19th Global Chemistry, Chromatography & Spectrometry Conference

March 20-21, 2019 | New York, USA

ACCEPTED ABSTRACTS *CHEMICAL SCIENCES JOURNAL 2019, VOLUME 10 | DOI: 10.4172/2150-3494-C1-033*

Development and validation of reversed-phase high-performance liquid chromatography method for simultaneous determination of metronidazole, norfloxacin and ciprofloxacin in bulk and dosage forms

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A simple, accurate, specific, precise and robust reversed phase-high performance liquid chromatography (RP-HPLC) method has been developed and validated for the simultaneous determination of metronidazole, norfloxacin, and ciprofloxacin. The separation was carried out on reverse phase Shodex C-18 (250mm×4.6mm i.d, 5µm) column. The mobile phase consisted of gradient mixtures of potassium dihydrogen ([time (min)/%B] 0/18 to 2/18, 5/21 to 7/21 and 9/18 to 14/18), pH 3.3 and acetonitrile (ACN). The flow rate was 1mL/minute, and the analytes were detected at 300nm. The percentage recoveries were 100.18% for metronidazole, 99.11% for norfloxacin and 99.85% for ciprofloxacin which showed the good accuracy of the developed method. The linear ranges were found to be 0.05-0.3mg/mL (r2=0.9996) for metronidazole, 0.05-0.3mg/mL (r2=0.9997) for norfloxacin and 0.05-0.3mg/mL (r2=0.9997) for ciprofloxacin. The percentage relative standard deviation for repeatability, intra-day precision, and inter-day precision was found to be less than 2% which comply with the ICH guidelines. The method as well showed adequate robustness to small variations in mobile phase pH, column temperature and buffer concentrations. Hence, the method could be successfully applied for routine quality control analysis of the three drugs ciprofloxacin.

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