Scienxt Journal of Pharmacy and Drug Research (SJPDR)

Method development and validation for the estimation of azelnidipine in bulk form and marketed pharmaceutical dosage form by using rp-hplc

Yamuna Puchhakayala[1], Gade Sammaiah*[2]

[1,2] Department of Pharmaceutical Chemistry, University College of Pharmaceutical Sciences (UCPSC) Kakatiya University, Hanamkonda, Warangal, Telangana

Corresponding Author: Gade Sammaiah

ABSTRACT

The present work includes a simple, economic, rapid, accurate and precise isocratic RP-HPLC method development for estimation of Azelnidipine in bulk form and its marketed formulation. Estimation was done at 286nm which was found to be λmax of Azelnidipine. The simple, selective, isocratic RP-HPLC method for Azelnidipine was developed on Phenomenex Luna (C_{18}) RP Column; 250 mm x 4.6 mm, 5µm with a mobile phase of Phosphate Buffer (pH-4.6) and Methanol were taken in the ratio of 65:35% v/v at a flow rate of 1.0 ml/min and detection wavelength 286nm. The developed method was validated successfully according to ICH Q2 (R1) guidelines. The chromatographic methods showed a good linear response with r2 values of 0.9995. The percentage relative standard deviation for method was found to be less than two, indicating that the methods were precise. The mean percentage recovery was for RP-HPLC method was 100.437%. From the results it could be concluded that both the developed method was specific, selective and robust. The method could be successfully applied for analysis of Bulk form and Marketed formulation of Azelnidipine.

Keywords: Azelnidipine, RP-HPLC, Method Development, Validation, ICH Guidelines.