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Method Development and Validation of Related Substances in Atorvastatin Calcium Amorphous by HPLC

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ABSTRACT

A rapid high performance liquid chromatographic method was developed and validated for determination of Atorvastatin related substances (9 impurities), and degradation products in bulk drugs. The chromatographic separation was achieved on a polar RP 80 A (Synergic) (250mm×4.6mm), 4µcolumn by employing a gradient elution with Water–Acetonitrile–Formic acid-Tetrahydrofuran as the mobile phase in a shorter run time of 75 min. The flow rate was 1.1 mL min^{-1} and the detection wavelength was 254 nm. The drug substance was subjected to stress studies such as hydrolysis, oxidation, photolysis, and thermal degradation, and considerable degradation was observed in acidic hydrolysis, oxidative, thermal, and photolytic stress conditions. The method was validated as per ICH guidelines.

Keywords: Atorvastatin calcium, HPLC Validation, Degradation studies, Forced degradation, related substances.