Validated UPLC and TLC-Densitometry Stability Indicating Methods for the Determination of Rafoxanide in Presence of Its Degradation products

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Abstract

Two sensitive and accurate stability-indicating chromatographic methods were developed and validated for the determination of rafoxanide (RFX). Degradation products were identified by mass spectrometry and IR spectroscopy. The first is ultra-performance liquid chromatography method where separation was performed using acetonitrile:0.005 M potassium dihydrogen orthophosphate (pH 3.5) in a ratio of 80:20 by volume as a mobile phase using a Hypersil GOLD Ê C8 column 1.9 mm (50 Ĭ 2.1 mm), UV detection was adjusted at 220 nm and the flow rate was 0.6 mL min-1 The other is a thin-layer chromatography-densitometry method where separation was achieved using a mobile phase composed of chloroform:ethyl acetate:toluene:ammonia (5:4:3:0.1 by volume) on silica gel 60 F254 plates, and densitometric detection was done at 280 nm. Validation was achieved as per the ICH guidelines. The proposed methods proved to be accurate, robust, specific and suitable for application as stability-indicating methods for routine analysis of RFX in quality control laboratories.

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