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A New RP-UPLC Method Developed for the Simultaneous Determination of Anti-Hypertensive Drugs in Dosage Forms

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ABSTRACT

A novel, precise, and sensitive ultra-performance liquid chromatograph method for simultaneous estimation of anti-hypertensive drugs in bulk and tablet dosage form was developed and validated. The chromatographic separation was achieved by using column HSS C18 (100 x 2.1 mm,1.8 µ). A combination of 0.01N Potassium dihydrogen ortho phosphate and ACN (70:30 v/v) was pumped through the column at a flow rate 0.3 mL/min, at 30 °C, eluents were observed at 260 nm and retention time of Telmisartan and Azelnidipine were found to be 1.636 min. and 1.153 min. The method obeys the Beer-Lambert's law in the range of 20-120 µg/mL (Telmisartan) and 2-12 µg/mL (Azelnidipine). The assay (%) was acquired 99.94 % w/w for Telmisartan and 98.96 % w/w Azelnidipine respectively. The force degradation studies were performed under different stress conditions like acidic, alkaline, oxidation, thermal, photolytic and water. The methods were validated according to ICH guidelines for system suitability, linearity, accuracy, precision, sensitivity, robustness, LOD and LOQ and can be conveniently used for the regular quality control analysis of the drugs in bulk and tablets.

Keywords: Anti-hypertensive drugs, RP-UPLC, ICH, Validation, Forced degradation

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