Quantitation of Tolmetin by High-performance Liquid Chromatography and Method validation

吳安邦
Chen FA;Chen CY;Chen CJ;and Wu AB

Abstract

A high-performance liquid chromatographic (HPLC) assay method for assessing the degradation of tolmetin (TLM) is developed and validated under acidic, basic, and photoirradiated conditions. The HPLC method includes an Inertsil 5 ODS-3V column (250- x 4.6-mm i.d.), guard column of Inertsil 7 ODS-3V (50- x 4.6-mm i.d.), mobile phase of CH(3)OH-1% HOAc (64:36, v/v), and UV detection at 254 nm. The developed method satisfies the system suitability criteria, peak integrity, and resolution for the parent drug and its degradants. The established assay method exhibits good selectivity and specificity suitable for stability measurements. From the intra- and interday tests of six replicates, the coefficients of variation are between 0.20% and 1.77% for the former, and 0.12% and 3.40% for the latter. Recoveries are found to be 98.7-101.7%. TLM is determined to be more reactive when exposed to light and acidic conditions, yet TLM is stable in a basic medium. A kinetic study of the photodegradation of TLM shows that it follows an apparent first-order reaction in three alcoholic solvents.