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Related Substances Test and Characterization of Seratrodast in Bulk Drugs

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SUMMARY. **A reversed-phase high-performance liquid chromatographic (RP-HPLC) method for related substances test of seratrodast in bulk drugs has been developed. The separation was achieved on a ZirChrom Kromasil C_{18} (200 mm×4.6 mm, 5 μm) column thermostated at 30 °C using acetonitrile-0.05 M pH 3.0 potassium dihydrogen orthophosphate buffer (60:40, v/v) as a mobile phase. Wavelength was set at 267 nm. An external standard method using a dilution of the sample solution as reference was used for the purity test. The method was found to be simple, rapid, specific and sensitive with detection limit of 0.67 ng. A thorough study has been undertaken to identify and characterize an unknown impurity at a level over the identification threshold of 0.1 %, and its structure was elucidated as 7-(3,5,6-trimethyl-1,4-benzoquinone-2-yl)-7-p-tolyl-heptanoic acid based on the data of MS, UV, IR and NMR spectra. Formation of the unknown impurity as well as the countermeasure was also discussed.**

KEY WORDS: HPLC method, purity test, seratrodast related substances, structure characterization.

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