ABSTRACT

Validation of HPLC method in dissolution test of combined antihypertensive tablet valsartan-amlodipine

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High Performance Liquid Chromatography (HPLC) method for dissolution test of combined antihypertensive tablet valsartan-amlodipine was validated. Method validation parameters such as specificity, linearity, accuracy, precision, stability, and robustness were determined according to United States Pharmacopeia (USP) XXXVII. Method was carried on Phenyl-Hexyl (150 mm x 4.6 mm, 5µm) column using acetonitrile : water : trifluoroacetic acid (50 : 50 : 0.2 v/v/v) as mobile phase with flow rate of 1.2 mL/min and at 40°C. The injection volume was 10 µL and the UV detector was set at 230 nm. The retention time for amlodipine and valsartan was 2.2 min and 4.2 min, respectively. Total analysis time was 5 min. The method showed good results and met all validation requirements. The linearity of calibration curve for each component in the desired concentration range was good. Intermediate precision was confirmed by different analysts and different equipments, showing good result.

Keywords : method validation, HPLC, dissolution, amlodipine, valsartan.