Analysis and determination of raw material atorvastatin and its organic impurities as a cholesterol-lowering drug

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Atorvastatin, a synthetic cholesterol-lowering agent, is a medicine called HMG-CoA (3-hydroxy-3-methylglutaryl-coenzyme A) reductase inhibitor. This enzyme is involved in cholesterol biosynthesis by catalyzing the conversion reaction of HMG-CoA to mevalonate. The function of lowering the amount of cholesterol leads to clearing the LDL (low-density lipoprotein) cholesterol in the blood by increased LDL receptors. In this research we achieve to new high performance liquid chromatography procedure for measuring the assay of atorvastatin and its organic impurities in raw material. The limit of assay and organic impurities are obtained according the United State Pharmacopoeia (USP). Acceptable criteria for atorvastatin related compound A, related compound B, related compound C, related compound D, any other individual impurity and total impurities are respectively 0.3%, 0.3%, 0.3%, 0.1%, 0.1% and 1.0%.

Keywords: Atorvastatin; Cholesterol-lowering agent; Organic impurities; Statins