Stability Indicating TLC ï Densitometric Method for Determination of Alcaftadine in Presence of its Degradation Products and Dosage form Preservatives

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Abstract

Stability indicating methods are essential to determine the stability of newly developed dosage forms. In this work a simple stability-indicating thin-layer chromatographic (TLC) method was developed and validated to determine Alcaftadine in presence of its main degradation products and preservative benzalkonium chloride in bulk powder and in pharmaceutical formulations. Separation was developed on TLC aluminum plates precoated with silica gel 60F-254 as a stationary phase using chloroform: methanol: ammonia (5:5:0.1, by volume) as a developing system. Densitometric scanning was carried out in the absorbance mode at 282nm. Alcaftadine was subjected to oxidation, acid and alkaline hydrolysis. It was observed that the drug is susceptible to oxidation only. Method validation was carried out according to ICH guidelines and the proposed method was successfully applied to analyze alcaftadine in pharmaceutical dosage form with no interference from dosage form additives or preservatives. Linearity range was found to be 0.50 - 12.00Õg/band with a good linear relationship r of 0.9998. Results obtained by the proposed TLC-densitometric method were statistically compared with those obtained by a reported spectrophotometric method and no differences were found.

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