Development and Validation of Analytical Method for Simultaneous Estimation of Cefixime Trihydrate and Moxifloxacin HCl in Bulk and its Formulation.

Submitted By

Hemina Pankajbhai Patel

Supervised By

Dr. Jawed Akhtar

M. Pharm., PhD

Associate Professor, Department of Quality Assurance

Parul Institute of Pharmacy and Research

Limda, Ta. Waghodia, Dist. Vadodara 391 760

ABSTRACT

A simple, accurate, precise and stability indicating RP-HPLC method was developed and validated for simultaneous estimation of cefixime trihydrate and moxifloxacin hydrochloride in bulk and tablet dosage form. The RP-HPLC method has shown adequate separation for cefixime trihydrate and moxifloxacin hydrochloride from its degradation products. The separation was achieved on a thermoscientific BDS HYPERSIL C_{18} (250mm X 4.6 mm i.d., 5 µm particle size) column with an isocratic mixture of Acetonitrile: 10 mM tetrabutyl ammonium hydrogen sulphate(TBAHS) + tetrabutyl ammonium bromide(TBAB) buffer pH 3.0 adjusted with glacial orthophosphoric acid in the ratio of 20:80 v/v. The mobile phase at a flow rate of 1.5 ml/min, injection volume 20µl and wavelength of detection was kept at 280.8 nm. The retention times for cefixime trihydrate and moxifloxacin hydrochloride were 5.202 ±0.1 min and 3.043 ± 0.1 min respectively. Force degradation study was carried out on combined dosage form as per ICH guidelines and it was exposed to hydrolysis (acid and base), oxidative, thermal and photo conditions to apply stress. The force degradation behavior showed that cefixime trihydrate was more prone to degradation compared to moxifloxacin hydrochloride. The linearity of the developed method was found in the range of 10-60µg/ml for both cefixime trihydrate and moxifloxacin hydrochloride. Correlation coefficient was 0.999 for both cefixime trihydrate and

moxifloxacin hydrochloride. The limit of detection was 0.929µg/ml and 0.873µg/ml for moxifloxacin hydrochloride and cefixime trihydrate respectively and the limit of quantification was 2.816µg/ml and 2.646µg/ml for moxifloxacin hydrochloride and cefixime trihydrate respectively. Developed stability indicating assay method was validated as per ICH guidelines for linearity, specificity, accuracy, precision and robustness for estimation of cefixime trihydrate and moxifloxacin hydrochloride using synthetically prepared tablet dosage form and results were found to be satisfactory.

Key words: Cefixime trihydrate, Moxifloxacin hydrochloride, RP-HPLC method, Force degradation studies, Stability indicating RP-HPLC method.