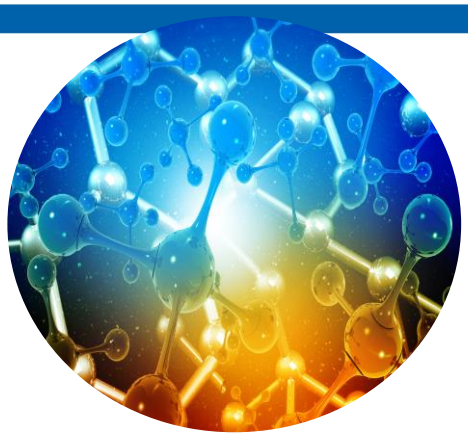

Meeting System Suitability Requirements for Atorvastatin Calcium per USP Monograph

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Overview

Atorvastatin Calcium is a competitive inhibitor of HMG-CoA reductase, the rate-controlling enzyme of the metabolic pathway that produces cholesterol and other isoprenoids. It decreases the amount of LDL-cholesterol in the blood and reduces blood levels of triglycerides and slightly increases levels of HDL-cholesterol. The development of a quick and efficient analysis of Atorvastatin Calcium is of interest for generic drug manufacturers.

In this application note, we report meeting system suitability requirements for the USP Monograph for Atorvastatin Calcium Tablets Assay using a Luna 5 µm C18(2) column and a Luna Omega 5 µm C18 column, which provide similar selectivity as the original Ultremex 5 µm C18 column.

System suitability per USP Monograph for the Atorvastatin Calcium Tablets Assay is a percent relative standard deviation (%RSD) no more than (NMT) 1.0 %, a symmetry factor NMT 1.5, and resolution not less than (NLT) 5.0 between Atorvastatin and Atorvastatin Related Compound H. The Luna 5µm C18(2) column, Luna Omega 5µm C18 column, and Ultremex 5µm C18 column met all system suitability requirements.

All solutions were prepared as indicated in the USP Monograph for Atorvastatin Calcium Tablets. Atorvastatin Calcium RS (Catalog No. 1044516) and Atorvastatin Related Compound H RS (Catalog No. 1044582) were purchased from USP.

LC-UV Conditions

Column: Luna™ 5 µm C18(2)
Luna Omega 5 µm C18
Ultremex™ 5 µm C18

Dimension: 250 x 4.6 mm

Part No.: 00G-4252-E0
00G-4785-E0
00F-0048-E0

Mobile Phase: Acetonitrile / stabilizer-free Tetrahydrofuran / Buffer (27:20:53, v/v/v)

Buffer: 0.05 M Ammonium Citrate buffer, pH 4.0

Flow Rate: 1.5 mL/min (Isocratic)

Injection Volume: 20 µL

Temperature: 30 °C

Detection: UV @ 244 nm

System: Agilent® 1260 Quaternary HPLC

Figure 1. Atorvastatin Calcium

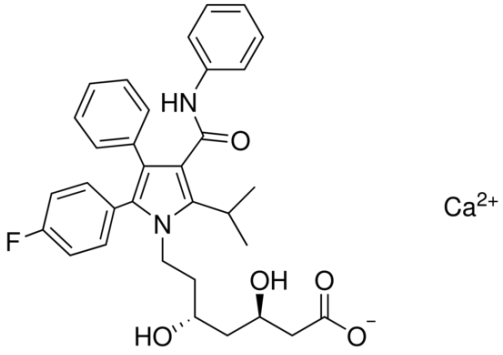
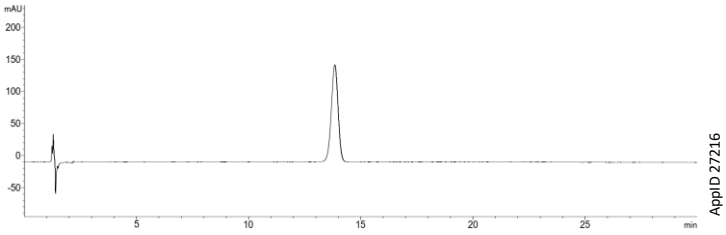


Table 1. Preparation of Solutions

Solution	Composition
Solution A	Dissolve 9.62 g of Anhydrous Citric Acid in 900 mL of Water, adjust with Ammonium Hydroxide to a pH of 7.4, and dilute with Water to 1000 mL.
Diluent	Acetonitrile and *Solution A* (1:1)
Standard Solution	0.1 mg/mL of Atorvastatin Calcium RS in *Diluent*. Shake mechanically for 15 min or until dissolved.
System Suitability Solution	0.1 mg/mL of Atorvastatin Calcium RS and 0.01 mg/mL of Atorvastatin Related Compound H RS in *Diluent*. Shake mechanically for 30 min or until dissolved.

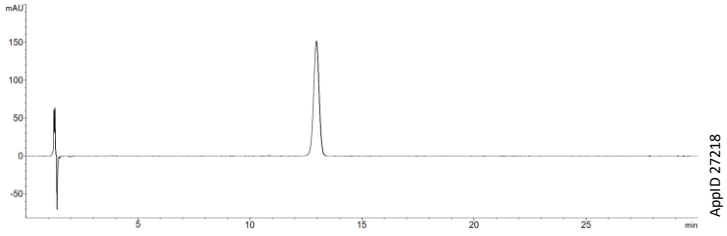
Figure 2. Standard Solution

Luna™ 5 µm C18(2) Column



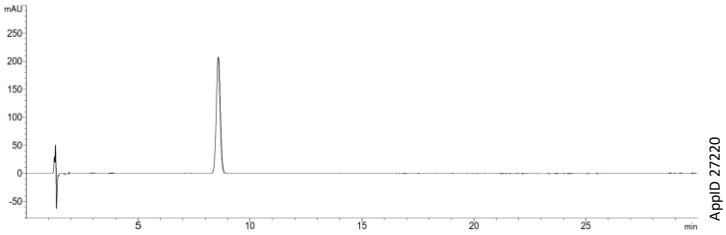
Analyte	Retention Time (min)	Height	Area	Area %RSD
Atorvastatin Calcium	13.862	121.0	2550	0.2
N = 5 Injections				

Luna Omega 5 µm C18 Column



Analyte	Retention Time (min)	Height	Area	Area %RSD
Atorvastatin Calcium	12.954	151.6	2594	0.1
N = 5 Injections				

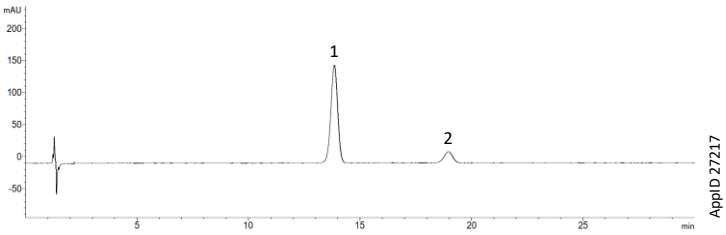
Ultremex™ 5 µm C18 Column



Analyte	Retention Time (min)	Height	Area	Area %RSD
Atorvastatin Calcium	8.603	207.2	2550.4	0.2
N = 5 Injections				

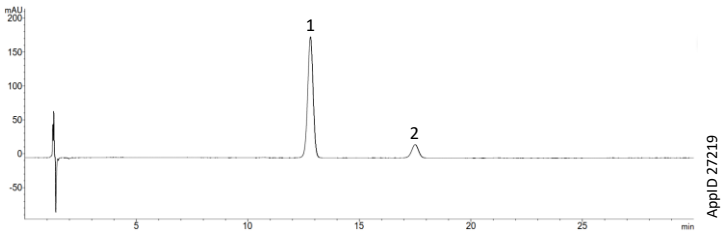
Figure 3. System Suitability Solution

Luna™ 5 µm C18(2) Column



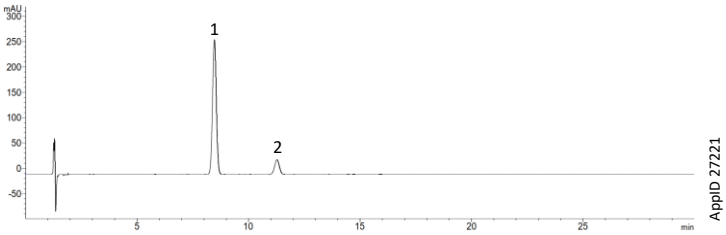
Peak No.	Analyte	Retention Time (min)	Symmetry Factor	Resolution
1	Atorvastatin Calcium	13.848	0.96	7.99
2	Related Compound H	18.961	0.95	

Luna Omega 5 µm C18 Column



Peak No.	Analyte	Retention Time (min)	Symmetry Factor	Resolution
1	Atorvastatin Calcium	12.805	0.98	9.31
2	Related Compound H	17.500	0.95	

Ultremex™ 5 µm C18 Column



Peak No.	Analyte	Retention Time (min)	Symmetry Factor	Resolution
1	Atorvastatin Calcium	8.470	1.02	8.00
2	Related Compound H	11.276	1.00	

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