Journal of Innovations in Pharmaceuticals and Biological Sciences
www.jipbs.com
JIPBS
ISSN: 2349-2759

Research Article

Development and Validation of a Stability-Indicating Assay (HPLC) Method for quantitative analysis of Prulifloxacin in Bulk Drug

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Abstract

A novel stability-indicating reversed-phase (RP) HPLC method has been developed and validated for quantitative analysis of prulifloxacin in the bulk drug. Use of a 250 mm × 4.6 mm, 5-µm particle size, C18 column with 50:50 (v/v) formic acid in water (pH 3.5)–acetonitrile as isocratic mobile phase enabled separation of the drug from its degradation products. The flow rate and detection wavelength were 1 mL min^{-1} and 277 nm respectively. The method was validated for linearity, limits of detection and quantification, accuracy, precision, selectivity, ruggedness and system suitability. The linearity of the method was excellent over the range 0.030–10.000 µg mL^{-1}. The mean values of slope, intercept, and correlation coefficient were 85169, 9332 and 0.9992 respectively. The limits of detection and quantification were 0.010 and 0.030 µg mL^{-1}, respectively. RSD in intra-day and inter-day precision studies was < 2 %. Recovery of prulifloxacin from bulk drug ranged from 100.08 and 102.00 %. Prulifloxacin was subjected to stress conditions (hydrolysis (acid, base), oxidation, photolysis, and thermal degradation) and the stressed samples were analysed by use of the method. Maximum degradation was observed in acid and base hydrolysis and oxidation. The drug was also susceptible to degradation under photolytic and thermal conditions. The degradation products were well resolved from main peak thus proving the stability indicating nature of the method.

Key words: Prulifloxacin; Stability indicating; Degradation products

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