Quantification of atorvastatin in human plasma by liquid chromatography tandem mass spectrometry and its application for bioequivalence study of three formulations

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ARTICLE INFO

Article history:
Available online 23 November 2015

Keywords:
Atorvastatin
Simvastatin
LC-MS/MS

Atorvastatin, a chemical ([R-(R*, R*)]-2-(4-fluorophenyl)-b,d-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]1 H-pyrole-1-heptanoic acid), is a synthetic HMG-CoA (3-hydroxy-3-methylglutaryl-coenzyme A) reductase inhibitor. It has been shown to be remarkably efficacious in decreasing the level of cholesterol and triglyceride [1]. In order to quantify the level of atorvastatin in plasma, it needs a sensitive, rapid and selective method. As per the literature, several LC-MS/MS methods have been reported for the determination of atorvastatin in human plasma [2].

This research developed a method to quantify atorvastatin in human plasma. Simvastatin was used as internal standard. Atorvastatin and simvastatin were extracted by liquid–liquid extraction using ethyl acetate. The analytical separation was performed using Acquity® UPLC BEH C18, 100 × 2.1 mm, 1.7 μm. The mobile phase used gradient elution of 0.2% formic acid in acetonitrile, with flow rate of 0.3 mL/min. The analysis was carried out by multiple reaction monitoring (MRM) in positive mode using precursor to product combination of m/z 559.05 > 440 for atorvastatin and m/z 419.15 > 199.05 for simvastatin. The method had a chromatographic run time of 5 minutes and linear calibration curve over the range of 0.2–100 ng/mL with a correlation coefficient (r) of 0.9998. All the validation parameters fulfilled the criteria [3] and the method can be successfully applied for pilot bioequivalence studies of three formulations of atorvastatin.

REFERENCES

