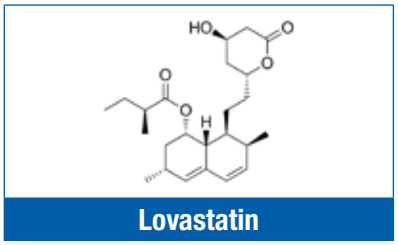
APPLICATION

Lovastatin
USP



Lovastatin

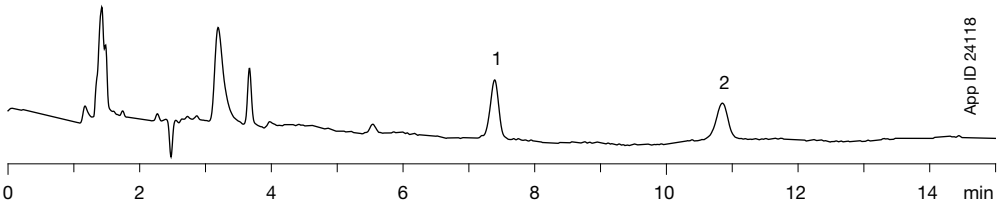
Overview
The related substances test of the USP monograph outlines the separation of all relevant impurities from Lovastatin. This method was studied and improvements were made to provide higher resolution (Rs) and a faster separation time within allowable adjustments.

USP Monograph: Lovastatin Details	
System Suitability Solution	Dissolve USP Lovastatin RS and USP Lovastatin Related Compound A RS in acetonitrile to obtain a concentration of 2.0 µg/mL of each
Standard Solution	Dissolve USP Lovastatin RS in acetonitrile to obtain a concentration of about 2.0 µg/mL
Test Solution	Dissolve 25 mg of Lovastatin in a 25 mL volumetric flask and dilute to volume with acetonitrile, mix
Column	
Size	250 x 4.6 mm
Stationary Phase	5 µm, L7: Octyl silane chemically bonded to totally or superficially porous silica particles, 1.5 to 10 µm in diameter, or a monolithic silica rod
Temperature	40 °C
Mobile Phase	Acetonitrile and 0.01 M Phosphoric acid (13:7)
Flow Rate	1.5 mL/min
Detection	Spectrophotometer @ 200 nm
Injection	10 µL
Relative Retention with Reference to Lovastatin*	
Related Compound A	about 1.3
System Suitability	
Minimum resolution of 6.0 between Lovastatin and Related Compound A	

* Retention times, relative retentions, and retardation factors are provided for information only and are not mandatory, no deviation allowance is defined.

Method 1
Original Method within as Described in the USP Monograph

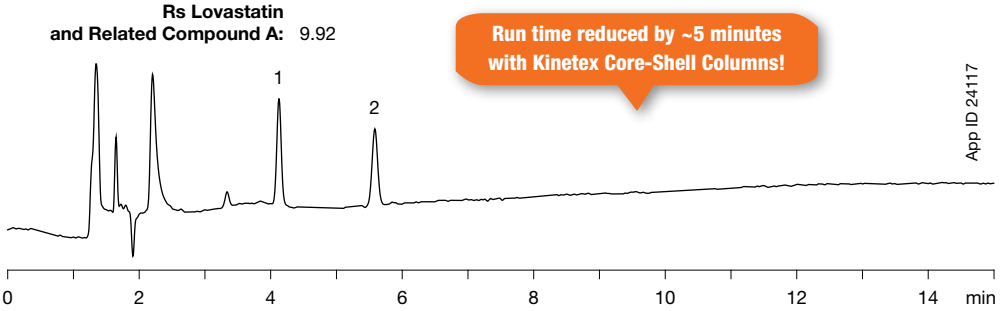
Column: Luna® C8(2) 5 µm Fully Porous
Dimensions: 250 x 4.6 mm
Part No.: 00G-4249-E0
Flow Rate: 1.5 mL/min
Sample: 1. Lovastatin
2. Related Compound A
Elution Time of Last Peak: 10.9 min
Rs Lovastatin and Related Compound A: 12.33



Method 2

Faster and Higher Resolution Within Allowable Adjustments

Column: Kinetex® Core-Shell C8 5 µm
Dimensions: 250 x 4.6 mm
Part No.: 00G-4608-E0
Flow Rate: 1.5 mL/min
Sample: 1. Lovastatin
2. Related Compound A
Elution Time of Last Peak: 5.6 min
Rs Lovastatin and Related Compound A: 9.92



Adjustments for Meeting System Suitability

Method Parameter	Allowed Adjustments (isocratic elution)	Method 1	Method 2
Mobile Phase pH	± 0.2 units	As specified	As specified
Concentration of Salts in Buffer	± 10 %	As specified in Monograph Details Table	As specified
Composition of the Mobile Phase	± 30 % Relative; cannot exceed ± 10 % Absolute change; cannot be reduced to zero	As specified in Monograph Details Table	As specified
Wavelength of Detector	No deviations permitted	200 nm (as specified)	As specified
Injection Volume	Can be adjusted as much as needed; must be consistent with linearity, precision, and detection requirements	10 µL (as specified)	As specified
Column Temperature	± 10 °C	40 °C (as specified)	As specified
Stationary Phase	No change of the identity of the substituent permitted (e.g. no replacement of C8 by C18)	L7 (as specified)	As specified
Column Length	Column length (L) to particle size diameter (dp) ratio can be adjusted between -25 % and +50 %*	250 mm (as specified)	As specified
Column Internal Diameter	Can be adjusted so long as linear velocity if maintained	4.6 mm (as specified)	As specified
Particle Size	Column length (L) to particle size diameter (dp) ratio can be adjusted between -25 % and +50 %*	5 µm (as specified)	As specified
Flow Rate	± 50 % (at given ID)	1.5 mL/min (as specified	As specified

*Alternatively (as for the application of particle size adjustment to superficially porous particles), other L/dp combinations can be used provided that the number of theoretical plates (N) is within -25 % to +50 %

Kinetex® Ordering Information

5 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
C8	—	00B-4608-AN	00D-4608-AN	—	AJ0-8784
					for 2.1 mm ID

5 µm MidBore™ Columns (mm)				SecurityGuard ULTRA Cartridges‡
Phases	50 x 3.0	100 x 3.0	150 x 3.0	3/pk
C8	00B-4608-Y0	00D-4608-Y0	—	AJ0-8777
				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
C8	00B-4608-E0	00D-4608-E0	00F-4608-E0	00G-4608-E0	AJ0-8770
					for 4.6 mm ID

‡SecurityGuard ULTRA Cartridges require holder, Part No.: AJ0-9000

Luna® Ordering Information

5 µm Microbore and Minibore Columns (mm)								SecurityGuard™ Cartridges (mm)
Phases	50 x 1.0	150 x 1.0	250 x 1.0	30 x 2.0	50 x 2.0	150 x 2.0	250 x 2.0	4 x 2.0*
								/10pk
C8(2)	—	00F-4249-A0	—	00A-4249-B0	00B-4249-B0	00F-4249-B0	00G-4249-B0	AJ0-4289
								for ID: 2.0-3.0 mm

5 µm MidBore and Analytical Columns (mm)								SecurityGuard™ Cartridges (mm)	
Phases	30 x 3.0	50 x 3.0	150 x 3.0	250 x 3.0	30 x 4.6	50 x 4.6	75 x 4.6	4 x 2.0*	4 x 3.0*
								/10pk	/10pk
C8(2)	00A-4249-Y0	00B-4249-Y0	00F-4249-Y0	00G-4249-Y0	00A-4249-E0	00B-4249-E0	00C-4249-E0	AJ0-4289	AJ0-4290
								for ID: 2.0-3.0 mm	3.2-8.0 mm

5 µm Analytical and Semi-Prep Columns (mm)					SecurityGuard™ Cartridges (mm)	
Phases	100 x 4.6	150 x 4.6	250 x 4.6	250 x 10	4 x 3.0*	10 x 10‡
					/10pk	/3pk
C8(2)	00D-4249-E0	00F-4249-E0	00G-4249-E0	00G-4249-N0	AJ0-4290	AJ0-7222
					for ID: 3.2-8.0 mm	9-16 mm

*SecurityGuard™ Analytical Cartridges require holder, Part No.: KJ0-4282
‡SemiPrep SecurityGuard Cartridges require holder, Part No.: AJ0-9281

guarantee

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

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