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Research Article

RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF RAMIPRIL AND S (-) AMLODIPINE IN TABLET DOSAGE FORM

P.P. Vairagar [1], S.V. Mulgund[1], S.P. Vassa*[1], R.V. Korhale[2]

[1] Department of Quality Assurance Technique, Sinhagad College of Pharmacy, Vadgaon (Bk.), Pune-411 041, **Maharashtra, India.**

[2] Analytical departments, Emcure R & D Center, Bhosari, Pune-411026, **Maharashtra, India**

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ABSTRACT

*The main objective of this study is to develop and validate a simple and rapid isocratic reversed-phase high-performance liquid chromatographic method (RP-HPLC) for the simultaneous estimation of S (-) Amlodipine besylate and Ramipril in combined dosage form. The HPLC system was operated isocratically at flow rate of 1ml/min at 40°C ± 0.5° C for 15 min. The mobile phase found to be most suitable for analysis was Acetonitrile: 0.02M Potassium dihydrogen ortho phosphate buffer (0.1 % of triethylamine, 0.1 % of 6-heptane sulphonic acid salt): 35:65% v/v, pH adjusted to 2.5 with O-phosphoric acid, detection was carried out at 210nm using Hypersil BDS C-18 (150*4.6mm) 5µ column with injection volume 20µl. The retention time of Ramipril and S (-) Amlodipine Besylate were 5.61±0.3and 7.41±0.3 respectively. The proposed method was validated according to International Conference on Harmonization [ICH $Q_2(R_1)$] and was found to be precise, accurate, selective and rapid for the simultaneous determination of Ramipril and S (-) Amlodipine Besylate in bulk and tablet dosage forms. The linearity for Ramipril (r^2=0.9914) and S (-) Amlodipine besylate (r^2=0.9930) was established in the range of 25.14-75.41 and 25.46-76.38µg/mL respectively. This new developed method was found to be precise with satisfactory %RSD values for inter and intraday precision.*

KEYWORDS: *S (-) Amlodipine besylate, Antihypertensive, High Performance Liquid Chromatography, Ramipril, Validation*