Chiral and achiral liquid chromatographic separation of palonosetron hydrochloride and its related impurities utilizing two different stationary phases: Polysaccharide and alkyl amide columns

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Abstract

In this work, two simple, sensitive and rapid liquid chromatographic (LC) methods were assessed; for the determination of palonosetron hydrochloride and its related impurities. Method A comprised stress study, chiral separation and quantification of palonosetron (PALO) and its six related impurities. The successful separation of PALO and its six related impurities was achieved using Chiralpak AD column (250 mm Ĭ 4.6 mm, 10 Õm), in a polar organic (PO) mode. PALO was eluted using gradient mode, consisting of the mobile phase A: 0.1% diethylamine in acetonitrile, the mobile phase B: isopropanol. Method B is a green UPLC method to estimate PALO in the presence of three of its related impurities. Effective separation was carried out on Bonus RP column (100 mm Ĭ 4.6 mm, 1.8 Õm), based on purified water- ethanol- triethylamine (75: 25: 0.1, v/v), pH 4.0 adjusted with 1 M acetic acid as the mobile phase. The validated methods showed excellent linearity (r2 ¸ 0.999) over the concentration ranges of 5.0ï100.0 εg mLīl and 0.1ï10.0 εg mLīl for method A and B, respectively. The values of the detection limit (LOD) and quantification limit (LOQ) of PALO and its six related impurities were found in the range of 0.014ï0.032 εg mLīl and 0.043ï0.097 εg mLīl, respectively for method A, while for method B; they were found to be in the range of 0.08 and 0.1 εg mLīl, respectively. The optimized methods have been validated and found to be appropriate for quality control of PALO in its pharmaceutical dosage form.

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