8. Selective Chromatographic Methods for the Determination of Rosuvastatin Calcium in the Presence of its Acid Degradation Products

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Abstract

Two accurate and sensitive stability-indicating methods for the determination of rosuvastatin calcium in the presence of its acid degradation products are presented. The first method utilizes quantitative spectrodensitometric evaluation thin-layer chromatography (TLC) of rosuvastatin calcium in the presence of its acid degradation products, using ethyl acetate/methanol/ammonia (7:3:0.01, by volume) as a mobile phase. Chromatograms are scanned at 245 nm. This method analyzes rosuvastatin calcium in a concentration range of 0.6–3.4 µg/band with mean percentage recovery of 99.78 ± 1.42. The second method is a high-performance liquid chromatography (HPLC) method for the simultaneous determination of rosuvastatin calcium in the presence of its acid degradation products. The mobile phase consists of water/acetonitrile/methanol (40:40:20, by volume). The standard curve of rosuvastatin calcium shows a good linearity over a concentration range of 10–60 µg mL⁻¹ with mean percentage recovery of 100.22 ± 0.86. These methods were successfully applied to the determination of rosuvastatin calcium in bulk powder, laboratory-prepared mixtures containing different percentages of the acid degradation products, and pharmaceutical dosage forms. The validity of results was assessed by applying standard addition technique. The results obtained were found to agree statistically with those obtained by a reported method, showing no significant difference with respect to accuracy and precision.