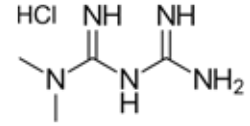


APPLICATION

Metformin Hydrochloride USP

Overview

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



Metformin Hydrochloride

USP Monograph: Metformin Hydrochloride Details

System Suitability Stock Solution	0.25 mg/mL of Metformin Hydrochloride and 0.1 mg/mL of Melamine in water
System Suitability Solution	Transfer 1.0 mL of system suitability stock solution to a 50 mL volumetric flask, dilute with mobile phase to volume
Standard Stock Solution	0.2 mg/mL of USP Metformin Related Compound A RS in water
Standard Solution	0.001 mg/mL of USP Metformin Related Compound A RS in Mobile Phase from Standard stock solution
Sample Solution	5 mg/mL of Metformin Hydrochloride in mobile phase
Diluted Sample Solution	0.005 mg/mL of Metformin Hydrochloride in Mobile Phase from the Sample solution

Column

Size	250 x 4.6 mm
Stationary Phase	L9: Irregular or spherical, totally porous silica gel having a chemically bonded, strongly acidic cation-exchange coating, 3 to 10 µm in diameter
Mobile Phase	17 g/L of monobasic ammonium phosphate in water, adjusted with phosphoric acid to a pH 3.0
Flow Rate	1.0 - 1.7 mL/min
Detection	Spectrophotometer @ 218 nm
Injection	20 µL
Run Time	Not less than twice the retention time of Metformin

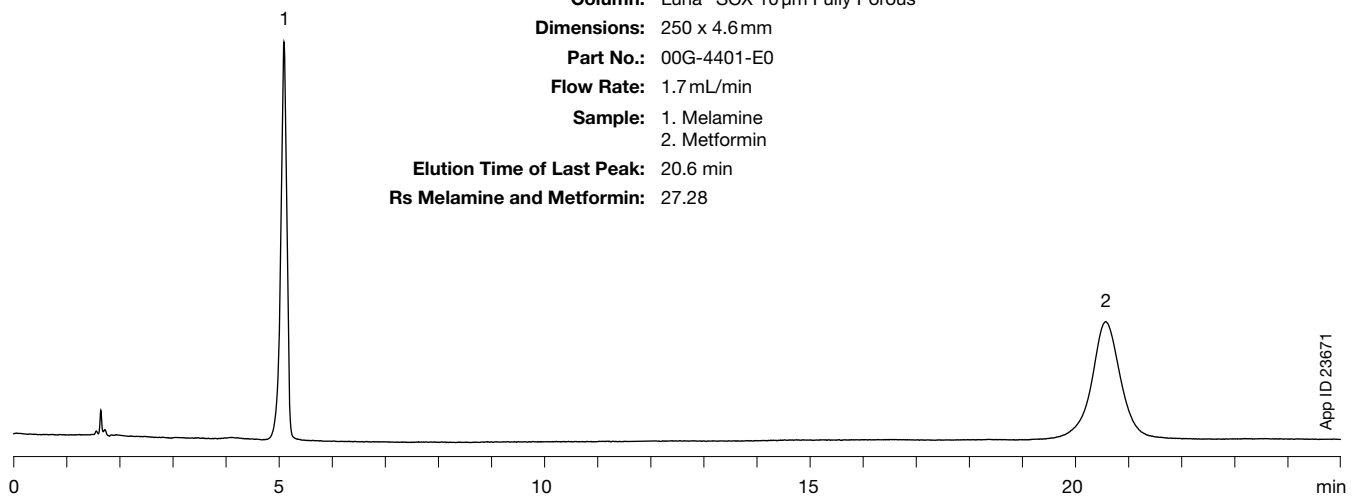
System Suitability

Minimum resolution of 10 between Melamine and Metformin

Method 1

Original Method as Described in the USP Monograph

Column: Luna[®] SCX 10 µm Fully Porous
Dimensions: 250 x 4.6 mm
Part No.: 00G-4401-E0
Flow Rate: 1.7 mL/min
Sample: 1. Melamine
 2. Metformin
Elution Time of Last Peak: 20.6 min
Rs Melamine and Metformin: 27.28



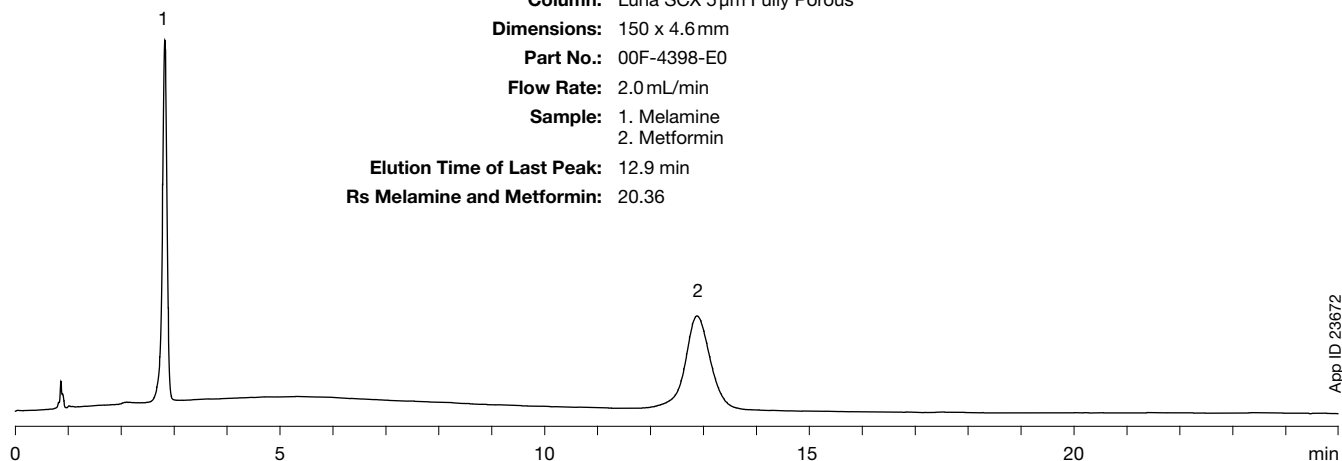
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Method 2
Faster Method Within Allowable Adjustments

Column: Luna SCX 5 µm Fully Porous
Dimensions: 150 x 4.6 mm
Part No.: 00F-4398-E0
Flow Rate: 2.0 mL/min
Sample: 1. Melamine
2. Metformin

Elution Time of Last Peak: 12.9 min
Rs Melamine and Metformin: 20.36



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	218 nm (as specified)	As specified
Injection Volume	Can be adjusted as much as needed; must be consistent with linearity, precision, and detection requirements	20 µL (as specified)	As specified
Column Temperature	± 10 °C	Ambient (as specified)	As specified
Stationary Phase	No change of the identity of the substituent permitted (e.g. no replacement of C18 by C8)	L9 (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)	150 mm (-40 %)
Column Internal Diameter	Can be adjusted so long as linear velocity is 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 %*	10 µm (as specified)	5 µm (as specified)
Flow Rate	± 50 % (at given ID)	1.7 mL/min (as specified)	2.0 mL/min (+18)

*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 %

Luna® Ordering Information

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*
SCX	—	—	00F-4398-Y0	—	—	00B-4398-E0	—	/10pk AJ0-4307	/10pk AJ0-4308
								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 ²
					/10pk AJ0-4308	/3pk AJ0-7369
SCX	00D-4398-E0	00F-4398-E0	00G-4398-E0	00G-4398-N0	for ID: 3.2-8.0 mm	9-16 mm

10 µm Analytical and Semi-Prep Columns (mm)			SecurityGuard Cartridges (mm)	
Phases	250 x 4.6	250 x 10	4 x 3.0*	10 x 10 ²
			/10 pk AJ0-4308	/3 pk AJ0-7369
SCX	00G-4401-E0	00G-4401-N0	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, similar phase and dimensions, return the product with comparative data within 45 days for a FULL REFUND.



APPLICATION

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