Stability-indicating HPLC Assay Method of Zomepirac

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Abstract

An HPLC assay method for determining the degradation of zomepirac was developed and validated under acidic, basic, and photo-irradiated conditions. The HPLC system consisted of an Inertsil 5 ODS-3V column (4.6 X 250 mm i.d.), and a guard column of Inertsil 7 ODS-3V (4.6 X 50 mm i.d.) using a mobile phase of CH3CN: CH3OH: 1%HOAc (2:64:34, v/v/v) with 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 results indicate that the established assay method shows good selectivity and specificity suitable for stability measurements of zomepirac. From the intra- and interday tests of 6 replicates, the coefficients of variations (CVs) were between 0.12% and 2.24% for the former and 0.15% and 3.93% for the latter. Recoveries were found to be between 97.14% and 101.58%. From the stress treatments, zomepirac was determined to be more sensitive to the light and acidic conditions, but it was stable in basic medium. A preliminary kinetic study of the photodegradation of zomepirac in methanol showed that it followed an apparent first-order reaction.

Key words: HPLC, zomepirac, photodegradation