

Journal of Applicable Chemistry

2017, 6 (3): 392-399

(International Peer Reviewed Journal)



ISSN: 2278-1862

Simultaneous Determination of Rosuvastatin Calcium and Amlodipine Besylate in Tablet Formulations by RP-HPLC Method

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Accepted on 15^{th} May 2017, Published online on 27^{th} May 2017

ABSTRACT

A new, simple, rapid, selective, precise and accurate isocratic reverse phase high performance liquid chromatography assay method has been developed for simultaneous estimation of Rosuvastatin calcium and Amlodipine besylate in tablet formulations. The separation was achieved by using YMC Pro C8 (150mm 4.6mm id, 5 µm particle size) column in mobile phase consisted of acetonitrile and 20mM potassium dihydrogen phosphate buffer pH adjusted to pH 3.5 with the help of dilute ortho-phosphoric acid in the ratio of (45:55 v/v). The flow rate was 1.0 mL.min-1 and the separated drugs were detected using UV detector at the wavelength of 242 nm. The retention time of Rosuvastatin calcium and Amlodipine besylate, was noted to be 4.42 and 2.91 respectively, indicative of rather shorter analysis time. The method was validated as per ICH guidelines. The proposed method was found to be accurate, reproducible and consistent.

Keywords: Liquid Chromatography, Rosuvastatin calcium, Amlodipine besylate, combined dosage forms, Simultaneous estimation, Validation.