Stability Indicating HPLC Method for the Simultaneous Determination of Ciprofloxacin Hydrochloride and Metronidazole in the Presence of Ciprofloxacin Acid Degradation Product.

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Abstract

A stability indicating HPLC method for the simultaneous determination of ciprofloxacin HCl (CIP)
and metronidazole (MET) in presence of ciprofloxacin acid degradation product (DEG) is presented (Method I,
MI). The present study is concerned with the development and validation of an environmentally friendly
method with relatively low organic composition of the mobile phase. The chromatographic separation of the
two drugs was performed using Kromasil 100-5C18 (150 mm x 4.6 mm) with UV detection at 280 nm and flow
rate of 1 mLmin-1. The mobile phase consisted of 0.5% aqueous phosphoric acid and acetonitrile (90:10 v/v)
MI. In addition, another HPLC method (MII) for the separation of the same binary mixture using 0.5% aqueous
phosphoric acid and acetonitrile (80:20 v/v) was presented. Retention times were 2.40, 3.10 & 22.94 min for
MET, DEG and CIP, respectively, MI. On the other hand, the retention times were 2.03 and 4.00 min for MET
and CIP, respectively MII. However, the relatively low organic composition of the mobile phase of 10% in MI
was advantageous regarding green analytical procedure concept. Linearity, accuracy and precision were
acceptable over the concentration range of 1-65 εgmL-1 for both drugs MI, and 1-80 εgmL-1 MII. The method
is new, simple , sensitive and suitable for the routine quality control and dosage form assay of both drugs in the
presence of the acid degradation product of ciprofloxacin. The method showed sufficient accuracy with a
mobile phase of only 10% organic composition showing advantage and trying to approach green
chromatographic conditions.

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