

Validated RP-HPLC Method for the Simultaneous Determination of Amlodipine Besylate, Valsartan, and Hydrochlorothiazide in Bulk and in Pharmaceutical Formulation

K. ANANDAKUMAR*, D. JOTHIESWARI, R. SUBATHRAL,
D.V. SANTHI, AND T. VETRICHELVAN

Department of Pharmaceutical Analysis, Adhiparasakthi College of Pharmacy,
Melmaruvathur – 603 319, Tamil Nadu, India
E-mail: anandkarunakaran@gmail.com

Summary. A reverse-phase high-performance liquid chromatographic (RP-HPLC) method was developed for the simultaneous estimation of amlodipine besylate (AMB), valsartan (VAL), and hydrochlorothiazide (HCT) in pharmaceutical formulation using RP-C₁₈ column. The mobile phase (acetonitrile:methanol:50 mM phosphate buffer adjusted to pH 3 with orthophosphoric acid) was pumped at a flow rate of 1.0 mL min⁻¹ in the ratio of 20:50:30% v/v and the eluents were monitored at 239 nm. Linearity was obtained in the concentration range of 0.5–5 µg mL⁻¹ for AMB, 4–40 µg mL⁻¹ for VAL, and 1–10 µg mL⁻¹ for HCT. The method was validated as per International Conference on Harmonization (ICH) guidelines and statistically. The method was validated for accuracy and precision. For precision, the coefficient of variance (COV) was found to be 0.3794, 0.1703 and 0.0578, and for accuracy, it was found to be 0.6351, 0.7688 and 1.1305 for AMB, VAL, and HCT, respectively. The COV values for all the drugs were found to be less than 2%, indicating high degree of precision and accuracy of the proposed high-performance liquid chromatographic (HPLC) method. Owing to its simplicity, rapidness, high precision and accuracy, the proposed HPLC method can be applied for determining AMB, VAL, and HCT in bulk and in pharmaceutical dosage form.

Key Words: amlodipine besylate, valsartan, hydrochlorothiazide, RP-HPLC

Introduction

Amlodipine besylate (AMB), 2-[(2-aminoethoxy)-methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridine dicarboxylic acid 3-ethyl-5-methyl ester, benzenesulfonate, is a potent dihydro calcium channel blocker [1]. Various analytical methods have been reported for the assay of AMB alone or in combination with other anti-hypertensive agents in pharmaceutical formulations. They include UV spectroscopy [2–4], high-performance liquid chromatography (HPLC) [5–8], high-performance thin-layer chromatography (HPTLC) [9, 10], LC-MS [11] and LC-MS/MS [12].

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