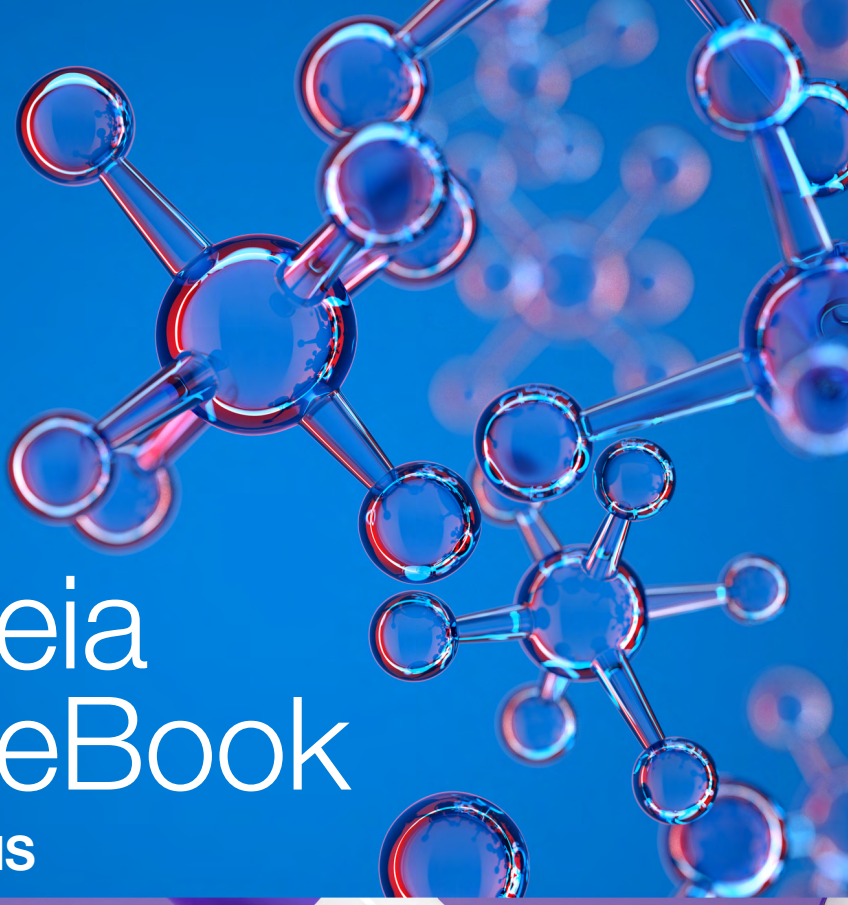
KINETEX
Core-Shell Technology



Pharmacopeia Application eBook

SMALL MOLECULE ANALYSIS

Improve United States Pharmacopeia (USP) Method Performance with Allowable Adjustments

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Click for LC Resource Centers and Downloads!

- **UHPLC/HPLC Method Transfer Tool**
- **USP and Ph. Eur. Allowable Adjustments Calculator**
- **Luna™ Omega C18 Application eBook**
- **New Micro LC Column and Trap Guide**
- **Genotoxic Nitrosamine Resource Center**

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United States Pharmacopeia Allowable Adjustments General Chapter <621>

This guide provides analysts with solutions to standard USP monographs and allows the incorporation of cutting edge and reproducible HPLC column technology to provide shorter separation times and improved resolution while meeting all the quality standards of the USP for years to come!

Isocratic Separations and Methods

Component	United States Pharmacopeia (USP)
Mobile phase minor component (≤ 50 %)	± 30 % Relative; Cannot exceed ± 10 % Absolute change; Cannot be reduced to zero
Mobile phase pH	± 0.2 pH units
Buffer concentration	± 10 %
Column temperature	± 10 °C
Injection volume	Can be adjusted as much as needed; Must be consistent with linearity, precision, and detection requirements
Detector wavelength	Cannot be modified
Flow rate	± 50 % (at given ID)
Column inner diameter	Can be adjusted so long as linear velocity is maintained
Column length	Column length (L) to particle size diameter (dp) ratio can be adjusted between -25 % and +50 %*
Particle size	Column length (L) to particle size diameter (dp) ratio can be adjusted between -25 % and +50 %*
Stationary phase	No change of the identity of the substituent permitted
Guards	Same stationary phase as column; Guard ID ≤ column ID; Guard length ≤ 15 % column length

* 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%.

Gradient Separations and Methods

Component	United States Pharmacopeia (USP)
Mobile phase minor component (≤ 50 %)	Changes to gradient composition are not recommended
Mobile phase pH	± 0.2 pH units
Buffer concentration	± 10 %
Column temperature	± 10 °C
Injection volume	Can be adjusted as much as needed; Must be consistent with linearity, precision, and detection requirements
Detector wavelength	Cannot be modified
Flow rate	Changes to flow rate are not allowed
Column inner diameter	Changes to column length, particle size, or inner diameter are not allowed
Column length	Changes to column length, particle size, or inner diameter are not allowed
Particle size	Changes to column length, particle size, or inner diameter are not allowed
Stationary phase	No change of the identity of the substituent permitted
Guards	Same stationary phase as column; Guard ID ≤ column ID; Guard length ≤ 15 % column length

Tip!

Reducing excess HPLC system volume will allow you to realize maximum separation power!

ON-DEMAND WEBINAR

Apply USP Chapter <621> Allowable Adjustments to Your USP Pharmacopeia Method

Click to View On-Demand Webinar

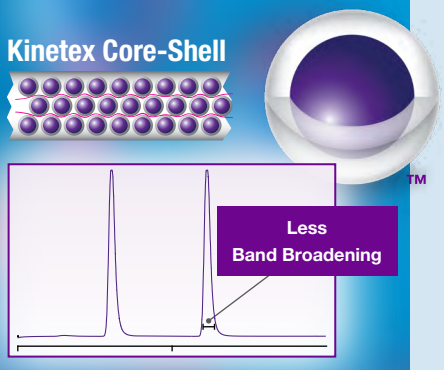
Walk-through with our scientists!

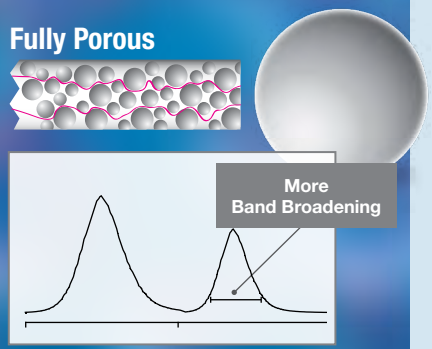
KINETEX
Core-Shell Technology

Why Choose Kinetex Core-Shell Columns?

- Performance Gains on Any LC System
- System-to-System and Lab-to-Lab Reproducibility
- Improve the Productivity of Older, Established Methods

Make the Easy-Switch to Kinetex!





Pharmacopeia Application Highlights

- Reduce Run Times Without Re-Validation
- Achieve Higher Resolution
- Stay Within Allowable Adjustment

Click Each!

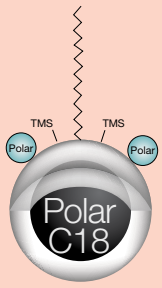
- Robust Separation of Hydrochlorothiazide and Chlorothiazide in Hydrochlorothiazide Tablets Using Kinetex 5 µm C18
- Limit of Free Salicylic Acid in Aspirin Tablets Using Kinetex 5 µm C18 Under USP Allowable Adjustments
- Robust Separation of Hydroxychloroquine and Chloroquine in Hydroxychloroquine Sulfate Tablets Using Kinetex 5 µm C18
- Separation of Ibuprofen and Valerophenone Using Kinetex 5 µm C18 and Under USP Allowable Adjustments
- Separation of Lovastatin and Related Impurity with Kinetex 5 µm C18 Under USP Allowable Adjustments
- Separation of Clavulanate and Amoxicillin Using Kinetex 5 µm C18 and Under USP Allowable Adjustments
- Separation of Doxapram Hydrochloride and its Organic Impurities per USP Monograph (AN-1091)
- Separation of Miconazole Nitrate and its Organic Impurities per USP Monograph using Kinetex 2.6 µm Phenyl-Hexyl Column (AN-1090)
- Separation of Doxapram Hydrochloride and its Organic Impurities per USP Monograph (AN-1091)
- Assay of Doxepin Hydrochloride According to USP Monograph Using Three Different HPLC Columns
- Purity of Trihexyphenidyl Hydrochloride Tablets per USP Monograph using Kinetex 2.6 µm XB C18 Column
- Meeting and Surpassing System Suitability for USP Sildenafil Tablets Assay and Organic Impurities Using Kinetex Core-Shell and Luna™ Omega HPLC/UHPLC Columns
- Meeting and Surpassing System Suitability for USP Sildenafil Citrate Assay and Organic Impurities Using Kinetex Core-Shell and Luna Omega HPLC/UHPLC Columns
- USP Tadalafil Assay on Luna 5 µm C8(2) and Kinetex 5 µm C8 (AN-1012)
- USP Colchicine Assay on Luna 5 µm C8(2) and Kinetex 5 µm C8 (AN-1006)

FROM UHPLC TO HPLC

Selectivity Recommendations

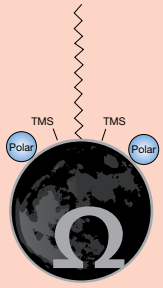
POLAR ACIDS

Kinetex™ Polar C18



pH Range: 1.5 – 8.5*
USP Classification: L1
Effective Carbon Load: 9%

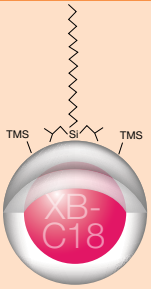
Luna™ Omega Polar C18



pH Range: 1.5 - 8.5*
USP Classification: L1
Effective Carbon Load: 9%

ACIDIC COMPOUNDS

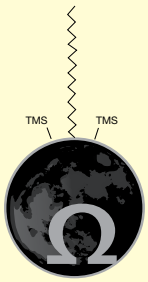
Kinetex XB-C18



pH Range: 1.5 - 8.5*
USP Classification: L1
Effective Carbon Load: 10%

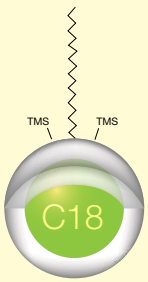
HYDROPHOBIC COMPOUNDS

Luna Omega C18



pH Range: 1.5 – 8.5*
USP Classification: L1
Effective Carbon Load: 11%

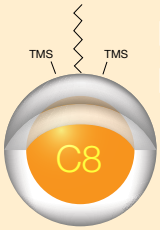
Kinetex C18



pH Range: 1.5 - 8.5*
USP Classification: L1
Effective Carbon Load: 12%

EXTREMELY HYDROPHOBIC

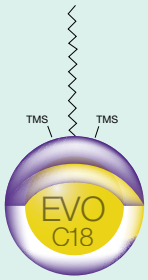
Kinetex C8



pH Range: 1.5 - 8.5*
USP Classification: L7
Effective Carbon Load: 8%

ALKALINE CONDITIONS

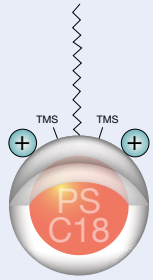
Kinetex EVO C18



pH Range: 1 – 12
USP Classification: L1
Effective Carbon Load: 11%

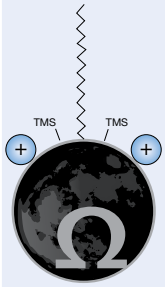
POLAR BASES

Kinetex PS C18



pH Range: 1.5 - 8.5*
USP Classification: L1
Effective Carbon Load: 9%

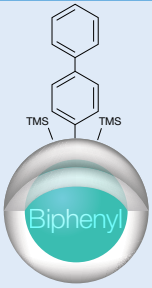
Luna Omega PS C18



pH Range: 1.5 - 8.5*
USP Classification: L1
Effective Carbon Load: 9%

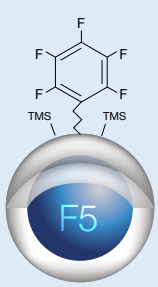
CLOSELY RELATED COMPOUNDS & AROMATIC HYDROCARBONS

Kinetex Biphenyl



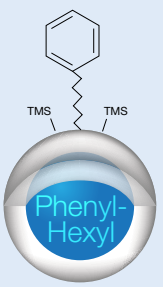
pH Range: 1.5 – 8.5*
USP Classification: L11
Effective Carbon Load: 11%

Kinetex F5



pH Range: 1.5 - 8.5*
USP Classification: L43
Effective Carbon Load: 9%

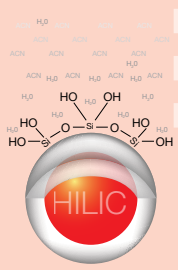
Kinetex Phenyl-Hexyl



pH Range: 1.5 – 8.5*
USP Classification: L11
Effective Carbon Load: 11%

EXTREMELY POLAR

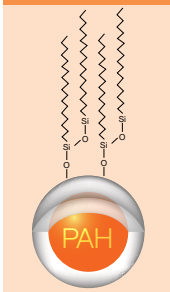
Kinetex HILIC



pH Range: 2.0 – 7.5
USP Classification: L3
Effective Carbon Load: —

PAH COMPOUNDS

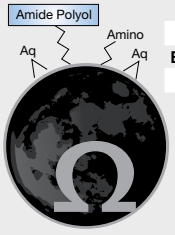
Kinetex PAH



pH Range: 1.5 - 8.5*
USP Classification: L118
Effective Carbon Load: 12%

SUGAR

Luna Omega SUGAR



pH Range: 2.0 - 7.0
USP Classification: L8
Effective Carbon Load: <2%

*Columns are pH stable from 1.5-10 under isocratic conditions. Columns are pH stable 1.5-8.5 under gradient conditions.

KINETEX
Core-Shell Technology

Kinetex core-shell particle LC columns provide unparalleled performance gains on ANY LC system!

Plus, you have your pick of 11 amazing stationary phases and 5 versatile particle sizes!

Ordering Information

KINETEX™ Core-Shell Technology

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**
EVO C18	00A-4633-AN	00B-4633-AN	00D-4633-AN	00F-4633-AN	AJ0-9298
F5	—	00B-4724-AN	00D-4724-AN	00F-4724-AN	AJ0-9322
Biphenyl	00A-4627-AN	00B-4627-AN	00D-4627-AN	—	AJ0-9209
XB-C18	00A-4605-AN	00B-4605-AN	00D-4605-AN	—	AJ0-8782
C18	00A-4601-AN	00B-4601-AN	00D-4601-AN	00F-4601-AN	AJ0-8782
C8	—	00B-4608-AN	00D-4608-AN	—	AJ0-8784
Phenyl-Hexyl	—	00B-4603-AN	—	—	AJ0-8788
HILIC	—	00B-4606-AN	—	—	AJ0-8786
					for 2.1 mm ID

5 µm MidBore™ Columns (mm)				SecurityGuard ULTRA Cartridges‡	
Phases	**30 x 3.0**	**50 x 3.0**	**100 x 3.0**	**150 x 3.0**	**3/pk**
EVO C18	00A-4633-Y0	00B-4633-Y0	00D-4633-Y0	00F-4633-Y0	AJ0-9297
F5	—	—	00D-4724-Y0	00F-4724-Y0	AJ0-9321
Biphenyl	—	00B-4627-Y0	00D-4627-Y0	00F-4627-Y0	AJ0-9208
XB-C18	—	00B-4605-Y0	00D-4605-Y0	00F-4605-Y0	AJ0-8775
C18	00A-4601-Y0	00B-4601-Y0	00D-4601-Y0	00F-4601-Y0	AJ0-8775
C8	—	00B-4608-Y0	00D-4608-Y0	—	AJ0-8777
Phenyl-Hexyl	—	00B-4603-Y0	00D-4603-Y0	—	AJ0-8781
					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**
EVO C18	00B-4633-E0	00D-4633-E0	00F-4633-E0	00G-4633-E0	AJ0-9296
F5	00B-4724-E0	00D-4724-E0	00F-4724-E0	00G-4724-E0	AJ0-9320
Biphenyl	00B-4627-E0	00D-4627-E0	00F-4627-E0	00G-4627-E0	AJ0-9207
XB-C18	00B-4605-E0	00D-4605-E0	00F-4605-E0	00G-4605-E0	AJ0-8768
C18	00B-4601-E0	00D-4601-E0	00F-4601-E0	00G-4601-E0	AJ0-8768
C8	00B-4608-E0	00D-4608-E0	00F-4608-E0	00G-4608-E0	AJ0-8770
Phenyl-Hexyl	00B-4603-E0	00D-4603-E0	00F-4603-E0	00G-4603-E0	AJ0-8774
HILIC	—	—	00F-4606-E0	00G-4606-E0	AJ0-8772
					for 4.6 mm ID

5 µm Semi-Preparative Columns (mm)				SecurityGuard SemiPrep Cartridges***
Phases	**100 x 10**	**150 x 10**	**250 x 10**	**10 x 10**
EVO C18	—	00F-4633-N0	00G-4633-N0	AJ0-9306
F5	—	—	00G-4724-N0	AJ0-9323
C18	00D-4601-N0	00F-4601-N0	00G-4601-N0	AJ0-9278
Biphenyl	—	00F-4627-N0	00G-4627-N0	AJ0-9280
XB-C18	—	00F-4605-N0	00G-4605-N0	AJ0-9278
				for 9-16 mm ID

5 µm Axia™ Packed Preparative Columns (mm)					SecurityGuard PREP Cartridges*
Phases	**50 x 21.2**	**100 x 21.2**	**150 x 21.2**	**250 x 21.2**	**15 x 21.2**
EVO C18	00B-4633-P0-AX	00D-4633-P0-AX	00F-4633-P0-AX	00G-4633-P0-AX	AJ0-9304
F5	—	—	00F-4724-P0-AX	00G-4724-P0-AX	AJ0-9324
Biphenyl	00B-4627-P0-AX	00D-4627-P0-AX	00F-4627-P0-AX	00G-4627-P0-AX	AJ0-9272
XB-C18	00B-4605-P0-AX	00D-4605-P0-AX	00F-4605-P0-AX	00G-4605-P0-AX	AJ0-9145
C18	00B-4601-P0-AX	00D-4601-P0-AX	00F-4601-P0-AX	00G-4601-P0-AX	AJ0-9145
C8	00B-4608-P0-AX	00D-4608-P0-AX	00F-4608-P0-AX	00G-4608-P0-AX	AJ0-9205
Phenyl-Hexyl	00B-4603-P0-AX	00D-4603-P0-AX	00F-4603-P0-AX	00G-4603-P0-AX	AJ0-9147
HILIC	—	00D-4606-P0-AX	00F-4606-P0-AX	00G-4606-P0-AX	AJ0-9277
					for 18-29 mm ID

5 µm Axia Packed Preparative Columns (mm)					SecurityGuard PREP Cartridges**
Phases	**50 x 30**	**100 x 30**	**150 x 30**	**250 x 30**	**15 x 30**
EVO C18	00B-4633-U0-AX	00D-4633-U0-AX	00F-4633-U0-AX	00G-4633-U0-AX	AJ0-9305
F5	00B-4724-U0-AX	00D-4724-U0-AX	00F-4724-U0-AX	—	AJ0-9325
Biphenyl	—	—	00F-4627-U0-AX	00G-4627-U0-AX	AJ0-9273
XB-C18	00B-4605-U0-AX	00D-4605-U0-AX	00F-4605-U0-AX	00G-4605-U0-AX	AJ0-9204
C18	00B-4601-U0-AX	00D-4601-U0-AX	00F-4601-U0-AX	00G-4601-U0-AX	AJ0-9204
C8	00B-4608-U0-AX	00D-4608-U0-AX	00F-4608-U0-AX	00G-4608-U0-AX	AJ0-9217
Phenyl-Hexyl	00B-4603-U0-AX	00D-4603-U0-AX	00F-4603-U0-AX	00G-4603-U0-AX	AJ0-9216
HILIC	—	—	00D-4606-U0-AX	—	—
					for 30-49 mm ID

3.5 µm Minibore, MidBore™, and Analytical Columns (mm)								SecurityGuard™ ULTRA Cartridges‡	
Phases	**50 x 2.1**	**150 x 2.1**	**100 x 3.0**	**100 x 4.6**	**150 x 4.6**	**250 x 4.6**	**3/pk**	**3/pk**	**3/pk**
XB-C18	—	—	—	00D-4744-E0	00F-4744-E0	—	—	—	AJ0-8768
PAH	00B-4764-AN	00F-4764-AN	00D-4764-Y0	00D-4764-E0	00F-4764-E0	00G-4764-E0	AJ0-9535	AJ0-9534	AJ0-9533
							for 2.1 mm ID	for 3.0 mm ID	for 4.6 mm ID

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

*** SemiPrep SecurityGuard Cartridges require holder, Part No.: AJ0-9281

** PREP SecurityGuard Cartridges require holder, Part No.: AJ0-8277

* PREP SecurityGuard Cartridges require holder, Part No.: AJ0-8223

Ordering Information

KINETEX™ Core-Shell Technology

BE-HAPPY™ GUARANTEE

Your happiness is our mission. Take 45 days to try our products. If you are not happy, we'll make it right.
www.phenomenex.com/behappy

2.6 µm Micro LC Columns (mm)						
Phases	**30 x 0.3**	**50 x 0.3**	**100 x 0.3**	**150 x 0.3**	**50 x 0.5**	**150 x 0.5**
Biphenyl	—	00B-4622-AC	—	00F-4622-AC	00B-4622-AF	—
C18	00A-4462-AC	00B-4462-AC	—	00F-4462-AC	00B-4462-AF	—
EVO C18	—	00B-4725-AC	—	00F-4725-AC	00B-4725-AF	—
F5	—	00B-4723-AC	00D-4723-AC	00F-4723-AC	00B-4723-AF	—
XB-C18	00A-4496-AC	00B-4496-AC	00D-4496-AC	00F-4496-AC	00B-4496-AF	00F-4496-AF

2.6 µm Microbore Columns (mm)			
Phases	**50 x 1.0**	**100 x 1.0**	**150 x 1.0**
C18	00B-4462-A0	—	—
XB-C18	00B-4496-A0	00D-4496-A0	00F-4496-A0

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**
EVO C18	00A-4725-AN	00B-4725-AN	—	00D-4725-AN	00F-4725-AN	AJ0-9298
PS C18	00A-4780-AN	00B-4780-AN	—	00D-4780-AN	00F-4780-AN	AJ0-8951
Polar C18	00A-4759-AN	00B-4759-AN	—	00D-4759-AN	00F-4759-AN	AJ0-9532
F5	00A-4723-AN	00B-4723-AN	—	00D-4723-AN	00F-4723-AN	AJ0-9322
Biphenyl	00A-4622-AN	00B-4622-AN	—	00D-4622-AN	00F-4622-AN	AJ0-9209
XB-C18	00A-4496-AN	00B-4496-AN	00C-4496-AN	00D-4496-AN	00F-4496-AN	AJ0-8782
C18	00A-4462-AN	00B-4462-AN	00C-4462-AN	00D-4462-AN	00F-4462-AN	AJ0-8782
C8	00A-4497-AN	00B-4497-AN	00C-4497-AN	00D-4497-AN	00F-4497-AN	AJ0-8784
HILIC	00A-4461-AN	00B-4461-AN	00C-4461-AN	00D-4461-AN	00F-4461-AN	AJ0-8786
Phenyl-Hexyl	00A-4495-AN	00B-4495-AN	00C-4495-AN	00D-4495-AN	00F-4495-AN	AJ0-8788

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**
EVO C18	00A-4725-Y0	00B-4725-Y0	—	00D-4725-Y0	00F-4725-Y0	AJ0-9297
PS C18	00B-4780-Y0	00D-4780-Y0	—	00D-4780-Y0	00F-4780-Y0	AJ0-8950
Polar C18	—	00B-4759-Y0	—	00D-4759-Y0	00F-4759-Y0	AJ0-9531
F5	—	00B-4723-Y0	—	00D-4723-Y0	00F-4723-Y0	AJ0-9321
Biphenyl	—	00B-4622-Y0	—	00D-4622-Y0	00F-4622-Y0	AJ0-9208
XB-C18	00A-4496-Y0	00B-4496-Y0	00C-4496-Y0	00D-4496-Y0	00F-4496-Y0	AJ0-8775
C18	00A-4462-Y0	00B-4462-Y0	00C-4462-Y0	00D-4462-Y0	00F-4462-Y0	AJ0-8775
C8	00A-4497-Y0	00B-4497-Y0	00C-4497-Y0	00D-4497-Y0	00F-4497-Y0	AJ0-8777
HILIC	00A-4461-Y0	—	—	00D-4461-Y0	00F-4461-Y0	AJ0-8779
Phenyl-Hexyl	—	00B-4495-Y0	—	00D-4495-Y0	00F-4495-Y0	AJ0-8781

for 3.0 mm ID

2.6 µm Analytical Columns (mm)							SecurityGuard ULTRA Cartridges‡
Phases	**30 x 4.6**	**50 x 4.6**	**75 x 4.6**	**100 x 4.6**	**150 x 4.6**	**250 x 4.6**	**3/pk**
EVO C18	00A-4725-E0	00B-4725-E0	—	00D-4725-E0	00F-4725-E0	00G-4725-E0	AJ0-9296
PS C18	00A-4780-E0	00B-4780-E0	—	00D-4780-E0	00F-4780-E0	00G-4780-E0	AJ0-8949
Polar C18	00A-4759-E0	00B-4759-E0	—	00D-4759-E0	00F-4759-E0	—	AJ0-9532
F5	00A-4723-E0	00B-4723-E0	—	00D-4723-E0	00F-4723-E0	—	AJ0-9320
Biphenyl	—	00B-4622-E0	—	00D-4622-E0	00F-4622-E0	—	AJ0-9207
XB-C18	—	00B-4496-E0	00C-4496-E0	00D-4496-E0	00F-4496-E0	—	AJ0-8768
C18	00A-4462-E0	00B-4462-E0	00C-4462-E0	00D-4462-E0	00F-4462-E0	—	AJ0-8768
C8	—	00B-4497-E0	00C-4497-E0	00D-4497-E0	00F-4497-E0	—	AJ0-8770
HILIC	—	00B-4461-E0	00C-4461-E0	00D-4461-E0	00F-4461-E0	—	AJ0-8772
Phenyl-Hexyl	—	00B-4495-E0	00C-4495-E0	00D-4495-E0	00F-4495-E0	—	AJ0-8774

for 4.6 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**
EVO C18	—	00B-4726-AN	00D-4726-AN	00F-4726-AN	AJ0-9298
F5	—	00B-4722-AN	00D-4722-AN	00F-4722-AN	AJ0-9322
Biphenyl	00A-4628-AN	00B-4628-AN	00D-4628-AN	00F-4628-AN	AJ0-9209
XB-C18	00A-4498-AN	00B-4498-AN	00D-4498-AN	00F-4498-AN	AJ0-8782
C18	00A-4475-AN	00B-4475-AN	00D-4475-AN	00F-4475-AN	AJ0-8782
C8	00A-4499-AN	00B-4499-AN	00D-4499-AN	00F-4499-AN	AJ0-8784
HILIC	00A-4474-AN	00B-4474-AN	00D-4474-AN	—	AJ0-8786
Phenyl-Hexyl	—	00B-4500-AN	00D-4500-AN	00F-4500-AN	AJ0-8788

for 2.1 mm ID

1.7 µm Microbore Columns (mm)			
Phases	**50 x 1.0**	**100 x 1.0**	**150 x 1.0**
EVO C18	00B-4726-A0	00D-4726-A0	00F-4726-A0
Biphenyl	00B-4628-A0	00D-4628-A0	—

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-Y0	00B-4498-Y0	00D-4498-Y0	AJ0-8775
C18	—	00B-4475-Y0	00D-4475-Y0	AJ0-8775
C8	00A-4499-Y0	00B-4499-Y0	00D-4499-Y0	AJ0-8777
Phenyl	—	—	00D-4500-Y0	AJ0-8781
HILIC	—	00B-4474-Y0	—	AJ0-8779

for 3.0 mm ID

1.3 µm Minibore Columns (mm)		
Phases	**30 x 2.1**	**50 x 2.1**
C18	00A-4515-AN	00B-4515-AN

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

Pharmacopeia Application eBook

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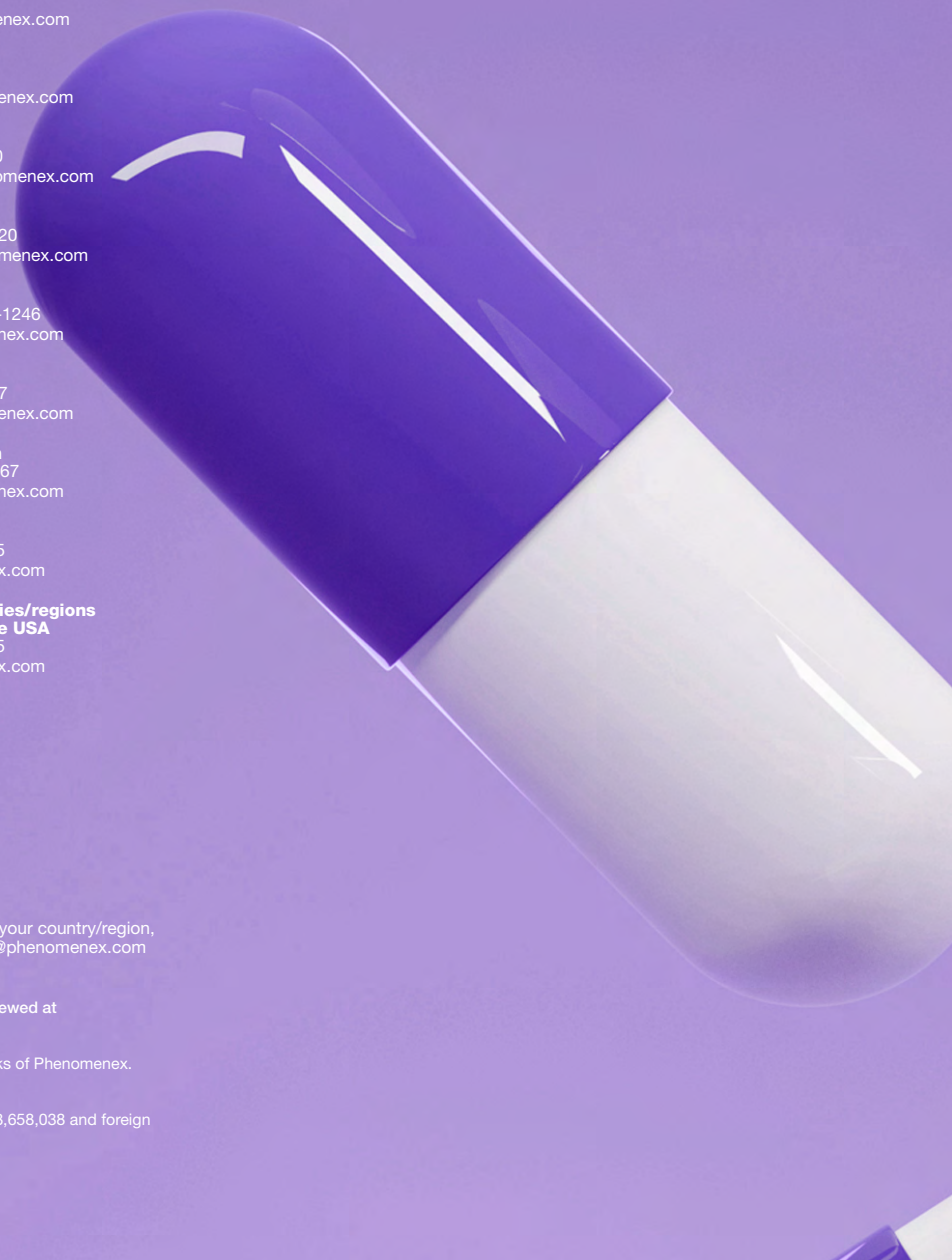

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