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A validated stability-indicating RP-HPLC assay method for the determination of Zaltoprofen

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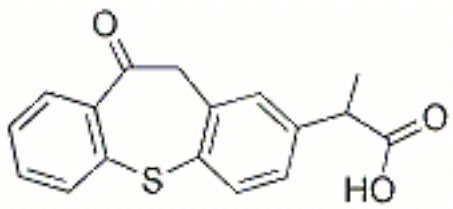
A validated specific stability indicating reversed-phase high-performance liquid chromatography method was developed for the quantitative assay determination of Zaltoprofen (ZPF). The analyte peak was well resolved from its process impurities (Imp-1, Imp-2 & Imp-3) and degradent impurities as well. The method was employed on Inertsil ODS-2 column (150 mmx4.6 mm, 5.0 µm) with a mobile phase consisting of phosphate buffer (pH 3.0) and acetonitrile (45:55, v/v), and detection at 240 nm at a flow rate of 0.8 ml/min. The stress testing of Zaltoprofen was carried out under acidic, alkaline, neutral, oxidation, thermal and photolytic conditions as recommended by International Conference on Harmonization (ICH) guidelines. Significant degradation of ZPF was observed in base degradation. The molecule was found to be stable in all other degradation conditions. The assay of ZPF was unaffected by the presence of its impurities and degradation products and thus confirms the stability indicating power of developed method. The proposed method was validated for specificity, linearity, accuracy and precision. Regression analysis showed correlation coefficient value is greater than 0.999. Accuracy of the method was established based on the recovery obtained between 98.0% and 100% for Zaltoprofen.



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