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Stability-Indicating Assay Method for Determination of Rosuvastatin in Nano-Formulation and Pharmaceutical Dosage form By RP-HPLC

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Abstract : A simple, precise, isocratic, reverse phase high performance liquid chromatography (RP-HPLC) method was developed for the rapid determination of rosuvastatin using Kromasil C-18, 4.6 x 250 mm (id), 5 µm HPLC column. The run-time was 8 min with retention time of rosuvastatin at 4.72 min. RP-HPLC method was validated according to ICH guidelines with respect to linearity, accuracy, precision and robustness. The limit of detection and limit of quantitation was found to be 0.17 and 0.7µg/ mL, respectively. Developed method was found to be linear in the concentration range of 1.56 to 50 µg/ mL with regression coefficient of 0.9998. Further, the proposed method was found to be reproducible and convenient for stability indicating analysis of rosuvastatin in marketed tablet dosage form and developed solid lipid nanoparticles.

Keywords : Rosuvastatin; Forced degradation studies; RP-HPLC; Stability-indicating.

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