

Allowable Adjustments to Pharmacopoeia Methods

Isocratic Separations

Component	European Pharmacopoeia (Ph. Eur.)
Composition of the mobile phase	$\pm 30\%$ Relative or $\pm 2\%$ absolute, whichever is the larger; Cannot exceed $\pm 10\%$ absolute change
Mobile phase pH	± 0.2 pH units; ± 1.0 for non-ionizable substances
Buffer concentration	$\pm 10\%$
Column temperature	$\pm 10^\circ\text{C}$
Injection volume	Can be reduced so long as precision and detection limits are met
Detector wavelength	Cannot be modified
Flow rate	$\pm 50\%$ (at given ID; flow rates may be adjusted more when changing inner diameter)
Column inner diameter	$\pm 25\%$
Column length	Column length may be adjusted $\pm 70\%$
Particle size	Particle diameter may be reduced as much as 50%
Stationary Phase	No change of the identity of the substituent permitted
Guards	There is no statement not allowing guard columns as long as it has same material as the column

Gradient Separations

Component	European Pharmacopoeia (Ph. Eur.)
Composition of the mobile phase + gradient	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	No adjustment permitted
Buffer concentration	No adjustment permitted
Column temperature	$\pm 5^\circ\text{C}$
Injection volume	Can be reduced so long as precision and detection limits are met
Detector wavelength	Cannot be modified
Flow rate	Adjustment is permitted to maintain linear velocity when changing column dimensions
Column inner diameter	$\pm 25\%$
Column length	$\pm 70\%$
Particle size	No change permitted
Stationary Phase	No change of the identity of the substituent permitted
Guards	There is no statement not allowing guard columns as long as it has same material as the column



HPLC Column Selection by Ph. Eur. Listing

The European Pharmacopoeia (Ph. Eur.), of the Council of Europe is a pharmacopoeia, listing a wide range of active substances and excipients used to prepare pharmaceutical products in Europe. It includes general and specific monographs that give quality standards for all the main medicines used in Europe. All medicines sold in the 38 Member States of the European Pharmacopoeia must comply with these quality standards so that consumers have a guarantee for products obtained from pharmacies and other legal suppliers.

It is widely understood that all HPLC packings are not alike, and no single column can perform a myriad of desired separations. HPLC packings differ in hydrophobicity, surface coverage, surface area, pore size, and particle shape.

For each European Pharmacopoeia (*Ph. Eur.*) description of the HPLC stationary phase, you will find listed the most suitable Phenomenex HPLC column. Other possible columns can also be used for these analyses. Please contact Phenomenex for your specific LC column needs.

Description According to Pharm. Eur. 9 4.1.1. Reagents 2017	Number	Recommended Phenomenex Column
Silica gel AD for chiral separation coated with Amylose tris (3,5-dimethylphenylcarbamate)	1171700	Lux® Amylose-1
Silica gel for chiral separation, cellulose derivative coated with tris (3,5-dimethylphenylcarbamate)	1110300	Lux Cellulose-1
Silica gel BC for chiral chromatography. (Beta-Cyclodextrin)	1161300	Sumichiral™ OA-7000
Silica gel CR+ for chiral chromatography (crown-ether)	1192400	Sumichiral OA-8000
Silica gel for chromatography.	1076900	Kinetex® HILIC Luna® Silica(2)
Silica gel for chromatography, alkyl bonded for use with highly aqueous mobile phases.	1160200	Luna Omega Polar C18 Synergi™ Hydro-RP Synergi Fusion-RP Gemini® C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18 Kinetex Polar C18
Silica gel for chromatography, alkyl bonded for use with highly aqueous mobile phases, endcapped.	1176900	Luna Omega Polar C18 Synergi Hydro-RP Synergi Fusion-RP Gemini C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18 Kinetex Polar C18
Silica gel for chromatography, alkylsilyl, solid core, endcapped. Spherical silica particles containing a non-porous solid silica core surrounded by a thinner outer porous silica coating with alkylsilyl groups. To minimize any interaction with basic compounds it is carefully endcapped to cover most of the remaining silanol groups.	1194300	Kinetex C8 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18 Kinetex Polar C18
Silica gel for chromatography, aminopropylmethylsilyl.	1102400	SphereClone™ NH ₂ (Amino) PhenoSphere™ NH ₂ (Amino)
Silica gel for chromatography, aminopropylsilyl.	1077000	SphereClone NH ₂ (Amino) PhenoSphere NH ₂ (Amino)
Silica gel for chromatography, Amylose derivative of.	1109800	Lux Amylose-1 Lux Amylose-2
Silica gel for chromatography, butylsilyl. Spheroidal 300 Å; pore volume: 0.6 cm ³ /g; area: 80 m ² /g.	1076200	Aeris™ WIDEPORE C4
Silica gel for chromatography, butylsilyl, endcapped.	1170500	Aeris WIDEPORE C4 Jupiter® 300 C4
Silica gel for chromatography compatible with 100 % aqueous mobile phase, octadecylsilyl, endcapped.	1188400	Luna Omega Polar C18 Synergi Hydro-RP Synergi Fusion-RP Kinetex EVO C18 Kinetex Polar C18
Silica gel for chromatography, crown-ether.	1178000	Sumichiral™ OA-8000
Silica gel for chromatography, cyanosilyl.	1109900	Luna CN (Cyano) HyperClone™ CN (Cyano) PhenoSphere CN (Cyano)
Silica gel for chromatography, cyanopropylsilyl, endcapped, base-deactivated.	1194200	Luna CN (Cyano)
Silica gel for chromatography, cyanopropylsilyl, endcapped.	1195000	Luna CN (Cyano)
Silica gel for chromatography, di-isobutyloctadecylsilyl.	1140000	Kinetex XB-C18 ZORBAX® StableBond C18
Silica gel for chromatography, diisopropylcyanopropylsilyl.	1168100	ZORBAX StableBond CN
Silica gel for chromatography, dimethyloctadecylsilyl. Irregular; area: 300 m ² /g.	1115100	Bondclone™ C18

Description According to Pharm. Eur. 9 4.1.1. Reagents 2017	Number	Recommended Phenomenex Column
Silica gel for chromatography, diol dihydroxypropyl, 100 Å pore size.	1110000	Luna® HILIC
Silica gel for chromatography, dodecylsilyl, endcapped.	1179700	Synergi™ Max-RP
Silica gel for chromatography, hexylsilyl.	1077100	SphereClone™ C6 PhenoSphere™ C6
Silica gel for chromatography, hexylsilyl, endcapped.	1174400	SphereClone C6 PhenoSphere C6
Silica gel for chromatography, hydrophilic surface has been modified to provide hydrophilic characteristics.	1077200	Luna HILIC Kinetex® HILIC
Silica gel for chromatography, nitrile cyanopropylsilyl.	1077300	Luna CN (Cyano) HyperClone™ CN (Cyano) PhenoSphere CN (Cyano)
Silica gel for chromatography, nitrile R1 chemically bonded nitrile groups.	1077400	Luna® CN (Cyano) HyperClone CN (Cyano) PhenoSphere™ CN (Cyano)
Silica gel for chromatography, nitrile R2 ultrapure silica (<20 ppm metal) with cyanopropylsilyl groups.	1119500	Luna CN (Cyano) HyperClone CN (Cyano) PhenoSphere CN (Cyano)
Silica gel for chromatography, nitrile, endcapped with cyanopropylsilyl groups.	1174500	Luna CN (Cyano)
Silica gel for chromatography, octadecylsilyl.	1077500	Luna C18(2) Luna Omega C18 Luna Omega PS C18 Luna Omega Polar C18 Synergi Hydro-RP Synergi Fusion-RP Gemini® C18 Gemini NX-C18 HyperClone C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18 Kinetex Polar C18 SphereClone™ C18 ODS(1) or (2)
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) Luna Omega C18 Luna Omega PS C18 Luna Omega Polar C18 Synergi Hydro-RP Synergi Fusion-RP Gemini C18 Gemini NX-C18 Jupiter C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18 Kinetex Polar C18
Silica gel for chromatography, octadecylsilyl R2 ultrapure silica; 150 Å pore size; 20% C-load; optimized for the analysis of PAHs.	1115300	EnviroSep™-PP Prodigy™ ODS-2
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) Luna Omega C18 Luna Omega PS C18 Luna Omega Polar C18 Gemini C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18 Kinetex Polar C18
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) Luna Omega C18 Luna Omega PS C18 Luna Omega Polar C18 Gemini C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18 Kinetex Polar C18
Silica gel for chromatography, octadecylsilyl, endcapped R1 ultrapure silica (<20 ppm metal) 100 Å pore size; 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
Silica gel for chromatography, octadecylsilyl, endcapped, base-deactivated; 100 Å pore size; 16% C-load, 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) Prodigy ODS-3 Gemini C18 Gemini NX-C18
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) Luna Omega C18 Luna Omega PS C18 Luna Omega Polar C18 Gemini C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18 Kinetex Polar C18
Silica gel for chromatography, octadecylsilyl, monolithic.	1154500	Onyx™ C18

Description According to Pharm. Eur. 9 4.1.1. Reagents 2017	Number	Recommended Phenomenex Column
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
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
Silica gel for chromatography, octadecylsilyl, ethylene-bridged (hybrid material). Synthetic, spherical ethylene-bridged hybrid particles, containing both organic (organosiloxanes) and inorganic (silica) components.	1190500	Kinetex® EVO C18 Gemini® NX-C18
Silica gel for chromatography, octadecylsilyl, extra-dense bonded, endcapped.	1188500	Luna® C18(2) Luna Omega C18 Luna Omega PS C18 Luna Omega Polar C18 Gemini C18 Gemini NX-C18 Kinetex C18 Kinetex EVO C18 Kinetex XB-C18 Kinetex Polar 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 Kinetex Polar C18 Aeris™ PEPTIDE XB-C18 Aeris WIDEPORE XB-C18
Silica gel for chromatography, octadecylsilyl, with extended pH range, endcapped (resistant to bases up to pH 11).	1196700	Gemini C18 Gemini NX-C18 Kinetex EVO C18
Silica gel for chromatography, octylsilyl.	1077700	Kinetex C8 Luna C8(2) Prodigy™ C8 HyperClone™ C8 (MOS) SphereClone™ C8
Silica gel for chromatography, octylsilyl R1. Bonding of octylsilyl and methyl groups (double bonded phase).	1077701	Kinetex C8 Luna C8(2) Prodigy C8 HyperClone C8 (MOS) SphereClone™ C8
Silica gel for chromatography, octylsilyl R3 ultrapure silica, bonding of octylsilyl groups and sterically protected with branched hydrocarbons at the silanes.	1155200	ZORBAX® StableBond C8
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) Prodigy C8 HyperClone C8 (BDS)
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) Prodigy C8 HyperClone C8 (BDS)
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) Prodigy C8 HyperClone C8 (BDS)
Silica gel for chromatography, octylsilyl, extra-dense bonded, endcapped.	1200900	Luna C8(2) Kinetex C8
Silica gel for chromatography, phenylhexylsilyl.	1153900	Kinetex Phenyl-Hexyl Luna Phenyl-Hexyl Gemini C6-Phenyl
Silica gel for chromatography, phenylhexylsilyl, endcapped. 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
Silica gel for chromatography, phenylhexylsilyl, solid core, endcapped. Silica gel with spherical silica particles containing a non-porous solid silica core surrounded by a thin outer porous silica coating with phenylhexylsilyl groups. To minimize any interaction with basic compounds it's carefully endcapped to cover most of the remaining silanol groups.	1198900	Kinetex Phenyl-Hexyl
Silica gel for chromatography, phenylsilyl.	1110200	Synergi Polar-RP Luna Phenyl-Hexyl Gemini C6-Phenyl Prodigy Phenyl-3 (PH3) Kinetex Biphenyl Kinetex Phenyl-Hexyl
Silica gel for chromatography, phenylsilyl, R1 spherical silica; pore size: 80 Å; surface area: 180 m ² /g; C-load: 5.5 %.	1075700	ZORBAX StableBond Phenyl
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 Prodigy Phenyl-3 (PH3) Kinetex Biphenyl Kinetex Phenyl-Hexyl
Silica gel for chromatography, phenylsilyl, endcapped, base-deactivated.	1197900	Synergi Polar-RP Luna Phenyl-Hexyl Gemini C6-Phenyl Prodigy Phenyl-3 (PH3) Kinetex Phenyl-Hexyl Kinetex Biphenyl

Description According to Pharm. Eur. 9 4.1.1. Reagents 2017	Number	Recommended Phenomenex Column
Silica gel for chromatography, (hybrid material), phenylsilyl, ethylene-bridged, endcapped. Synthetic, spherical ethylene-bridged hybrid particles containing both organic (organosiloxanes) and inorganic (silica) components, chemically modified at the surface by bonding of phenylsilyl groups. To minimize any interaction with basic compounds it's carefully endcapped to cover most of the remaining silanol groups.	1200700	Gemini® C6-Phenyl
Silica gel for chromatography, propoxybenzene, endcapped.	1174600	Synergi™ Polar-RP
Silica gel for chromatography, propylsilyl.	1170700	ZORBAX® StableBond C3
Silica gel for chromatography, strong anion-exchange bonding of quaternary ammonium groups; pH limit of use: 2 to 8.	1077800	PhenoSphere™ SAX
Silica gel for chromatography, strong cation-exchange bonding of sulfonic acid groups.	1161400	Luna® SCX
Silica gel for chromatography, trimethylsilyl.	1115500	Develosil® TMS-UG (C1) Capcell Pak® C1 UG PhenoSphere C1
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 x 10 ³ to 3 x 10 ⁵ .	1077900	BioSep™-SEC-S3000
Silica gel OD for chiral separations.	1110300	Lux® Cellulose-1
Silica gel OJ for chiral separations coated with cellulose tris (4-methylbenzoate).	1179800	Lux Cellulose-3
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
Vinyl polymer for chromatography, amino alkyl. Spherical particles (5 µm) of a vinyl alcohol copolymer, bonding of amino alkyl groups.	1191500	Asahipak® NH ₂ -P
Vinyl polymer for chromatography, octadecyl. Spherical particles (5 µm) of a vinyl alcohol copolymer, bonding of octadecyl groups on the hydroxyl groups.	1155400	Asahipak ODP-50
Vinyl polymer for chromatography, octadecylsilyl. Spherical particles (5 µm) of a vinyl alcohol copolymer bonded to an octadecylsilane. C-load: 17 %.	1121600	Asahipak ODP-50
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. A resin in protonated form with sulfonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with 8 % divinylbenzene. Available as spherical beads.	1016700	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

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