10. Stability Indicating Methods for the Determination of Rosuvastatin Calcium in the Presence of its oxidative Degradation Products

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Abstract

Four different accurate, sensitive and reproducible stability-indicating methods for the determination of rosuvastatin calcium in the presence of its oxidative degradation products are presented. The first method is Second-derivative (2D) method at 243.6 nm in a concentration range of 5-30 μg mL−1 with mean percentage recovery of 99.94±1.171. The second method is based on ratio-spectra 1st derivative (1DD) spectrophotometry of the drug at 240 nm, over a concentration range of 5-35 μg mL−1 with mean percentage recovery of 99.77±0.974. The third method utilizes quantitative densitometric evaluation of thin-layer chromatography of rosuvastatin calcium in the presence of its oxidative degradation products, using ethyl acetate: methanol: ammonia (7:3:0.01, v/v/v) as a mobile phase. Chromatograms are scanned at 245 nm. This method analyses rosuvastatin calcium in a concentration range of 0.6-3.4 μgspot-1with mean percentage recovery of 99.78±1.419. The fourth method is an HPLC method for the simultaneous determination of rosuvastatin calcium in the presence of its oxidative 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±0.859. These methods were successfully applied to the determination of rosuvastatin calcium in bulk powder, laboratory-prepared mixtures containing different percentages of the 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.

International Journal Pharmaceutical Biomedical Science, 3 (4), 193-202 (2012) - 2012, January