Quantitative Determination of Amlodipine Besylate in Tablets by High Performance Liquid Chromatography and UV Spectrophotometry

Helen D. LEITE * , Maria Inês R.M. SANTORO, João M.A. PORTO, Pedro LÓPEZ GARCÍA, Mariana M. de ALMEIDA, Vanessa F. TAVARES & Erika R.M. KEDOR-HACKMANN

Department of Pharmacy, Faculty of Pharmaceutical Sciences, University of São Paulo, CP 66083, CEP 05508-900, São Paulo, SP, Brazil

SUMMARY. The purpose of this study was to develop and validate analytical methods for determination of amlodipine besylate in tablets. Simple, accurate and precise liquid chromatographic and spectrophotometric methods are proposed. For the chromatographic method, the conditions were: a LiChrospher®100 RP-18 Merck® (125 mm x 4.6 mm, 5 μ m) column; methanol/water containing 1 % of trietylamine adjusted to pH 5.0 with phosphoric acid (35:65) as mobile phase; a flow rate of 1.0 mL/min and UV detector at 238 nm. Linearity was in the range of 50.0 - 350.0 μ g/mL with a correlation coefficient (r) = 0.9999. For the spectrophotometric method, the first dilutions of samples were performed in methanol and the consecutives in ultrapure water. The quantitation was made at 364.4 nm. Linearity was determined within the range of 41.0 - 61.0 μ g/mL with a correlation coefficient (r) = 0.9996. Our results demonstrate that both methods can be used in routine analysis for quality control of tablets containing amlodipine besylate.

KEY WORDS: Amlodipine besylate, Chromatographic method, Methods validation, Spectrophotometric method.

* Author to whom correspondence should be addressed. E-mail: helendl@usp.com.br