

APPLICATION



Optimized USP Method for Atorvastatin Calcium using Kinetex® 1.7 µm XB-C18 Core-Shell Column

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Overview

According to the original U.S. Pharmacopeial Convention (USP) monograph for atorvastatin calcium, the method has a run time of 115 minutes. It calls for a 5 µm, 250 x 4.6 mm L7 column. The goal of this application note is to minimize runtime without sacrificing resolution. Mobile phase components remained unchanged from the original USP method for ease of adoption. However, for this particular optimization, the changes exceeded what is currently allowed by the USP's General Chapter <621> without revalidation.

By using a Kinetex 1.7 µm XB-C18 core-shell column and modifying a gradient step, the runtime was drastically reduced while exceeding the USP's resolution requirement of 1.5 between atorvastatin calcium and related compound B. The runtime was cut to only 18 minutes (including re-equilibration) and the resolution between the critical pair was 1.68. Reference standards were purchased from the USP and prepared in N,N-dimethylformamide.

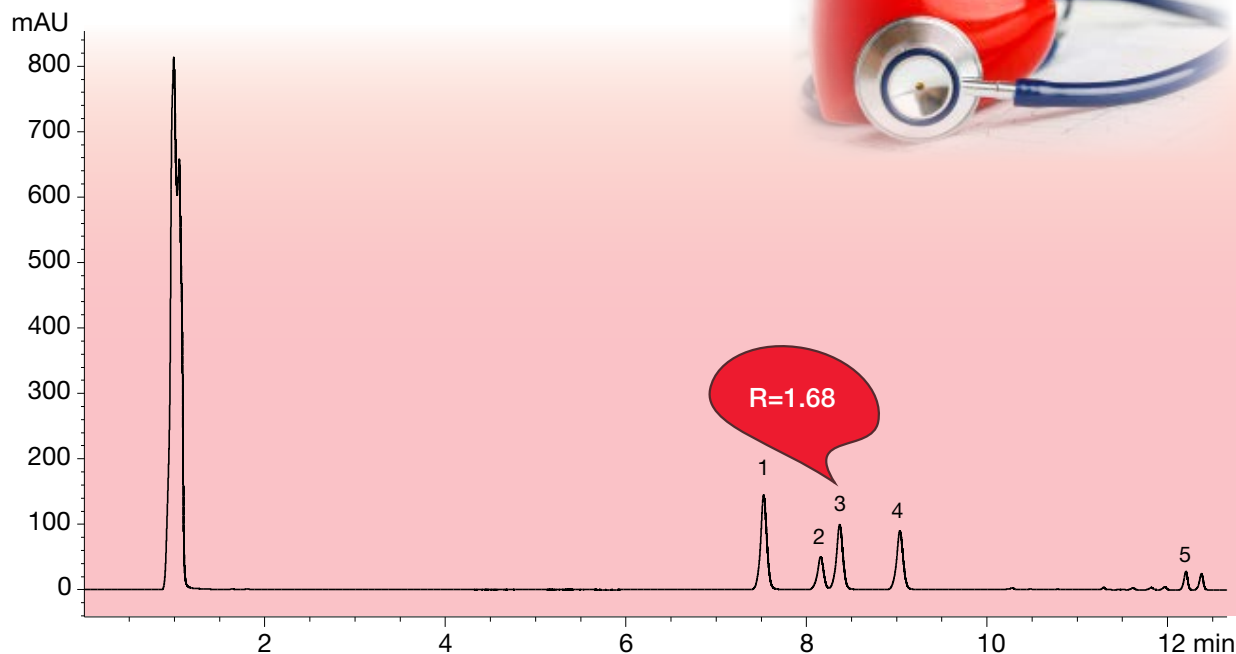
LC/UV Conditions

Column: Kinetex 1.7 µm XB-C18 100Å
Dimensions: 100 x 3.0 mm
Part No.: 00D-4498-Y0
Mobile Phase: A: Acetonitrile/THF/50 mM Ammonium Acetate Buffer, pH 5 (21:12:67)
 B: Acetonitrile/THF/50 mM Ammonium Acetate Buffer, pH 5 (61:12:27)

Gradient:	Time (min)	% B
	0	0
	8	25
	10	80
	15	100
	16	100
	16.1	0
	18	0

Flow Rate: 0.4 mL/min
Injection: 2 µL
Temperature: Ambient
Detection: UV @ 244 nm
Sample: 1. Related Compound A
 2. Related Compound B
 3. Atorvastatin Calcium
 4. Related Compound C
 5. Related Compound D

Separation of USP reference standards



App ID 23405



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Kinetex[®] XB-C18 Core-Shell LC Columns

5 µm Minibore Columns (mm)				SecurityGuard [™] ULTRA Cartridges [†]	5 µm MidBore [™] Columns (mm)				SecurityGuard [™] ULTRA Cartridges [†]
Phases	30 x 2.1	50 x 2.1	100 x 2.1	3/pk	Phases	50 x 3.0	100 x 3.0	150 x 3.0	3/pk
XB-C18	00A-4605-AN	00B-4605-AN	00D-4605-AN	AJO-8782	XB-C18	00B-4605-YO	00D-4605-YO	00F-4605-YO	AJO-8775
				for 2.1 mm ID					for 3.0 mm ID

5 µm Analytical Columns (mm)					SecurityGuard [™] ULTRA Cartridges [†]
Phases	50 x 4.6	100 x 4.6	150 x 4.6	250 x 4.6	3/pk
XB-C18	00B-4605-E0	00D-4605-E0	00F-4605-E0	00G-4605-E0	AJO-8768
					for 4.6 mm ID

2.6 µm Minibore Columns (mm)						SecurityGuard [™] ULTRA Cartridges [†]
Phases	30 x 2.1	50 x 2.1	75 x 2.1	100 x 2.1	150 x 2.1	3/pk
XB-C18	00A-4496-AN	00B-4496-AN	00C-4496-AN	00D-4496-AN	00F-4496-AN	AJO-8782
						for 2.1 mm ID

2.6 µm MidBore [™] Columns (mm)						SecurityGuard [™] ULTRA Cartridges [†]
Phases	30 x 3.0	50 x 3.0	75 x 3.0	100 x 3.0	150 x 3.0	3/pk
XB-C18	00A-4496-YO	00B-4496-YO	00C-4496-YO	00D-4496-YO	00F-4496-YO	AJO-8775
						for 3.0 mm ID

1.7 µm Minibore Columns (mm)					SecurityGuard [™] ULTRA Cartridges [†]
Phases	30 x 2.1	50 x 2.1	100 x 2.1	150 x 2.1	3/pk
XB-C18	00A-4498-AN	00B-4498-AN	00D-4498-AN	00F-4498-AN	AJO-8782
					for 2.1 mm ID

1.7 µm MidBore [™] Columns (mm)				SecurityGuard [™] ULTRA Cartridges [†]
Phases	30 x 3.0	50 x 3.0	100 x 3.0	3/pk
XB-C18	00A-4498-YO	00B-4498-YO	00D-4498-YO	AJO-8775
				for 3.0 mm ID



If Phenomenex products in this technical note do not provide at least an equivalent separation as compared to other products of the same phase and dimensions, return the product with comparative data within 45 days for a FULL REFUND.

[†]SecurityGuard Ultra Cartridges require holder, Part No.: AJO-9000

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