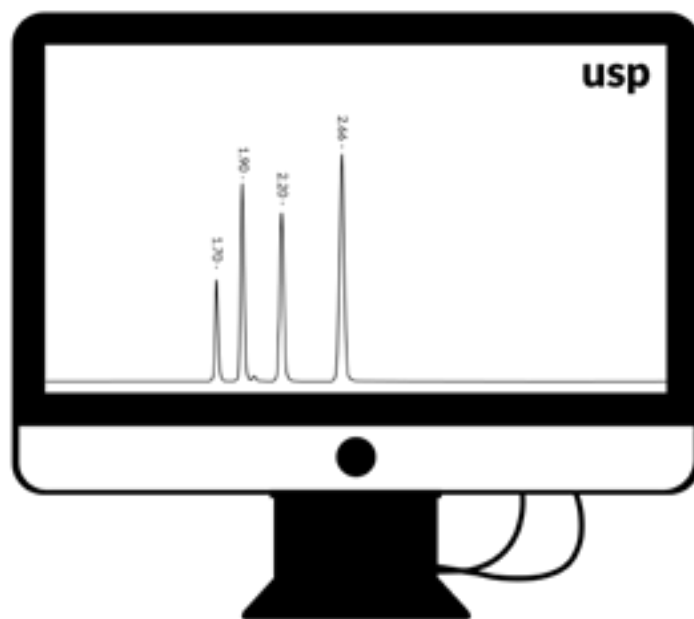


Dr. Maisch

Any Column, Any Size, Any Media



UNITED STATES PHARMACOPEIA (USP) CHROMATOGRAPHIC COLUMNS

INCLUDING ALLOWABLE CHANGES

MADE BY DR. MAISCH

Component	ISOCRATIC	GRADIENT
Stationary phase	No changes allowed. e.g. No replacement of C18 by C12, additional physico chemical characteristics must be similar. Change from fully-porous silica (e.g. ReproSil, Reprospher) to core-shell particles (ReproShell) allowed.	
Particle size and column length	Fully-porous silica: L/d_p -ratio remains constant or in the range between -25 % and +50 %. Core-Shell silica: Other combinations of L and d_p can be used, if N is between -25 % and +50 % of the original column. <i>L</i> = column length (mm) <i>d_p</i> = particle size (µm) <i>N</i> = efficiency (plates/m)	Fully-porous silica: L/d_p -ratio remains constant or in the range between -25 % and +50 %. Core-Shell silica: Other combinations of L and d_p can be used, if the ratio (<i>t_R</i> / <i>W_h</i>)² is between -25 % and +50 % of the original column, for each peak used to test the system suitability. <i>t_R</i> = Retention time <i>L</i> = column length (mm) <i>d_p</i> = particle size (µm) <i>N</i> = efficiency (plates/m) <i>W_h</i> = width at half height of the peak
Column inner diameter	Flexible	Flexible
Flow rate	± 50 % (after the adjustment due to changes in column ID and particle size) $F_2 = F_1 \times \frac{dc_2^2 \times dp_1}{dc_1^2 \times dp_2}$ <i>F₁</i> = Flow rate (ml/min) indicated in the monograph method <i>F₂</i> = Adjusted flow rate (ml/min) <i>dc₁</i> = ID (mm) of the column mentioned in the monograph method <i>dc₂</i> = ID (mm) of the new column <i>dp₁</i> = particle size (µm) mentioned in the monograph <i>dp₂</i> = particle size (µm) of the new column	
Gradient volume	n/a	Adjust each segment of the gradient by means of the gradient time using the following equation: $t_{G2} = t_{G1} \times \left(\frac{F_1}{F_2} \right) \times \frac{[L_1 \times dc_2^2]}{[L_1 \times dc_1^2]}$ <i>t_{G1}</i> = Gradient volume or gradient time (initial) <i>t_{G1}</i> = New gradient time <i>F₁</i> = Flow rate (ml/min) indicated in the monograph method <i>F₂</i> = Adjusted flow rate (ml/min) <i>dc₁</i> = ID (mm) of the column mentioned in the monograph method <i>dc₂</i> = ID (mm) of the new column <i>L₁</i> = Initial column length (mm) <i>L₂</i> = New column length (mm)

Injection volume	Adjusting of the column volume when changing column ID based on the following formula: $V_{inj2} = V_{inj1} \times \frac{L_2 \times dc_2^2}{L_1 \times dc_1^2}$ V_{inj1} = Injection volume (μl) mentioned in the method V_{inj2} = New Injection volume (μl) L_1 = Column length (mm) in the USP method L_2 = Column length (mm) in the new method dp_1 = particle size (μm) mentioned in the monograph method dp_2 = particle size (μm) of the new column	
Column temperature	± 10 °C	± 5 °C
Composition of the mobile phase	Minor component ± 30 % & ± 10 % absolute. Only 1 minor component can be changed in ternary mixtures. <i>(Minor Component = less than 50 % of the Mobile phase)</i>	Adjustments allowed, if: • The principal peak(s) elute(s) within ± 15 % of the indicated retention time(s). This requirement does not apply when the column dimensions are changed. • The composition of the mobile phase and the gradient are such the first peaks are sufficiently retained and the last peaks are eluted. • The system suitability criteria are fulfilled
Mobile phase pH	± 0.2 units	± 0.2 units
Concentration of salts in the buffer	± 10 %	± 10 %
Detector wavelength	No adjustment permitted.	

USP Harmonized Standards Home Page. Supplement USP Stage 4 Harmonization, Official, December 1, 2022 (latest revision in April 2023).

Code	Specification	Dr. Maisch Phases
USP-L1	Octadecyl silane chemically bonded to porous or nonporous silica particles or superficially porous particles or ceramic micro-particles, 1.5 to 10 µm in diameter, or a monolithic rod.	ReproSil-XR 120 C18
		ReproSil-XR 300 C18
		ReproSil 100 C18 (XBD)
		ReproSil-Pur C18-AQ
		ReproSil-Pur ODS-3
		ReproSil Gold C18
		ReproSil Saphir C18
		ReproSil 80 ODS-2
		ReproSil-Pur Basic C18 (HD)
		Reprospher C18 (DE)
		Reprobond C18
		Repropack C18
		ReproShell ODS-1
		ReproShell ODS-3
USP-L2	Octadecylsilane chemically bonded to silica gel of a controlled surface porosity that has been bonded to a solid spherical core, 30 to 50 µm.	Reprobond C18, 45 µm
USP-L3	Porous silica particles or superficially porous particles, 1.5 to 10 µm in diameter, or a monolithic rod.	ReproSil-XR 120 Si
		ReproSil 100 Si
		ReproSil-Pur Si
		ReproSil 80 Si
		Reprospher Si
		Reproshell Si
USP-L4	Silica gel of controlled surface porosity bonded to a solid spherical core, 30 to 50 µm in diameter.	Reprobond Si, 45 µm
USP-L7	Octylsilane chemically bonded to totally porous or superficially porous silica particles 1.5 to 10 µm in diameter, or a monolithic rod.	ReproSil-XR 120 C8
		ReproSil-XR 300 C8
		ReproSil 100 C8
		ReproSil-Pur C8
		ReproSil Gold C8
		ReproSil -Pur Basic C8 (HD)
		ReproSil 80 C8
		Reprospher C8 (DE)
USP-L8	An essentially monomolecular layer of aminopropylsilane chemically bonded to totally porous silica gel support, 1.5 to 10 µm in diameter, or a monolithic silica rod.	ReproSil XR 120 NH ₂
		ReproSil 100 NH ₂
		ReproSil-Pur NH ₂
		ReproSil 80 NH ₂
		Reprospher NH ₂
USP-L9	Irregular or spherical, totally porous silica gel having a chemically bonded, strongly acidic cation-exchange coating, 3 to 10 µm in diameter.	ReproSil-XR 120 SCX
		ReproSil-XR 300 SCX
		ReproSil 80 SCX
		ReproSil Saphir SCX
USP-L10	Nitrile groups chemically bonded to porous silica particles or superficially porous particles, 1.5 to 10 µm in diameter, or a monolithic silica rod.	ReproSil-XR 120 CN
		ReproSil 100 CN
		ReproSil-Pur CN
		ReproSil 80 CN
		Reprospher CN (DE)

Code	Specification	Dr. Maisch Phases
USP-L11	Phenyl groups chemically bonded to porous or superficially porous silica particles, 1.5 to 10 µm in diameter, or a monolithic silica rod.	ReproSil-XR 120 Phenyl
		ReproSil 100 Phenyl
		ReproSil-Pur Phenyl
		Reprospher Biphenyl
		Reprospher Phenyl (DE)
		ReproShell Phenyl-Hexyl
		ReproShell Biphenyl
USP-L13	Trimethylsilane (C1, SAS) chemically bonded to porous silica particles 3 to 10 µm.	ReproSil-Pur C1
		ReproSil 80 C1
USP-L14	Silica gel having a chemically bonded, strongly basic quaternary ammonium anion-exchange coating, 5 to 10 µm in diameter.	ReproSil-XR 120 SAX
		ReproSil 80 SAX
USP-L15	Hexylsilane chemically bonded to totally porous silica particles, 3 to 10 µm in diameter.	ReproSil 80 C6
USP-L16	Dimethyl silane (C2) chemically bonded to porous silica particles, 3 to 10 µm.	ReproSil-XR 120 C2
		ReproSil Gold 120 C2
		ReproSil Gold 300 C2
USP-L17	Strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the H ⁺ Form, 7 to 11 µm.	Repromer H
		Reprogel H
USP-L18	Amino and cyano groups chemically bonded to porous silica particles, 3 to 10 µm in diameter.	Adsorbosphere PAC
USP-L19	Strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the calcium form, 5 to 15 µm in diameter.	Repromer Ca
		Reprogel Ca
USP-L20	Dihydropropane groups chemically bonded to porous silica particles, 1.5 to 10 µm in diameter, or a monolithic silica rod.	ReproSil 70 Diol
		ReproSil-Pur 300 Diol
		ReproSil 300 Diol
		ReproSil-Pur 200 Diol
		Reprospher 100 Diol
USP-L21	A rigid, spherical styrene-divinylbenzene copolymer, 3 to 30 µm in diameter.	Repromer 100 RPS
		Repromer 300 RPS
		Repromer 1000 RPS
USP-L22	A cation-exchange resin made of porous polystyrene gel with sulfonic acid groups, 5 to 15 µm in diameter.	Repromer H
USP-L25	Packing having the capacity to separate compounds with a molecular weight range from 100 - 5000 (as determined by polyethylene oxide), applied to neutral anionic and cationic water-soluble polymers. A polymethacrylate resin base, cross-linked with polyhydroxylated ether (surface contained some residual carboxyl functional groups) was found suitable.	Repromer OH-2500
USP-L26	Butyl silane chemically bonded to totally porous or superficially porous silica particles, 1.5 to 10 µm in diameter.	ReproSil-XR 120 C4
		ReproSil-XR 300 C4
		ReproSil 100 C4
		ReproSil-Pur C4
		ReproSil Gold C4
		Reprospher C4 (DE)
USP-L27	Porous silica particles, 30 to 50 µm in diameter.	ReproSil 70 / 100
USP-L30	Ethyl silane chemically bonded to totally porous silica particles, 3 to 10 µm in diameter.	ReproSil-XR 120 C2
		ReproSil Gold 120 C2
		ReproSil Gold 300 C2

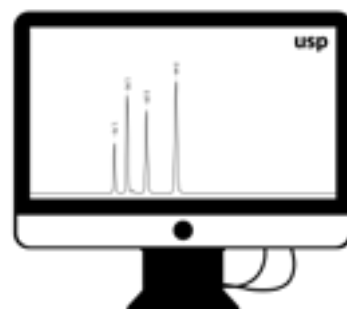
Code	Specification	Dr. Maisch Phases
USP-L32	A chiral ligand-exchange resin packing L-proline copper complex covalently bonded to irregular shaped silica particles, 5 to 10 µm in diameter.	ReproSil Chiral-L-Hydroxy-Prolin
USP-L33	Packing having the capacity to separate dextrans by molecular size over a range of 4,000 to 500,000 daltons. It is spherical, silica-based, and processed to provide pH stability.	ReproSil 200 SEC
USP-L34	Strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the lead form, 7 to 9 µm in diameter.	Repromer Pb
		Reprogel Pb
USP-L36	A 3,5-dinitrobenzoyl derivative of L-phenylglycine covalently bonded to 5 µm aminopropyl silica.	ReproSil Chiral-PhenylGlycin
USP-L37	Packing having the capacity to separate proteins by molecular size over a range of 2,000 to 40,000 daltons. It is a polymethacrylate gel.	Repromer OH-3000
		Repromer OH-2500
USP-L38	A methacrylate-base size-exclusion packing for water-soluble samples.	Repromer OH (all)
USP-L39	A hydrophilic polyhydroxymethacrylate gel of totally porous spherical resin.	Repromer OH (all)
USP-L40	Cellulose tris-3,5-dimethylphenylcarbamate coated porous silica particles, 3 to 20 µm in diameter.	ReproSil Chiral-OM
USP-L41	Immobilized alfa1-acid glycoprotein on spherical silica particles, 5 µm in diameter.	Chiral-AGP
USP-L43	Pentafluorophenyl groups chemically bonded to porous or superficially porous silica particles by a propyl spacer, 1.5 to 10 µm in diameter.	Reprospher 100 PFP
		Reproshell PFP
		ReproSil Fluosil PFP
USP-L45	Beta cyclodextrin, R,S-hydroxypropyl ether derivative, bonded to porous silica particles, 3 to 10 µm in diameter.	ReproSil Chiral Beta-CD
		ReproSil Chiral Beta-PM
USP-L47	High capacity anion-exchange microporous substrate, fully functionalized with trimethylamine groups, 8 µm in diameter.	RCX-10
		RCX-30
USP-L51	Amylose tris-3,5-dimethylphenylcarbamate-coated, porous, spherical, silica particles, 3 to 10 µm in diameter.	ReproSil Chiral-AM
USP-L52	A strong cation exchange resin made of porous silica with sulfopropyl groups, 1 to 10 µm in diameter.	ReproSil-XR 120 SCX
		ReproSil-XR 300 SCX
		ReproSil 80 SCX
		ReproSil Saphir SCX
USP-L55	A strong cation exchange resin made of porous silica coated with polybutadiene-maleic acid copolymer, about 5 µm in diameter.	ReproSil CAT
USP-L56	Propyl silane chemically bonded to totally or superficially porous silica particles, 3 to 10 µm in diameter.	Ultrasep ES RP3
USP-L57	A chiral recognition protein, ovomucoid, chemically bonded to silica particles, about 5 µm in diameter, with pore size of 120 Å.	Ultron ES-OVM
USP-L58	Strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the sodium form, about 6 to 30 µm in diameter.	Repromer Na
		Reprogel Na
USP-L59	Packing having the capacity to separate proteins by molecular weight over the range of 5 to 7000 kDa. The packing is spherical 1.5 to 10 µm silica or hybrid packing with a hydrophilic coating.	Macrosphere SEC
		ReproSil SEC
USP-L60	Spherical, porous or superficially porous silica particles, 10 µm or less in diameter, the surface of which has been covalently modified with alkyl amide groups and endcapped.	ReproSil Amid C18e
		ReproSil Amid-C18 ABZ
USP-L62	C30-silane bonded phase on a fully spherically silica, 3 to 15 µm.	Reprospher 200 C30 DE
		Reprospher C30

Code	Specification	Dr. Maisch Phases
USP-L63	Glycopeptide teicoplanin linked through multiple covalent bonds to a 100 Angstrom units spherical silica.	ReproSil Chiral-TAG
USP-L68	Spherical, porous silica, 10 µm or less in diameter, the surface of which has been covalently modified with alkyl amide groups and not endcapped.	ReproSil Amid-C18(-ABZ)
		ReproSil Amid-C12
USP-L70	Cellulose tris(phenyl carbamate) coated on 5 µm silica.	ReproSil Chiral-CM
USP-L72	(S)-phenylglycine and 3,5-dinitroaniline urea linkage covalently bonded to silica.	Sumichiral OA-3300S
USP-L73	A rigid spherical polydivinylbenzene particle, 5 to 10 µm in diameter.	Repromer 100-RPS
USP-L78	A silane ligand that consists of both reversed-phase (an alkyl chain longer than C8) and anion-exchange (primary, secondary, tertiary, or quaternary amino groups) functional groups chemically bonded to porous or non-porous silica or ceramic micro-particles, 1.0 to 50 µm in diameter, or a monolithic rod.	Exsil Quattro (BS-C23)
		Stability BS-C17/C23
USP-L79	A chiral-recognition protein, human serum albumin (HSA), chemically bonded to silica particles, about 5 µm in diameter.	ReproSil Chiral-HSA
USP-L80	Cellulose tris (4-methylbenzoate)-coated, porous, spherical, silica particles, 5 to 20 µm in diameter.	ReproSil Chiral-JM
USP-L85	A silane ligand that consists of both reversed-phase (an alkyl chain longer than C8) and weak cation-exchange (carboxyl groups) functional groups chemically bonded to porous or non-porous particles, 1.0 to 50 µm in diameter.	Reprospher 100 C18/WCX
USP-L87	Dodecyl silane chemically bonded to porous or superficially porous silica particles, 1.5 to 10 µm in diameter.	Reprospher 100 C12
USP-L90	Amylose tris-[(S)-alpha-methylbenzylcarbamate] coated on porous, spherical silica particles, 3 to 10 µm in diameter.	ReproSil Chiral-AMS
USP-L93	Cellulose tris (3,5-dimethylphenylcarbamate) reversed phase chiral stationary phase coated on 3 or 5 µm silica gel particles.	ReproSil Chiral-OM-R
USP-L96	Alkyl chain, reversed-phase bonded totally or superficially porous silica designed to retain hydrophilic and other polar compounds when using highly aqueous mobile phases, including 100% aqueous, 1.5 µm to 10 µm.	Platinum C18-EPS
		Platinum C8-EPS
		Reprospher 100 C18 Aqua
		ReproSil-Pur C18 AQ
USP-L107	Cellulose tris(4-methylbenzoate)-coated porous spherical particles, 3 to 5 µm in diameter, for use with reversed phase mobile phases.	ReproSil Chiral-JM-R
USP-L114	Sulfobetaine graft-polymerized to totally or superficially porous silica, 1.5 to 10 µm in diameter, or a monolithic rod. Packing having densely bonded zwitterionic groups with 1:1 charge balance.	ReproSil Star ZIK HILIC
USP-L119	Cellulose tris-(3,5-dichlorophenylcarbamate), immobilized on porous, spherical, silica particles, 3 to 5 µm in diameter.	ReproSil Chiral-MIC

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