass spectral data.

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