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Designing Safer, More Effective Drugs

Pharmaceutical formulations has a growing need for better analytical performance as the excipients (or “non-active” ingredients) along with the active ingredients are becoming more scrutinized by regulatory agencies. Scientists are now looking for ways to more easily qualify and quantitate a large variety of ingredients. Take a quick look at our solutions for ways you can improve your formulations analysis, today.

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What are excipients?

Excipients are the inactive ingredients within a pharmaceutical formulation that hold the active pharmaceutical ingredient (API) and ensure the conveniently sized dose is delivered efficiently and effectively to the targeted area. Excipients are typically inert substances, but sometimes they can result in adverse side effects. Modern pharmaceutical regulations require formulation analysis for all ingredients within a pharmaceutical drug to identify all excipient components and guarantee safety of the end product.

Formulation analysis can be achieved through several modes of chromatography including reversed phase, ion-exclusion, size exclusion chromatography (SEC), which includes gel permeation chromatography (GPC) and gel filtration chromatography (GFC), and gas chromatography (GC). Phenomenex offers a wide breadth of products for reliable and reproducible excipient analysis.

Recommended Chromatography Technique by Excipient Category

Excipient	Technique
Binders	Size Exclusion Chromatography (SEC) Reversed Phase Ion-Exchange Gas Chromatography (GC)
Coatings	Size Exclusion Chromatography (SEC) Reversed Phase
Fillers / Sweeteners	Ion-Exclusion/Ligand Exchange Reversed Phase
Solubilizers / Surfactants	Size Exclusion Chromatography (SEC) Gas Chromatography (GC)
Residual Solvents	Gas Chromatography (GC)



Phenomenex Premier Solutions by Technique

HPLC/UHPLC	Recommended
Size Exclusion Chromatography (SEC)	
Gel Permeation Chromatography (GPC)	
• Polymer-Based Non-Aqueous GPC/SEC	Phenogel™
Gel Filtration Chromatography (GFC)	
• Silica-Based Aqueous GFC/SEC	Yarra™ (1.8 μm, 3 μm), BioSep™ (5 μm)
• Polymer-Based Aqueous GFC/SEC	PolySep™
Ion-Exclusion/Ligand Exchange	Rezex™
Reversed Phase	Kinetex® (1.3 μm, 1.7 μm, 2.6 μm, 3.5 μm, 5 μm) Luna® (1.6 μm, 2.5 μm, 3 μm, 5 μm)
Ion-Exchange	Luna SCX
GC	Recommended
Gas Chromatography	Zebtron™ ZB-1ms, ZB-5ms, ZB-5MS ^{PLUS} ™, ZB-35, ZB-50, ZB-624, ZB-WAX ^{PLUS} ™, ZB-FFAP

Pharmacopoeia Classifications

Ph. Eur. Recommendations

Column recommendations provided by the European Pharmacopoeia (Ph. Eur.) are generally given as a description of the media along with the column dimensions. For instance, a monograph may call for “a stainless steel column 0.3 m long and 7.8 mm in internal diameter packed with strong cation-exchange resin (calcium form) R (9 µm) and maintained at a temperature of 85 ± 1 °C.” This would be the precise description of our Rezex™ RCM-Monosaccharide 300 x 7.8 mm column (P/N 00H-0130-K0).

Description According to Pharm. Eur. 8.6 4.1.1. Reagents 2016	Number	Recommended Phenomenex Column	Indicated Particle Size (µm)
Silica gel for chromatography.	1076900	Kinetex® HILIC Luna® Silica(2)	3 to 10
Silica gel for chromatography, alkyl bonded for use with highly aqueous mobile phases.	1160200	Synergi™ Hydro-RP Synergi Fusion-RP Gemini® C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18	
Silica gel for chromatography, alkyl bonded for use with highly aqueous mobile phases, endcapped.	1176900	Synergi Hydro-RP Synergi Fusion-RP Gemini C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18	
Silica gel for chromatography, butylsilyl. Spheroidal 300 Å; pore volume: 0.6 cm ³ /g; area: 80 m ² /g.	1076200	Aeris™ WIDEPOR C4	3 to 10
Silica gel for chromatography, butylsilyl, endcapped.	1170500	Aeris WIDEPOR C4 Jupiter® 300 C4	3 to 10
Silica gel for chromatography, cyanosilyl.	1109900	Luna CN (Cyano)	3 to 10
Silica gel for chromatography, di-isobutyloctadecylsilyl.	1140000	Kinetex XB-C18	
Silica gel for chromatography, diol dihydroxypropyl, 100 Å.	1110000	Luna HILIC	5
Silica gel for chromatography, dodecylsilyl, endcapped.	1179700	Synergi Max-RP	

[See More](#) ▶

Pharmacopoeia Classifications

Description According to Pharm. Eur. 8.6 4.1.1. Reagents 2016	Number	Recommended Phenomenex Column	Indicated Particle Size (µm)
Silica gel for chromatography, hydrophilic surface has been modified to provide hydrophilic characteristics.	1077200	Luna® HILIC	3 to 10
Silica gel for chromatography, nitrile cyanopropylsilyl.	1077300	Luna CN (Cyano)	3 to 10
Silica gel for chromatography, nitrile R1 chemically bonded nitrile groups.	1077400	Luna CN (Cyano)	3 to 10
Silica gel for chromatography, nitrile R2 ultrapure silica (<20 ppm metal) with cyanopropylsilyl groups.	1119500	Luna CN (Cyano)	3 to 10
Silica gel for chromatography, nitrile, endcapped with cyanopropylsilyl groups.	1174500	Luna CN (Cyano)	3 to 10
Silica gel for chromatography, octadecylsilyl.	1077500	Luna C18(2) Synergi™ Hydro-RP Synergi Fusion-RP Gemini® C18 Gemini NX-C18 Kinetex® C18 Kinetex EVO C18 Kinetex XB-C18	3 to 10
Silica gel for chromatography, octadecylsilyl R1 ultrapure silica (<20 ppm metals), pore size and C-load are indicated in the method.	1110100	Luna C18(2) Synergi Hydro-RP Synergi Fusion-RP Gemini C18 Gemini NX-C18 Jupiter C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18	3 to 10
Silica gel for chromatography, octadecylsilyl, base-deactivated pretreated before the bonding by careful washing and hydrolyzing most of the superficial siloxane bridges to minimize the interaction with basic components.	1077600	Luna C18(2) Gemini C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18	3 to 10
Silica gel for chromatography, octadecylsilyl, endcapped. To minimize any interaction with basic compounds it's carefully endcapped to cover most of the remaining silanol groups.	1115400	Luna C18(2) Gemini C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18	3 to 10
Silica gel for chromatography, octadecylsilyl, endcapped R1 ultrapure silica (<20 ppm metal), 19 % C-load. To minimize any interaction with basic compounds it's carefully endcapped to cover most of the remaining silanol groups.	1115401	Luna C18 Synergi Hydro-RP	
Silica gel for chromatography, octadecylsilyl, endcapped, base-deactivated; pore size 100 Å, C-load:16 %, pretreated before the bonding by careful washing and hydrolyzing most of the superficial siloxane bridges. To further minimize any interaction with basic compounds it's carefully endcapped to cover most of the remaining silanol groups.	1108600	Luna C18(2) Gemini C18 Gemini NX-C18	3 to 10
Silica gel for chromatography, octadecylsilyl, endcapped, base-deactivated R1; pretreated before the bonding by careful washing and hydrolyzing most of the superficial siloxane bridges. To further minimize any interaction with basic compounds it's carefully endcapped to cover most of the remaining silanol groups.	1162600	Luna C18(2) Gemini C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18	3 to 10

Pharmacopoeia Classifications

Description According to Pharm. Eur. 8.6 4.1.1. Reagents 2016	Number	Recommended Phenomenex Column	Indicated Particle Size (µm)
Silica gel for chromatography, octadecylsilyl, monolithic.	1154500	Onyx™ C18	
Silica gel for chromatography, octadecylsilyl, with polar embedded groups, endcapped; the particles are based on a mixture of silica chemically modified at the surface by the bonding of octadecylsilyl groups and silica chemically modified with a reagent providing a surface with chains having embedded polar groups.	1177900	Synergi™ Fusion-RP	3 to 10
Silica gel for chromatography, octadecylsilyl, with polar incorporated groups, endcapped; the particles are based on silica, chemically modified with a reagent providing a surface with chains having polar incorporated groups and terminating octadecyl groups.	1165100	Synergi Fusion-RP	3 to 10
Silica gel for chromatography, octadecylsilyl, ethylene-bridged (hybrid material). Synthetic, spherical ethylene-bridged particles, containing both organic and inorganic (silica) components.	1190500	Kinetex® EVO C18 Gemini® NX-C18	
Silica gel for chromatography compatible with 100 % aqueous mobile phase, octadecylsilyl, endcapped.	1188400	Kinetex EVO C18 Synergi Hydro-RP Synergi Fusion-RP	
Silica gel for chromatography, octadecylsilyl, extra-dense bonded, endcapped.	1188500	Luna® C18(2) Gemini C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18	
Silica gel for chromatography, octadecylsilyl, solid core, endcapped with spherical silica particles containing a non-porous solid silica core surrounded by a thin outer porous silica coating with octadecylsilyl groups. To minimize any interaction with basic compounds it is carefully endcapped to cover most of the remaining silanol groups.	1193900	Kinetex C18 Kinetex XB-C18 Kinetex EVO C18 Aeris™ PEPTIDE XB-C18 Aeris WIDEPOR XB-C18	
Silica gel for chromatography, octylsilyl.	1077700	Kinetex C8 Luna C8(2)	3 to 10
Silica gel for chromatography, octylsilyl R1. Bonding of octylsilyl and methyl groups (double bonded phase).	1077701	Kinetex C8 Luna C8(2)	3 to 10
Silica gel for chromatography, octylsilyl, base-deactivated pretreated before the bonding by careful washing and hydrolyzing most of the superficial siloxane bridges to minimize the interaction with basic components.	1131600	Kinetex C8 Luna C8(2)	3 to 10
Silica gel for chromatography, octylsilyl, endcapped. To minimize any interaction with basic compounds it's carefully endcapped to cover most of the remaining silanol groups.	1119600	Kinetex C8 Luna C8(2)	3 to 10
Silica gel for chromatography, octylsilyl, endcapped, base-deactivated pretreated before the bonding by careful washing and hydrolyzing most of the superficial siloxane bridges to minimize the interaction with basic components. To further minimize any interaction with basic compounds it's carefully endcapped to cover most of the remaining silanols.	1148800	Kinetex C8 Luna C8(2)	3 to 10
Silica gel for chromatography, phenylhexylsilyl.	1153900	Kinetex Phenyl-Hexyl Luna Phenyl-Hexyl Gemini C6-Phenyl	3 to 10
Silica gel for chromatography, phenylhexylsilyl, endcapped 3 µm. To minimize any interaction with basic compounds it's carefully endcapped to cover most of the remaining silanol groups.	1170600	Kinetex Phenyl-Hexyl Luna Phenyl-Hexyl Gemini C6-Phenyl	3
Silica gel for chromatography, phenylsilyl.	1110200	Synergi Polar-RP Luna Phenyl-Hexyl Gemini C6-Phenyl Kinetex Biphenyl Kinetex Phenyl-Hexyl	5 to 10

[See More](#)

Pharmacopoeia Classifications

Description According to Pharm. Eur. 8.6 4.1.1. Reagents 2016	Number	Recommended Phenomenex Column	Indicated Particle Size (µm)
Silica gel for chromatography, phenylsilyl, endcapped. To minimize any interaction with basic compounds it's carefully endcapped to cover most of the remaining silanol groups.	1154900	Synergi™ Polar-RP Luna® Phenyl-Hexyl Gemini® C6-Phenyl Kinetex® Biphenyl Kinetex Phenyl-Hexyl	5 to 10
Silica gel for chromatography, propoxybenzene, endcapped.	1174600	Synergi Polar-RP	3 to 10
Silica gel for chromatography, strong cation-exchange bonding of sulfonic acid groups.	1161400	Luna SCX	5 to 10
Silica for size-exclusion chromatography. 10 µm silica with a very hydrophilic surface. Pore size average: 30 nm; pH stability 2 to 8; exclusion range for proteins: 1×10^3 to 3×10^5 .	1077900	BioSep™-SEC-S3000	10
Organosilica polymer, amorphous, octadecylsilyl. Synthetic, spherical hybrid particles containing both inorganic (silica) and organic (organosiloxanes) components, chemically modified at the surface by trifunctionally bonded octadecylsilyl groups.	1144200	Kinetex EVO C18 Gemini C18 Gemini NX-C18	
Organosilica polymer, amorphous, octadecylsilyl, endcapped. Synthetic, spherical hybrid particles containing both inorganic (silica) and organic (organosiloxanes) components, chemically modified at the surface by trifunctionally bonded octadecylsilyl groups. To minimize any interaction with basic compounds, it is carefully endcapped to cover most of the remaining silanol groups.	1178600	Kinetex EVO C18 Gemini C18 Gemini NX-C18	
Organosilica polymer for mass spectrometry, amorphous, octadecylsilyl, endcapped. Synthetic, spherical hybrid particles containing both inorganic (silica) and organic (organosiloxanes) components. To minimize any interaction with basic compounds, it is carefully endcapped to cover most of the remaining silanol groups.	1164900	Kinetex EVO C18 Gemini C18 Gemini NX-C18	
Ion-exclusion resin for chromatography. A resin with sulfonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with divinylbenzene.	1131000	Rezex™ ROA-Organic Acid Rezex RHM-Monosaccharide	
Cation-exchange resin, strong. Strong cation-exchange resin in protonated form with sulfonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with divinylbenzene.	1156800	Rezex ROA-Organic Acid Rezex RHM-Monosaccharide	
Cation-exchange resin (Calcium form), strong. Resin in calcium form with sulfonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with 8 % divinylbenzene	1104600	Rezex RCM-Monosaccharide Rezex RCU-USP Sugar Alcohols	
Cation-exchange resin (Sodium form), strong. Resin in sodium form with sulfonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with divinylbenzene.	1176100	Rezex RNM-Carbohydrate	

Pharmacopoeia Classifications

USP Packings (L classifications)

USP Column Classification	Recommended Phenomenex Column	Particle Shape
L1 Octadecyl silane chemically bonded to porous or non-porous silica or ceramic microparticles, 1.5 to 10 µm in diameter, or a monolithic rod.	Gemini® NX-C18	Spherical
	Kinetex® C18	Core-Shell
	Kinetex EVO C18	Core-Shell
	Kinetex XB-C18	Core-Shell
	Luna® C18(2)	Spherical
	Gemini C18	Spherical
	Synergi™ Hydro-RP Synergi Fusion-RP	Spherical Spherical
L3 Porous silica particles, 1.5 to 10 µm in diameter, or a monolithic silica rod.	Kinetex HILIC	Core-Shell
	Luna Silica(2)	Spherical
	Onyx™ Silica	Monolith
L7 Octyl silane chemically bonded to totally or superficially porous silica particles, 1.5 to 10 µm in diameter, or a monolithic silica rod.	Kinetex C8	Core-Shell
	Luna C8(2)	Spherical
	Onyx C8	Monolith
L8 An essentially monomolecular layer of aminopropyl-silane chemically bonded to totally porous silica gel support, 1.5 to 10 µm in diameter, or a monolithic silica rod.	Luna NH ₂	Spherical
L9 Irregular or spherical, totally porous silica gel having a chemically bonded, strongly acidic cation-exchange coating, 3 to 10 µm in diameter.	Luna SCX	Spherical
	Aeris™ WIDEPORE XB-C8	Core-Shell
L10 Nitrile groups chemically bonded to porous silica particles, 1.5 to 10 µm in diameter, or a monolithic silica rod.	Luna CN 100 Å	Spherical
L11 Phenyl groups chemically bonded to porous silica particles, 1.5 to 10 µm in diameter, or a monolithic silica rod.	Kinetex Biphenyl	Core-Shell
	Kinetex Phenyl-Hexyl	Core-Shell
	Synergi Polar-RP	Spherical
	Luna Phenyl-Hexyl	Spherical
	Gemini C6-Phenyl	Spherical
	Prodigy™ PH-3	Spherical
L17 Strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the hydrogen form, 6 to 12 µm in diameter.	Rezex™ RHM-Monosaccharide	Spherical
	Rezex ROA-Organic Acid	Spherical
L19 Strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the calcium form, 5 to 15 µm in diameter.	Rezex RCM-Monosaccharide	Spherical
	Rezex RCU-Sugar Alcohols	Spherical
L20 Dihydroxypropane groups chemically bonded to porous silica or hybrid particles, 1.5 to 10 µm in diameter, or a monolithic silica rod.	Luna HILIC	Spherical
	BioSep™-SEC-S	Spherical
L21 A rigid, spherical styrene-divinylbenzene copolymer, 3 to 30 µm in diameter.	PolymerX™ RP-1	Spherical
	Phenogel™ 100 Å	Spherical
L22 A cation-exchange resin made of porous polystyrene gel with sulfonic acid groups, 5 to 15 µm in diameter.	Rezex ROA-Organic Acid	Spherical
	Yarra™ SEC	Spherical
L26 Butyl silane chemically bonded to totally porous silica particles, 1.5 to 10 µm in diameter.	Jupiter® 300 C4	Spherical
	Aeris WIDEPORE C4	Core-Shell

Pharmacopoeia Classifications

USP Packings (L classifications cont'd)

USP Column Classification	Recommended Phenomenex Column	Particle Shape
L33 Packing having the capacity to separate dextrans by molecular size over a range of 4,000 to 500,000 daltons. It is spherical, silica-based and processed to provide pH stability.	Yarra™ SEC-2000 BioSep™-SEC-S2000 Yarra SEC-3000 BioSep-SEC-S3000	Spherical Spherical Spherical Spherical
L34 Strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the lead form, 7 to 9 µm in diameter.	Rezex™ RPM-Monosaccharide	Spherical
L35 A zirconium-stabilized spherical silica packing with a hydrophilic (diol-type) molecular monolayer bonded phase having a pore size of 150Å.	(BioSep-SEC-S2000 or Yarra SEC-2000 may be used)	Spherical Spherical
L37 Polymethacrylate gel packing having the capacity to separate proteins by molecular size over a range of 2,000 to 40,000 daltons.	PolySep™-GFC-P3000	Spherical
L38 Methacrylate-based size-exclusion packing for water-soluble samples.	PolySep-GFC-P series	Spherical
L39 Hydrophilic polyhydroxymethacrylate gel of totally porous spherical resin.	PolySep-GFC-P series	Spherical
L43 Pentafluorophenyl groups chemically bonded to silica particles by a propyl spacer, 1.5 to 10 µm in diameter.	Kinetex® F5 Luna® PFP(2)	Core-Shell Spherical
L58 Strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the sodium form, about 6 to 30 µm in diameter.	Rezex RNM-Carbohydrate	Spherical
L59 Size-exclusion separations of proteins (separation by molecular weight) over the range of 5 to 7000 kDa. Spherical (1.5 to 10 µm), silica or hybrid packing with a hydrophilic coating.	Yarra SEC-2000 BioSep-SEC-S2000 Yarra SEC-3000 BioSep-SEC-S3000	Spherical Spherical Spherical Spherical

USP Phase Designation (G classifications)

Phase Type	Phase Description	Recommended Zebron™ GC Columns
G1	Dimethylpolysiloxane Oil	ZB-1, ZB-1ms, ZB-1HT Inferno™
G2	Dimethylpolysiloxane Gum	ZB-1, ZB-1ms, ZB-1HT
G3	50 % Phenyl 50 % Methylpolysiloxane	ZB-50
G9	Methylvinylpolysiloxane	ZB-1ms, ZB-1HT Inferno, ZB-1
G14	Polyethylene Glycol (Average MW 950 - 1,050)	ZB-WAX, ZB-WAX _{PLUS} ™
G15	Polyethylene Glycol (Average MW 3,000 - 3,700)	ZB-WAX, ZB-WAX _{PLUS}
G16	Polyethylene Glycol (Average MW 15,000)	ZB-WAX, ZB-WAX _{PLUS}
G17	75 % Phenyl 25 % Methylpolysiloxane	ZB-50
G20	Polyethylene Glycol (Average MW 380 - 420)	ZB-WAX, ZB-WAX _{PLUS}
G25	Polyethylene Glycol TPA (Carbowax 20M Terephthalic Acid)	ZB-FFAP
G27	5 % Phenyl 95 % Methylpolysiloxane	ZB-5, ZB-5MSi, ZB-5HT Inferno
	5 % Phenyl-Arylene 95 % Methylpolysiloxane	ZB-5ms, ZB-5MS _{PLUS} , ZB-SemiVolatiles
G28	25 % Phenyl 75 % Methylpolysiloxane	ZB-35, ZB-35HT Inferno
G32	20 % Phenylmethyl 80 % Dimethylpolysiloxane	ZB-35, ZB-35HT Inferno
G35	Polyethylene Glycol / Diepoxide Esterified with Nitroterephthalic Acid	ZB-FFAP
G36	1 % Vinyl 5 % Phenylmethylpolysiloxane	ZB-5, ZB-5MSi, ZB-5HT Inferno
G38	Phase G1 / Small % Tailing Inhibitor	ZB-1, ZB-1ms, ZB-1HT Inferno
G39	Polyethylene Glycol (Average MW 1,500)	ZB-WAX, ZB-WAX _{PLUS}
G41	Phenylmethyldimethylsilicone (10 % Phenyl Substituted)	ZB-5, ZB-5MSi, ZB-5HT Inferno
G42	35 % Phenyl 65 % Dimethylpolysiloxane	ZB-35, ZB-35HT Inferno
G43	6 % Cyanopropylphenyl 94 % Dimethylpolysiloxane	ZB-624
G46	14 % Cyanopropylphenyl 86 % Methylpolysiloxane	ZB-1701, ZB-1701P
G47	Polyethylene Glycol (Average MW 8,000)	ZB-WAX _{PLUS} , ZB-WAX

Allowable Adjustments

Recent revisions of both the USP and Ph. Eur. have better defined the “allowable adjustments” one can make to an existing monograph without requiring revalidation. Below are the isocratic and gradient summaries for the ranges of these parameter changes, or prohibition thereof.

Allowable Adjustments to Pharmacopoeia Methods for Isocratic Separations

Component	United States Pharmacopoeia (USP)	European Pharmacopoeia (Ph. Eur.)
Mobile phase minor component ($\leq 50\%$)	$\pm 30\%$ Relative; Cannot exceed $\pm 10\%$ Absolute change; Cannot be reduced to zero	$\pm 30\%$ Relative or $\pm 2\%$ absolute, whichever is the larger; Cannot exceed $\pm 10\%$ Absolute change
Mobile phase pH	± 0.2 pH units	± 0.2 pH units; ± 1.0 for non-ionizable substances
Buffer concentration	$\pm 10\%$	$\pm 10\%$
Column temperature	$\pm 10^\circ\text{C}$	$\pm 10^\circ\text{C}$
Injection volume	Can be adjusted as much as needed; must be consistent with linearity, precision, and detection reqs.	Can be reduced so long as precision and detection limits are met
Detector wavelength	Cannot be modified	Cannot be modified
Flow rate	$\pm 50\%$ (at given ID)	$\pm 50\%$ (at given ID; flow rates may be adjusted more when changing inner diameter)
Column inner diameter	Can be adjusted so long as linear velocity is maintained	$\pm 25\%$
Column length	Column length (L) to particle size diameter (dp) ratio can be adjusted between -25% and $+50\%$ *	Column length may be adjusted $\pm 70\%$
Particle size	Column length (L) to particle size diameter (dp) ratio can be adjusted between -25% and $+50\%$ *	Particle diameter may be reduced as much as 50%
Stationary phase	No change of the identity of the substituent permitted	No change of the identity of the substituent permitted
Guards	Same stationary phase as column; guard ID \leq column ID; guard length $\leq 15\%$ column length	There is no statement not allowing guard columns as long as it has same material as the column

*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 $+50\%$

Allowable Adjustments to Pharmacopoeia Methods for Gradient Separations

Component	United States Pharmacopoeia (USP)	European Pharmacopoeia (Ph. Eur.)
Mobile phase minor component ($\leq 50\%$)	Changes to gradient composition are not recommended	Minor adjustments of the composition of the mobile phase and the gradient are acceptable, if the system suitability requirements are met, the principle peak(s) elute(s) within $\pm 15\%$ of the indicated retention time(s) and the final elution power of the mobile phase is not weaker.
Mobile phase pH	± 0.2 pH units	No adjustment permitted
Buffer concentration	$\pm 10\%$	No adjustment permitted
Column temperature	$\pm 10^\circ\text{C}$	$\pm 5^\circ\text{C}$
Injection volume	Can be adjusted as much as needed; must be consistent with linearity, precision, and detection reqs.	Can be reduced so long as precision and detection limits are met
Detector wavelength	Cannot be modified	Cannot be modified
Flow rate	Changes to flow rate are not allowed	Adjustment is permitted to maintain linear velocity when changing column dimensions
Column inner diameter	Changes to column length, particle size, or inner diameter are not allowed	$\pm 25\%$
Column length	Changes to column length, particle size, or inner diameter are not allowed	$\pm 70\%$
Particle size	Changes to column length, particle size, or inner diameter are not allowed	No change permitted
Stationary phase	No change of the identity of the substituent permitted	No change of the identity of the substituent permitted
Guards	Same stationary phase as column; guard ID \leq column ID; guard length $\leq 15\%$ column length	There is no statement not allowing guard columns as long as it has same material as the column

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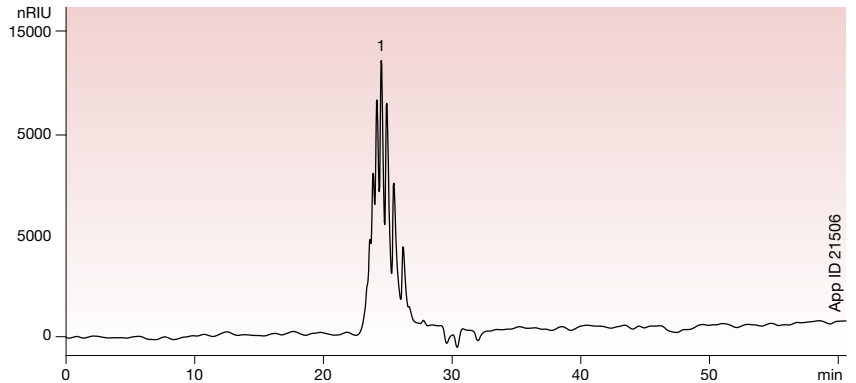
Binders

Binders are the most extensively used excipient and are typically polymers that hold all of the ingredients together. A major benefit of binders is the addition of mechanical strength to the tablet to ensure rigid shape, high stability, and long storage lifetimes. Binders can also be considered fillers when adding bulk to a tablet.

Polyethylene Glycol (PEG)

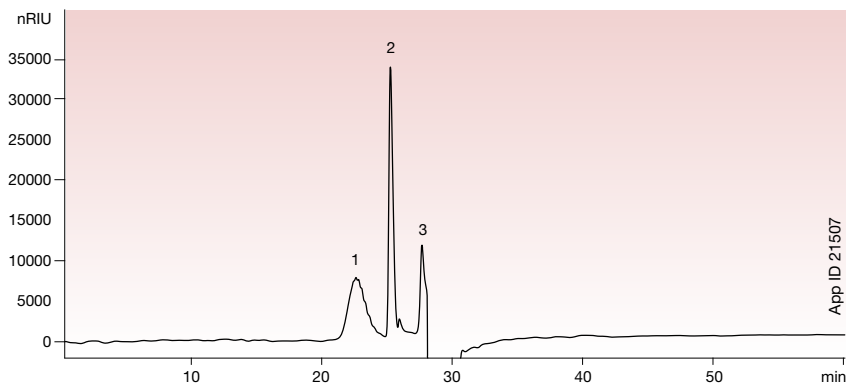
GPC separation of a polyethylene glycol (PEG) standard using 3 fixed pore size Phenogel™ columns (50 Å, 100 Å, and 500 Å) and THF mobile phase at 1 mL/min. Fixed pore size columns can provide increased resolution of narrower MW ranges compared to the mixed bed linear phases. Note that discrete MW species can be resolved.

- Column:** Phenogel 5 µm 50 Å, 100 Å, 500 Å
- Dimensions:** 300 x 7.8 mm
- Mobile Phase:** THF
- Flow Rate:** 1 mL/min
- Detection:** Refractive Index (RI)
- Temperature:** 40 °C
- Sample:** 1. PEG 300



GPC separation of an Advil® Cold & Sinus LIQUI-GELS® sample. Note the corresponding peaks to API as peak 3, PEG as peak 2, and a larger disperse polymer (i.e., gelatin) as peak 1. The combination of the 3 fixed pore size Phenogel columns (50 Å, 100 Å, and 500 Å) in series can give a slightly wider range than one specific fixed pore size column.

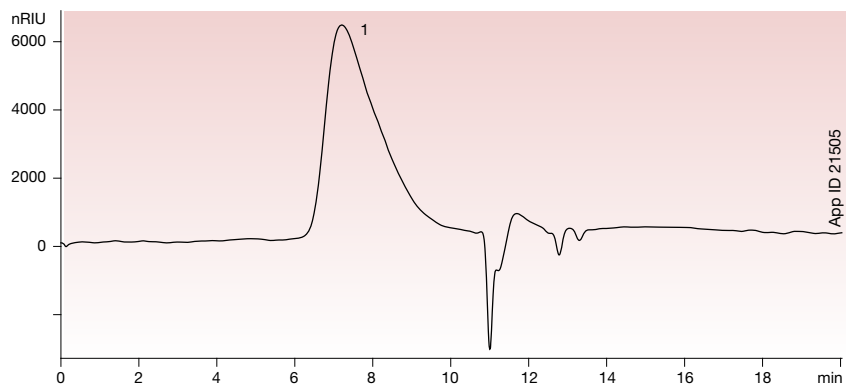
- Column:** Phenogel 5 µm 50 Å, 100 Å, 500 Å
- Dimensions:** 300 x 7.8 mm
- Mobile Phase:** THF
- Flow Rate:** 1 mL/min
- Detection:** Refractive Index (RI)
- Temperature:** 40 °C
- Sample:** 1. API Unknown Peak A
2. PEG 106
3. API Unknown Peak B



Polyvinylpyrrolidone (PVP, Povidone)

Separation of polyvinylpyrrolidone (povidone) on 2x Phenogel Linear(2) column using DMF as mobile phase. Povidone is a common binder and filler agent used in tablet formulations. Note the wide MW distribution on a GPC column.

- Column:** Phenogel 5 µm Linear(2) x2
- Dimensions:** 300 x 7.8 mm
- Part No.:** 00H-3259-K0-DF
- Mobile Phase:** 10 mM Lithium Bromide in DMF
- Flow Rate:** 2 mL/min
- Detection:** Refractive Index (RI)
- Temperature:** 40 °C
- Sample:** 1. Polyvinylpyrrolidone (PVP)

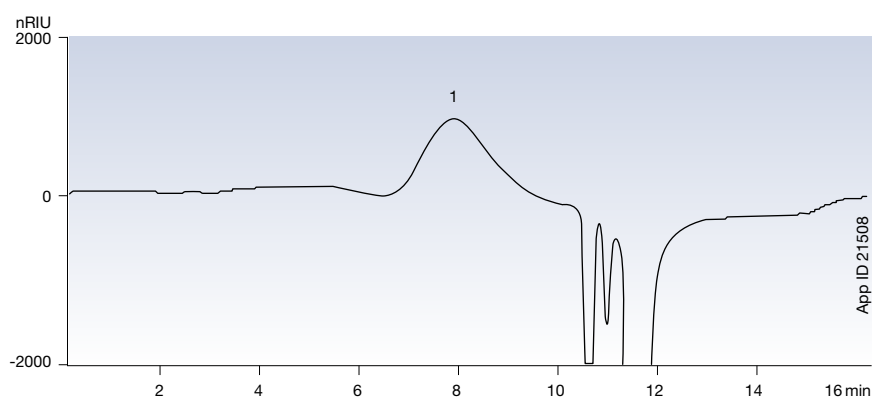


Coatings

Polymer coatings on pharmaceuticals help seal the drug, prevent dissolution, and enable drug targeting. Some coatings can also facilitate a delayed dosage for an accurately timed release of the active ingredient.

Cellulose Acetate

GPC separation of cellulose acetate using 2x Phenogel™ Linear(2) columns. Cellulose acetate is also used as a binder for tablets and is very polydisperse leading to a very broad peak. Mixed bed linear phases are well suited for wide MW distribution separations.



Column: Phenogel 5 μ m Linear(2) x2
Dimensions: 300 x 7.8 mm
Part No.: 00H-3259-K0-DF
Mobile Phase: 10 mM Lithium Bromide in DMF
Flow Rate: 2 mL/min
Detection: Refractive Index (RI)
Temperature: 40 °C
Sample: 1. Cellulose acetate



Fillers/Sweeteners

As the name implies, fillers bulk up a tablet or capsule in order to make it a suitable size for manufacturing, packaging, and ingestion. Many fillers are coupled as sweeteners to combat the bitter taste of other active and non-active ingredients.

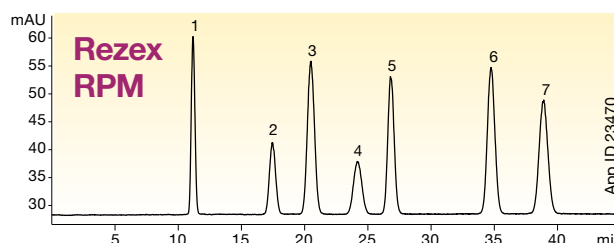
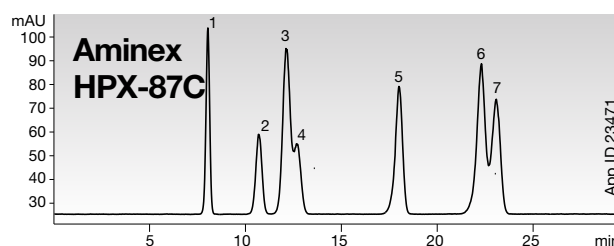
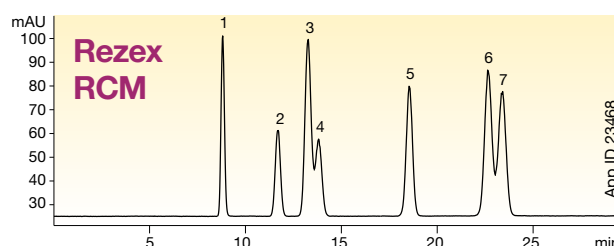
Sugar Alcohols

Optimizing Pharmacopoeia (Ph. Eur. & USP) Monographs of Sugar Alcohol Excipients Using Rezex™ Ion-Exclusion HPLC Columns

Rezex ion-exclusion HPLC columns are the solution for several published European Pharmacopoeia (Ph. Eur.) and United States Pharmacopoeia (USP) methodologies, particularly for excipients like sugar alcohols such as sorbitol, mannitol, isomalt, maltitol, lactitol, xylitol, trehalose, erythritol, etc. The Rezex RCM/RCU phases contain the strong cation-exchange resin (calcium form), or L19 USP packing, that is recommended by most pharmacopoeia monographs for sugar alcohols, while the Rezex RPM (lead form), or L34 USP packing, will provide stronger separation power.

In this example, we study a mixture of 7 sugar alcohols whose monographs typically call for a column with calcium form, or L19 packing. A Bio-Rad® Aminex HPX-87C is commonly recommended, however, the direct replacement, Rezex RCM, provides sharper peak shape and higher resolution as shown by the comparison below. As an excellent alternative, Rezex RPM provides stronger retention and higher resolution of the more closely eluting peaks compared to Rezex RCM.

Rezex RCM vs. Aminex™ HPX-87C



Column Cross Reference Chart

Phenomenex Rezex	Bio-Rad Aminex
RCM-Monosaccharide	HPX-87C 125-0095
RHM-Monosaccharide	HPX-87H 125-0140
RPM-Monosaccharide	HPX-87P 125-0098
RNM-Carbohydrate	HPX-87N 125-0143
RSO-Oligosaccharide	HPX-42A 125-0097
ROA-Organic Acid	HPX-87H 125-0140
RFQ-Fast Acid	Fast Acid 125-0100
RKP-Potassium	HPX-87K 125-0142
RCU-USP Sugar Alcohols	Sugar Alcohols 125-0094

Conditions for all columns:

Dimensions: 300 x 7.8 mm

Mobile Phase: Water

Flow Rate: 0.6 mL/min

Detection: ELSD

Temperature: 85 °C

Sample: 1. Trehalose

2. Isomalt

3. Maltitol

4. Isomaltitol

5. Mannitol

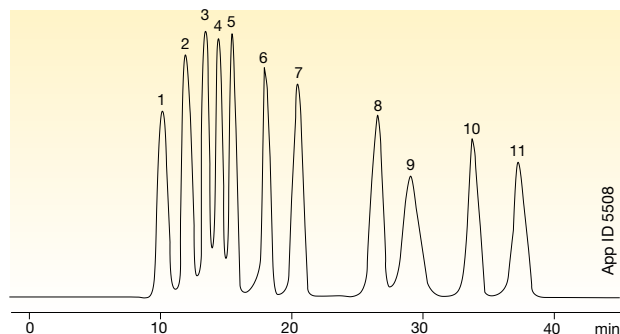
6. Xylitol

7. Sorbitol

Comparative separations may not be representative of all applications.

Separation of a Complex Mixture of Sugar Alcohols on Rezex™ RPM-Monosaccharide

A mixture of sugars and sugar alcohols run on a Rezex RPM 300 x 7.8mm column. Note the wide separation between Mannitol (8), Xylitol (10) and Sorbitol (11).

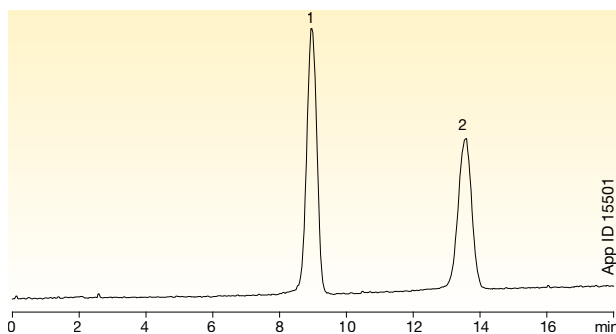


Column: Rezex RPM-Monosaccharide
Dimensions: 300 x 7.8mm
Part No.: 00H-0135-K0
Mobile Phase: Water
Flow Rate: 0.6mL/min
Detection: RI (Ambient)
Column Temperature: 75°C

Sample: 1. Stachyose 8. Mannitol
 2. Maltose 9. Salicin
 3. Glucose 10. Xylitol
 4. Xylose 11. Sorbitol
 5. Galactose
 6. Fructose
 7. Meso-Erythritol

Reduce Analysis Times Using Shorter Rezex RPM-Monosaccharide

A mixture of mannitol (1) and sorbitol (2) run on a Rezex RPM-Monosaccharide 100 x 7.8mm column using similar conditions to the USP method. Note the reduced run time of 15 minutes for separating the two excipients.

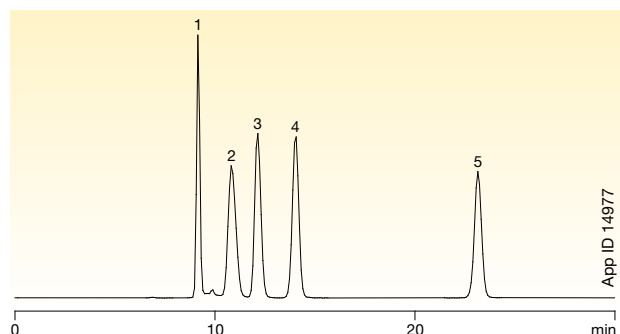


Column: Rezex RPM-Monosaccharide
Dimensions: 100 x 7.8mm
Part No.: 00D-0135-K0
Mobile Phase: Water
Flow Rate: 0.6mL/min
Detection: ELSD (Ambient)
Column Temperature: 80°C

Sample: 1. Mannitol
 2. Sorbitol

Alternative Selectivity of Rezex RCM-Monosaccharide Phase Offers

A mixture of sugars and sugar alcohols run on a Rezex RCM-Monosaccharide 300 x 7.8mm column. Note the different retention times for compounds, despite using similar column dimensions and flow rates. Rezex RCM offers different selectivity versus the Rezex RPM column.

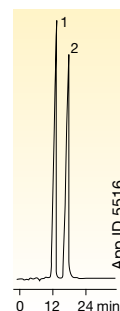


Column: Rezex RCM-Monosaccharide
Dimensions: 300 x 7.8mm
Part No.: 00H-0130-K0
Mobile Phase: Water
Flow Rate: 0.6mL/min
Detection: ELSD (Ambient)
Column Temperature: 80°C

Sample: 1. Sucrose 4. Fructose
 2. Glucose 5. Sorbitol
 3. Galactose

Rezex RCU-USP Sugar Alcohols: Well Suited for Published USP Methodologies

A mixture of (1) mannitol and (2) sorbitol run on a Rezex RCU-USP Sugar Alcohols 250 x 4.0mm column using a method similar to the published USP method. The Rezex RCU offers a different option for the Mannitol and Sorbitol application.



Column: Rezex RCU-USP Sugar Alcohols
Dimensions: 250 x 4.0mm
Part No.: 00G-0130-D0
Mobile Phase: Water
Flow Rate: 0.2mL/min
Detection: RI (Ambient)
Column Temperature: 85°C

Sample: 1. Mannitol
 2. Sorbitol

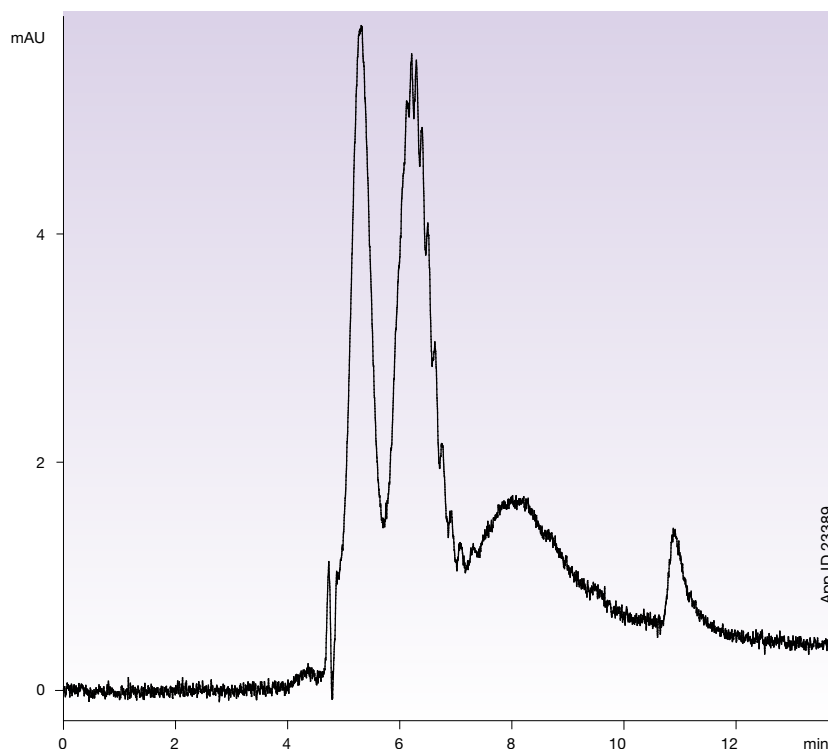
Solubilizers/Surfactants

In order to ensure solubility of an API in various forms such as tablets, vaccines, and intravenous preparations, solubilizers are added to the excipient formulation. They can also be helpful for the dissolution of a tablet after ingestion.

Polysorbate 80 (TWEEN® 80)

HPLC-UV Analysis on a Yarra™ 1.8µm SEC-X150 Aqueous GFC/SEC Column

Polysorbate 80, also known as TWEEN 80, is very popular in the pharmaceutical, food, and cosmetic industries as an excipient, or inactive ingredient, in products such as tablets, vaccines, intravenous preparations, lotions, and soaps. The primary role of this pharmaceutical excipient is a solubilizing agent acting as a surfactant to assist with the solubility of all other pharmaceutical ingredients and also dissolution of the tablet. In this application, TWEEN 80 is analyzed by HPLC-UV using a Yarra 1.8µm SEC-X150 150 x 4.6mm aqueous size exclusion (SEC), or gel filtration chromatography (GFC), column in under 12 minutes.



LC/UV Conditions

Column: Yarra 1.8µm SEC-X150
Dimensions: 150 x 4.6 mm
Part No.: 00F-4631-E0
Mobile Phase: Water/Acetonitrile (65:35)
Flow Rate: 0.4 mL/min
Temperature: Ambient
Detection: UV @ 245 nm
Sample: TWEEN 80

App ID 23389

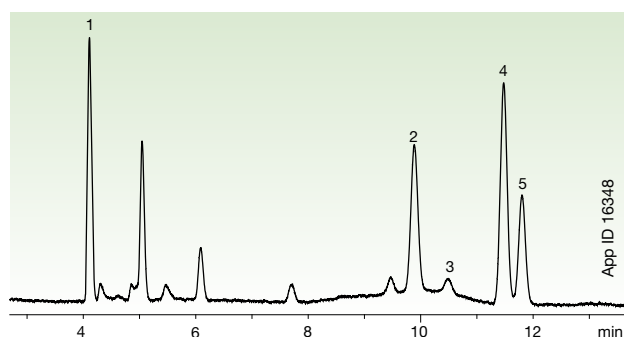
Residual Solvents

Residual solvents are trace-level chemical residues in drug substances and drug products that are byproducts of manufacturing, or that form during packaging and storage. It is the responsibility of the drug manufacturers to ensure that these residues are removed, or are present only in limited concentrations.

USP Monograph <467>

In 2008, the United States Pharmacopoeia (USP) revised the general chapter on residual solvent analysis, USP <467>, to reflect the International European Pharmacopoeia (Ph. Eur.) guidelines for the identification, control and quantification of residual solvents. This revision significantly increased the requirements a pharmaceutical company must meet in order to demonstrate that all drug products (not just new) are compliant with Chapter <467> limits.

Procedure A – Class 1

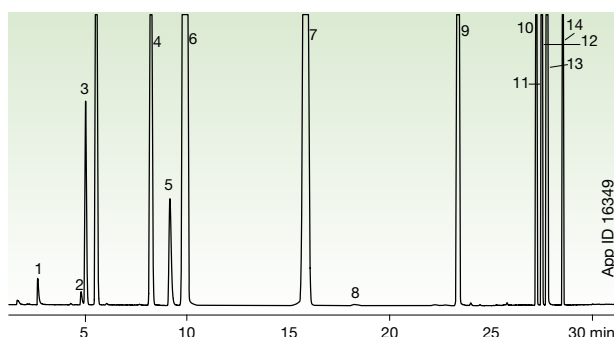


GC/FID Conditions

Column: Zebtron™ ZB-624
Dimensions: 30 meter x 0.32 mm x 1.80 μm
Part No.: 7HM-G005-31
Injection: Headspace 5:1 @ 140 °C, 1 mL
Carrier Gas: Helium @ 35 cm/sec (constant flow)
Oven Program: 40 °C for 20 min to 240 °C @ 10 °C/min for 20 min
Detector: FID @ 250 °C
Sample: Sample prepared as per USP guidelines

1. 1,1-Dichloroethene	4. Benzene
2. 1,1,1-Trichloroethane	5. 1,2-Dichloroethane
3. Carbon tetrachloride	

Procedure A – Class 2 Mix A

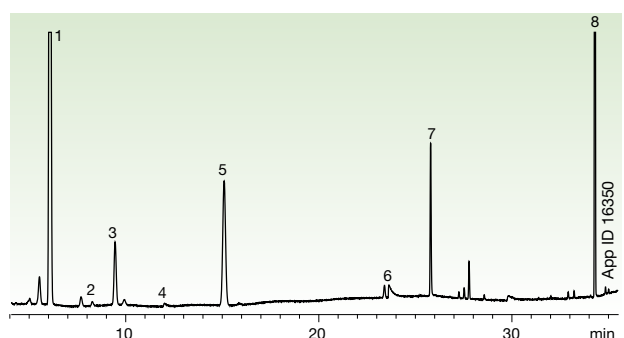


GC/FID Conditions

Column: Zebtron ZB-624
Dimensions: 30 meter x 0.32 mm x 1.80 μm
Part No.: 7HM-G005-31
Injection: Headspace 5:1 @ 140 °C, 1 mL
Carrier Gas: Helium @ 35 cm/sec (constant flow)
Oven Program: 40 °C for 20 min to 240 °C @ 10 °C/min for 20 min
Detector: FID @ 250 °C
Sample: Sample prepared as per USP guidelines

1. Methanol	8. 1,4-Dioxane
2. Acetonitrile	9. Toluene
3. Dichloromethane	10. Chlorobenzene
4. cis-1,2-Dichloroethene	11. Ethylbenzene
5. THF	12. m-Xylene
6. Cyclohexane	13. p-Xylene
7. Methylcyclohexane	14. o-Xylene

Procedure A – Class 2 Mix B



GC/FID Conditions

Column: Zebtron ZB-624
Dimensions: 30 meter x 0.32 mm x 1.80 μm
Part No.: 7HM-G005-31
Injection: Headspace 5:1 @ 140 °C, 1 mL
Carrier Gas: Helium @ 35 cm/sec (constant flow)
Oven Program: 40 °C for 20 min to 240 °C @ 10 °C/min for 20 min
Detector: FID @ 250 °C
Sample: Sample prepared as per USP guidelines

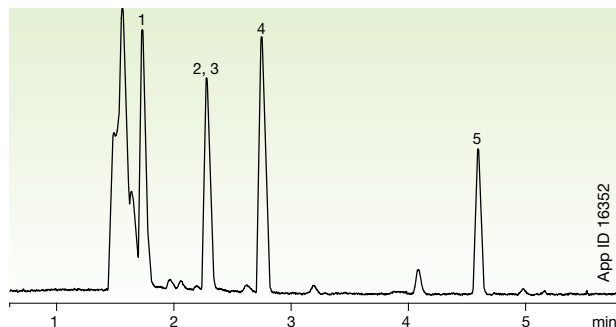
1. Hexane	5. Trichloroethylene
2. Nitromethane	6. Pyridine
3. Chloroform	7. Methylbutylketone
4. 1,2-Dimethoxyethane	8. Tetralin



Residual Solvents

USP Monograph <467>

Procedure B – Class 1

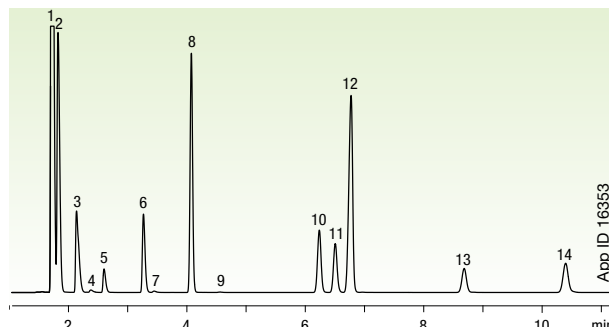


GC/FID Conditions

Column: Zebtron™ ZB-WAX_{PLUS}™
Dimensions: 30 meter x 0.32 mm x 0.25 μm
Part No.: 7HM-G013-11
Injection: Headspace 5:1 @ 140 °C, 1 mL
Carrier Gas: Helium @ 35 cm/sec (constant flow)
Oven Program: 50 °C hold 20 min to 165 °C @ 6 °C/min hold 20 min
Detector: FID @ 250 °C
Sample: Sample prepared as per USP method

- 1,1-Dichloroethene
- Carbon tetrachloride
- 1,1,1-Trichloroethane
- Benzene
- 1,2-Dichloroethane

Procedure B – Class 2 Mix A

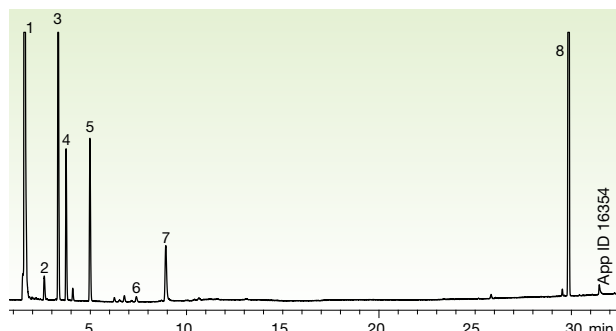


GC/FID Conditions

Column: Zebtron ZB-WAX_{PLUS}
Dimensions: 30 meter x 0.32 mm x 0.25 μm
Part No.: 7HM-G013-11
Injection: Headspace 5:1 @ 140 °C, 1 mL
Carrier Gas: Helium @ 35 cm/sec (constant flow)
Oven Program: 50 °C hold 20 min to 165 °C @ 6 °C/min hold 20 min
Detector: FID @ 250 °C
Sample: Sample prepared as per USP method

1. Cyclohexane	8. Toluene
2. Methylcyclohexane	9. 1,4-Dioxane
3. THF	10. Ethylbenzene
4. Methanol	11. p-Xylene
5. Dichloromethane	12. m-Xylene
6. cis-1,2-Dichloroethene	13. o-Xylene
7. Acetonitrile	14. Chlorobenzene

Procedure B – Class 2 Mix B

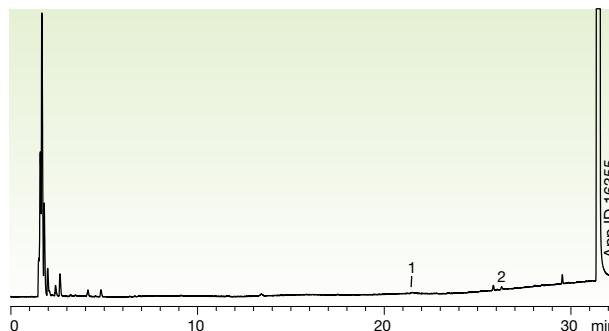


GC/FID Conditions

Column: Zebtron ZB-WAX_{PLUS}
Dimensions: 30 meter x 0.32 mm x 0.25 μm
Part No.: 7HM-G013-11
Injection: Headspace 5:1 @ 140 °C, 1 mL
Carrier Gas: Helium @ 35 cm/sec (constant flow)
Oven Program: 50 °C hold 20 min to 165 °C @ 6 °C/min hold 20 min
Detector: FID @ 250 °C
Sample: Sample prepared as per USP method

1. Hexane	5. Methylbutylketone
2. 1,2-Dimethoxyethane	6. Nitromethane
3. Trichloroethylene	7. Pyridine
4. Chloroform	8. Tetralin

Procedure B – Class 2 Mix C



GC/FID Conditions

Column: Zebtron ZB-WAX_{PLUS}
Dimensions: 30 meter x 0.32 mm x 0.25 μm
Part No.: 7HM-G013-11
Injection: Headspace 5:1 @ 140 °C, 1 mL
Carrier Gas: Helium @ 35 cm/sec (constant flow)
Oven Program: 50 °C hold 20 min to 165 °C @ 6 °C/min hold 20 min
Detector: FID @ 250 °C
Sample: Sample prepared as per USP method

1. N,N-Dimethylformamide
2. N,N-Dimethylacetamide

GC (Gas Chromatography)

Zebbron Phase	ID (mm)	df (µm)	10 meter	15 meter	30 meter	60 meter
ZB-1ms Very low bleed for GC/MS analyses; recommended for active compounds and boiling point separations	0.10	0.10	7CB-G011-02			
	0.18	0.18	7CD-G011-08			
	0.25	0.10			7HG-G011-02	
	0.25	0.25		7EG-G011-11	7HG-G011-11	7KG-G011-11
	0.25	0.50			7HG-G011-17	
	0.25	1.00			7HG-G011-22	7KG-G011-22
	0.32	0.25	7EM-G011-11		7HM-G011-11	
	0.32	1.00			7HM-G011-22	7KM-G011-22
ZB-5ms Stable, low bleed 5% phenyl-arylene phase for GC and GC/MS; recommended for a variety of pharmaceutical applications	0.10	0.10	7CB-G010-02			
	0.18	0.18	7CD-G010-08			
	0.25	0.25		7EG-G010-11	7HG-G010-11	7KG-G010-11
	0.25	0.50			7HG-G010-17	
	0.25	1.00			7HG-G010-22	
	0.32	0.25			7HM-G010-11	7KM-G010-11
	0.32	0.50			7HM-G010-17	
ZB-5MS^{PLUS}™ Highly inert 5% phenyl-arylene phase for chemical, biological, and other pharmaceutical testing	0.25	0.25		7EG-G030-11	7HG-G030-11	7KG-G030-11
	0.25	0.50			7HG-G030-17	
	0.25	1.00			7HG-G030-22	
	0.32	0.25			7HM-G030-11	
	0.32	1.00			7HM-G030-22	
ZB-35 Rugged, inert, intermediate polarity phase for versatile separations	0.25	0.25		7EG-G003-11	7HG-G003-11	7KG-G003-11
	0.25	0.50		7EG-G003-17	7HG-G003-17	
	0.32	0.25			7HM-G003-11	7KM-G003-11
	0.53	0.50			7HK-G003-17	
	0.53	1.00		7EK-G003-22	7HK-G003-22	
ZB-50 Recommended for phenolic antioxidants and amino acids	0.25	0.15		7EG-G004-05		
	0.25	0.25		7EG-G004-11	7HG-G004-11	7KG-G004-11
	0.25	0.50			7HG-G004-17	7KG-G004-17
	0.32	0.25	7EM-G004-11		7HM-G004-11	
	0.32	0.50	7EM-G004-17		7HM-G004-17	
	0.53	1.00	7EK-G004-22		7HK-G004-22	
ZB-624 Specifically designed for VOC separations, including OVIs and residual solvents	0.25	1.40			7HG-G005-27	7KG-G005-27
	0.32	1.80			7HM-G005-31	7KM-G005-31
	0.53	3.00			7HK-G005-36	7KK-G005-36
ZB-WAX^{PLUS}™ 100% aqueous stable with high retention of alcohols and chlorinated solvents; recommended for alcohols, flavors, and residual solvent applications	0.10	0.10	7CB-G013-02			
	0.25	0.25		7EG-G013-11	7HG-G013-11	7KG-G013-11
	0.32	0.25			7HM-G013-11	7KM-G013-11
	0.32	0.50			7HM-G013-17	7KM-G013-17
	0.53	1.00		7EK-G013-22	7HK-G013-22	7KK-G013-22
ZB-FFAP High polarity nitroterephthalic acid modified PEG phase with good peak shape for underivatized acids; especially suited for organic acids, free fatty acids, and alcohols	0.25	0.25		7EG-G009-11	7HG-G009-11	7KG-G009-11
	0.32	0.25		7EM-G009-11	7HM-G009-11	
	0.32	0.50		7EM-G009-17	7HM-G009-17	
	0.32	1.00			7HM-G009-22	
	0.53	1.00		7EK-G009-22	7HK-G009-22	



Explore Tips and Tools Online:
www.phenomenex.com/GC

Gel Filtration (GFC)

Yarra



Column Specifications

	SEC-X150	SEC-2000	SEC-3000	SEC-4000
Resin Type	Silica	Silica	Silica	Silica
Particle Size (µm)	1.8	3	3	3
Pore Size (Å)	150	145	290	500
MW Range (Da)	1K-450K	1K-300K	5K-700K	15K-1500K
pH Range	1.5 - 8.5	2.5 - 7.5	2.5 - 7.5	2.5 - 7.5
Typical Backpressure (psi)	3,250	1,300	1,300	1,000
Max Backpressure (psi)	7,000	3,000	3,000	1,700
Typical Efficiency	> 30,000 (150 x 4.6 mm)	48,000 (300 x 7.8 mm)	48,000 (300 x 7.8 mm)	38,000 (300 x 7.8 mm)
Max. Flow Rate (mL/min)	0.4	1.5	1.5	1.2

Yarra 1.8µm SEC Column (mm)

	Analytical
Phase	150 x 4.6
1.8µm SEC-X150	00F-4631-E0



Yarra 3µm SEC Columns (mm)

	Narrow Bore	Analytical	Analytical	SecurityGuard™ Cartridges (mm)
Phases	300 x 4.6	150 x 7.8	300 x 7.8	4 x 3.0*
				/10pk
Yarra 3µm SEC-2000	00H-4512-E0	00F-4512-K0	00H-4512-K0	AJ0-4487
Yarra 3µm SEC-3000	00H-4513-E0	00F-4513-K0	00H-4513-K0	AJ0-4488
Yarra 3µm SEC-4000	00H-4514-E0	—	00H-4514-K0	AJ0-4489

for ID 4.6–7.8 mm

*SecurityGuard Analytical cartridges require holder, Part No.: KJ0-4282

Polymeric Gel Filtration (GFC)

PolySep



Technical Data and Specifications

Phase	1000	2000	3000	4000	5000	6000	Linear
Exclusion Limits in Daltons:							
PEG	2 x 10 ³	9 x 10 ³	5 x 10 ⁴	2 x 10 ⁵	2 x 10 ⁶	1 x 10 ⁷	1 x 10 ⁷
Pullulans	3.5 x 10 ³	1 x 10 ⁴	1 x 10 ⁵	3.5 x 10 ⁵	4 x 10 ⁶	2 x 10 ⁷	2 x 10 ⁷
Separation Range (Da)	20 - 3K	100 - 10K	250 - 75K	3K - 400K	50K - 2M	100K - 15M	1K - 10M
Typical Efficiency Plates/meter	22,000	50,000	32,000	32,000	32,000	32,000	32,000
Maximum Organic Modifier:							
Methanol	20 %	95 %	70 %	70 %	70 %	70 %	70 %
Acetonitrile	20 %	70 %	70 %	70 %	70 %	70 %	70 %
pH Range	3.0 to 12.0						
Maximum Flow Rate	Depends on backpressure, do not exceed 1000 psi						
Column Hardware	Stainless steel or PEEK (Biocompatible hardware available upon request)						
Temperature	4 to 60 °C						
Maximum Salt	Maximum allowed 0.5 M with a flow rate not to exceed 0.5 mL/min						
Storage	For overnight, pump water at 0.2 mL/min, for longer storage use 0.05 % NaNO ₃ in water or 10 % methanol in water						
General	A guard column is recommended to improve column life						

PolySep Columns (mm)

	Analytical	Guards
Phases	300 x 7.8	35 x 7.8
1000	CH0-9226	CH0-9225
2000	CH0-9227	CH0-9225
3000	CH0-9228	CH0-9225
4000	CH0-9229	CH0-9225
5000	CH0-9230	CH0-9225
6000	CH0-9231	CH0-9225
Linear	CH0-9232	CH0-9225

Ion-Exclusion/Ligand Exchange

Rezex

REZEX™
Ion Exclusion LC

Columns

Part No.	Description	Size (mm)	Cross Linkage	Ionic Form	USP Packing	Price
00H-0130-K0	RCM-Monosaccharide	300 x 7.8	8%	Calcium	L19	
00F-0130-K0	RCM-Monosaccharide	150 x 7.8	8%	Calcium	L19	
00G-0130-D0	RCU-USP Sugar Alcohols	250 x 4.0	8%	Calcium	L19	
00H-0135-K0	RPM-Monosaccharide	300 x 7.8	8%	Lead	L34	
00D-0135-K0	RPM-Monosaccharide	100 X 7.8	8%	Lead	L34	

Guards

Part No.	Size (mm)	Price
03B-0130-K0	50 x 7.8	
03B-0130-K0	50 x 7.8	
03A-0130-D0	30 x 4.0	
03B-0135-K0	50 x 7.8	
03B-0135-K0	50 x 7.8	

SecurityGuard™ Cartridges (mm)

4 x 3.0' (10pk)	Price
AJO-4493	
AJO-4493	
AJO-4493	
AJO-4492	
AJO-4492	

for ID: 3.2-8.0 mm

*SecurityGuard Analytical Cartridges require universal holder Part No. KJ0-4282

Gel Permeation (GPC)

Phenogel

Phenogel™
Organic GPC/SEC

5 µm Analytical Columns (mm)		THF	Shipping Solvent Chloroform	DMF	SecurityGuard™ Cartridges (mm)
Pore Size	MW Range	300 x 7.8	300 x 7.8	300 x 7.8	4 x 3.0'
					/3pk
50 Å	100-3 K	00H-0441-K0	00H-0441-K0-CL	00H-0441-K0-DF	AJO-9292
100 Å	500-6 K	00H-0442-K0	00H-0442-K0-CL	00H-0442-K0-DF	AJO-9292
500 Å	1 K-15 K	00H-0443-K0	00H-0443-K0-CL	00H-0443-K0-DF	AJO-9292
10 ³ Å	1 K-75 K	00H-0444-K0	00H-0444-K0-CL	00H-0444-K0-DF	AJO-9292
10 ⁴ Å	5 K-500 K	00H-0445-K0	00H-0445-K0-CL	00H-0445-K0-DF	AJO-9292
10 ⁵ Å	10 K-1,000 K	00H-0446-K0	00H-0446-K0-CL	00H-0446-K0-DF	AJO-9292
10 ⁶ Å	60 K-10,000 K	00H-0447-K0	00H-0447-K0-CL	00H-0447-K0-DF	AJO-9292
		300 x 7.8	300 x 7.8	300 x 7.8	4 x 3.0'
Mixed Beds					/3pk
Linear(2)	100-10,000 K	00H-3259-K0	00H-3259-K0-CL	00H-3259-K0-DF	AJO-9292

for 3.2–8.0 mm ID

5 µm Narrow Bore (NB) Columns (mm)			SecurityGuard™ Cartridges (mm)
Pore Size	MW Range	300 x 4.6	4 x 3.0'
			/3pk
50 Å	100-3 K	00H-0441-E0	AJO-9292
100 Å	500-6 K	00H-0442-E0	AJO-9292
500 Å	1 K-15 K	00H-0443-E0	AJO-9292
10 ³ Å	1 K-75 K	00H-0444-E0	AJO-9292
10 ⁴ Å	5 K-500 K	00H-0445-E0	AJO-9292
10 ⁵ Å	10 K-1,000 K	00H-0446-E0	AJO-9292
10 ⁶ Å	60 K-10,000 K	00H-0447-E0	AJO-9292
		300 x 4.6	4 x 3.0'
Mixed Beds			/3pk
Linear(2)	100-10,000 K	00H-3259-E0	AJO-9292

for 3.2–8.0 mm ID

10 µm Analytical Columns (mm)			SecurityGuard™ Cartridges (mm)
Pore Size	MW Range	300 x 7.8	4 x 3.0'
			/3pk
50 Å	100-3 K	00H-0641-K0	AJO-9292
100 Å	500-6 K	00H-0642-K0	AJO-9292
500 Å	1 K-15 K	00H-0643-K0	AJO-9292
10 ³ Å	1 K-75 K	00H-0644-K0	AJO-9292
10 ⁴ Å	5 K-500 K	00H-0645-K0	AJO-9292
10 ⁵ Å	10 K-1,000 K	00H-0646-K0	AJO-9292
10 ⁶ Å	60 K-10,000 K	00H-0647-K0	AJO-9292
		300 x 7.8	4 x 3.0'
Mixed Beds			/3pk
Linear(2)	100-10,000 K	00H-3260-K0	AJO-9292

for 3.2–8.0 mm ID

*SecurityGuard Analytical Cartridges require holder, Part No.: KJ0-4282

Guard Cartridge Holder

Part No.	Description	Price
KJ0-4282	Reusable Holder (SecurityGuard Kit)	



Column Union

Part No.	Description	Unit	Price
AQ0-8507	Zero Dead Union, SS, with 10-32 fittings	ea	

Note: Additional union (AQ0-8507) may be necessary for SecurityGuard to fit in column oven with less than 30 cm length capacity.

Phenogel columns are routinely shipped in THF. However, columns are also available in commonly used solvents, Chloroform and DMF, for an additional charge. Please specify shipping solvent when ordering.

UHPLC/HPLC: Core-Shell



Kinetex

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
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

for 4.6 mm ID

3.5 µm Analytical Columns (mm)			SecurityGuard ULTRA Cartridges [‡]
Phases	100 x 4.6	250 x 4.6	3/pk

XB-C18	00D-4744-E0	00F-4744-E0	AJ0-8768
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for 4.6 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	3/pk

EVO C18	—	00B-4725-E0	—	00D-4725-E0	00F-4725-E0	AJ0-9296
F5	—	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

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

1.3 µm Minibore Columns (mm)		
Phases	30 x 2.1	50 x 2.1

C18	00A-4515-AN	00B-4515-AN
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UHPLC/HPLC: Fully Porous



Luna

	Omega 1.6 µm Minibore Columns (mm)			SecurityGuard™ ULTRA Cartridges†
	50 x 2.1	100 x 2.1	150 x 2.1	3/pk
C18	00B-4742-AN	00D-4742-AN	00F-4742-AN	AJ0-9502
Polar C18	00B-4748-AN	00D-4748-AN	00F-4748-AN	AJ0-9505

for 2.1 mm ID

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



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2.5 µm High Speed Technology (HST) Columns (mm)						
	50 x 1.0	30 x 2.0	50 x 2.0	100 x 2.0	50 x 3.0	100 x 3.0

C18 00B-4446-A0 00A-4446-B0 00B-4446-B0 00D-4446-B0 00B-4446-Y0 00D-4446-Y0

3 µm Analytical Columns (mm)	SecurityGuard Cartridges (mm)					
	30 x 4.6	50 x 4.6	75 x 4.6	100 x 4.6	150 x 4.6	4 x 3.0*
Phases						/10pk
Silica(2)	00A-4162-E0	00B-4162-E0	00C-4162-E0	00D-4162-E0	00F-4162-E0	AJ0-4348
C8(2)	00A-4248-E0	00B-4248-E0	00C-4248-E0	00D-4248-E0	00F-4248-E0	AJ0-4290
C18(2)	00A-4251-E0	00B-4251-E0	00C-4251-E0	00D-4251-E0	00F-4251-E0	AJ0-4287
CN	00A-4254-E0	00B-4254-E0	00C-4254-E0	00D-4254-E0	00F-4254-E0	AJ0-4305
Phenyl-Hexyl	00A-4256-E0	00B-4256-E0	00C-4256-E0	00D-4256-E0	00F-4256-E0	AJ0-4351
NH₂	—	00B-4377-E0	—	00D-4377-E0	00F-4377-E0	AJ0-4302
HILIC	—	—	—	00D-4449-E0	00F-4449-E0	AJ0-8329
PFP(2)	—	00B-4447-E0	—	00D-4447-E0	00F-4447-E0	AJ0-8327

for ID: 3.2-8.0 mm

5 µm Analytical Columns (mm)	SecurityGuard Cartridges (mm)						
	30 x 4.6	50 x 4.6	75 x 4.6	100 x 4.6	150 x 4.6	200 x 4.6	4 x 3.0*
Phases							/10pk
Silica(2)	—	00B-4274-E0	—	00D-4274-E0	00F-4274-E0	00G-4274-E0	AJ0-4348
C5	—	00B-4043-E0	—	00D-4043-E0	00F-4043-E0	00G-4043-E0	AJ0-4293
C8(2)	00A-4249-E0	00B-4249-E0	00C-4249-E0	00D-4249-E0	00F-4249-E0	00G-4249-E0	AJ0-4290
C18(2)	00A-4252-E0	00B-4252-E0	00C-4252-E0	00D-4252-E0	00F-4252-E0	00G-4252-E0	AJ0-4287
CN	00A-4255-E0	00B-4255-E0	00C-4255-E0	00D-4255-E0	00F-4255-E0	00G-4255-E0	AJ0-4305
Phenyl-Hexyl	00A-4257-E0	00B-4257-E0	—	00D-4257-E0	00F-4257-E0	00G-4257-E0	AJ0-4351
NH₂	00A-4378-E0	00B-4378-E0	—	00D-4378-E0	00F-4378-E0	00G-4378-E0	AJ0-4302
SCX	—	00B-4398-E0	—	00D-4398-E0	00F-4398-E0	00G-4398-E0	AJ0-4308
HILIC	—	—	—	00D-4450-E0	00F-4450-E0	00G-4450-E0	AJ0-8329
PFP(2)	—	00B-4448-E0	—	00D-4448-E0	00F-4448-E0	00G-4448-E0	AJ0-8327

3.2-8.0 mm

SecurityGuard™ Analytical Cartridges require universal holder, Part No.: KJ0-4282

guarantee

If Phenomenex products in this brochure 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

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Comparative separations may not be representative of all applications.

Kinetex EVO is patented by Phenomenex. U.S. Patent No. 7,563,367 and 8,658,038 and foreign counterparts.

SecurityGuard is patented by Phenomenex U.S. Patent No. 6, 162, 362.

CAUTION: this patent only applies to the analytical-sized guard cartridges holder, and dose not apply to SemiPrep, PREP or ULTRA holders, or to any cartridges.

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