Development and Validation of Stability Indicating RP-HPLC Method for Simultaneous Estimation of Ofloxacin and Cefpodoxime proxetil in Bulk and Tablet Dosage Form

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ABSTRACT

A simple, accurate, precise and stability Indicating RP-HPLC method was developed and validated for simultaneous estimation of ofloxacin and cefpodoxime proxetil in bulk and tablet dosage form. The RP-HPLC method has shown adequate separation for ofloxacin and cefpodoxime proxetil from its degradation products. The separation was achieved on a Phenomenex luna ODS C_{18} (250mm X 4.6 mm i.d., 5 µm particle size) with an isocratic mixture of acetonitrile: 30mM phosphate buffer pH 4.0 adjusted with ortho phosphoric acid in the ratio of 75:25 v/v. The mobile phase at a flow rate of 0.5 ml/min, injection volume 20µl and wavelength of detection was kept at 254nm. The retention time for ofloxacin and cefpodoxime proxetil was 4.380min and 6.649min, respectively. The linearity of the proposed method was investigated in the range of 2-26 µg/ml for ofloxacin and cefpodoxime proxetil respectively.

Correlation coefficient was 0.9995 and 0.9992 for ofloxacin and cefpodoxime proxetil, respectively. The limit of detection was 0.106µg/ml and 0.511µg/ml for ofloxacin and cefpodoxime proxetil, respectively and the limit of quantification was 0.332µg/ml and 1.548µg/ml for ofloxacin and cefpodoxime proxetil respectively. Force degradation study was carried out as per ICH guideline and the drugs were exposed to hydrolysis (acid and base hydrolysis), thermal and photolytic conditions to apply stress. Proposed methods were validated as per ICH guidelines for linearity, accuracy, precision, and robustness for estimation of ofloxacin and cefpodoxime proxetil in commercially available tablet dosage form and results were found to be satisfactory. Thus the developed and validated stability indicating method can be used successfully for marketed formulations.

Key words: ofloxacin, cefpodoxime proxetil, stability indicating RP-HPLC method, Force degradation