Allowable Adjustments to United States Pharmacopeia (USP) Methods for

ISOCRATIC SEPARATIONS

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 reqs.
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 %

Allowable Adjustments to United States Pharmacopeia (USP) Methods for

GRADIENT SEPARATIONS

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 reqs.
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

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HPLC Column Selection by USP Listing

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 Kinetex® C18 Kinetex EVO C18 Kinetex Polar C18 Kinetex XB-C18 Luna® C18(2) Luna Omega C18 Luna Omega PS C18 Luna Omega Polar C18 Gemini C18 Synergi™ Hydro-RP Synergi Fusion-RP Onyx™ C18 Jupiter® C18 Clarity® Oligo-RP Clarity Oligo-MS Clarity Oligo-XT Aeris™ WIDEPORE XB-C18 Aeris PEPTIDE XB-C18	Spherical Core-Shell Core-Shell Core-Shell Core-Shell Spherical Spherical Spherical Spherical Spherical Spherical Spherical Monolith Spherical Spherical Core-Shell Core-Shell Core-Shell Core-Shell
L3	Porous silica particles, 1.5 to 10 µm in diameter, or a monolithic silica rod.	Kinetex HILIC Luna Silica(2) Onyx Silica	Core-Shell Spherical 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 Luna C8(2) Onyx C8 Aeris WIDEPORE XB-C8	Core-Shell Spherical Monolith Core-Shell
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
L10	Nitrile groups chemically bonded to porous silica particles, 1.5 to 10 µm in diameter, or a monolithic silica rod.	Luna CN	Spherical
L11	Phenyl groups chemically bonded to porous silica particles, 1.5 to 10 µm in diameter, or a monolithic silica rod.	Kinetex Biphenyl Kinetex Phenyl-Hexyl Synergi Polar-RP Luna Phenyl-Hexyl Gemini C6-Phenyl Prodigy™ PH-3	Core-Shell Core-Shell Spherical Spherical Spherical Spherical
L13	Trimethylsilane chemically bonded to porous silica particles, 3 to 10 µm in diameter.	Develosil® TMS-UG (C1) 130 Å	Spherical
L14	Silica gel having a chemically bonded, strongly basic quaternary ammonium anion-exchange coating, 5 to 10 µm in diameter.	PhenoSphere™ SAX	Spherical
L15	Hexyl silane chemically bonded to totally porous silica particles, 3 to 10 µm in diameter.	PhenoSphere C6	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 Rezex ROA-Organic Acid	Spherical 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 Rezex RCU-Sugar Alcohols	Spherical 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 BioSep™-SEC-S Yarra™ SEC	Spherical Spherical Spherical
L21	A rigid, spherical styrene-divinylbenzene copolymer, 3 to 30 µm in diameter.	PolymerX™ RP-1 Phenogel™ 100 Å	Spherical 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
L23	An anion-exchange resin made of porous polymethacrylate or polyacrylate gel with quaternary ammonium groups, 7-12 µm in size.	Shodex® IEC QA-825	Spherical
L25	Packing having the capacity to separate compounds with a MW range from 100 to 5000 daltons (as determined by polyethylene oxide), applied to neutral, anionic, and cationic water-soluble polymers. A polymethacrylate resin base, crosslinked with poly-hydroxylated ether (surface contained some residual carboxyl functional groups) was found suitable.	PolySep™-GFC-P2000 Shodex OHpak SB-802.5HQ	Spherical Spherical

HPLC Column Selection by USP Listing

USP Column Classification		Recommended Phenomenex Column	Particle Shape
L26	Butyl silane chemically bonded to totally porous or superficially porous silica particles, 1.5 to 10 µm in diameter.	Jupiter® 300 C4 Aeris™ WIDEPORE C4	Spherical Core-Shell
L27	Porous silica particles, 30 to 50 µm in diameter.	Sepra™ Silica	Irregular
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 Yarra SEC-X150 Yarra SEC-X300	Spherical Spherical 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 150 Å.	(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 Shodex® OHpak SB-803HQ	Spherical Spherical
L38	Methacrylate-based size-exclusion packing for water-soluble samples.	PolySep-GFC-P series Shodex OHpak SB-800HQ	Spherical Spherical
L39	Hydrophilic polyhydroxymethacrylate gel of totally porous spherical resin.	PolySep-GFC-P series Shodex OHpak SB-800HQ series Shodex RSpak DM-614	Spherical Spherical Spherical
L40	Cellulose tris-3,5-dimethylphenylcarbamate coated porous silica particles, 3 to 20 µm in diameter.	Lux® Cellulose-1	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
L45	Beta cyclodextrin, R, S-hydroxypropyl ether derivative, bonded to porous silica particles, 3 to 10 µm in diameter	Shiseido® Chiral CD-Ph	Spherical
L51	Amylose tris-3,5-dimethylphenylcarbamate-coated, porous, spherical, silica particles, 3 to 10 µm in diameter.	Lux Amylose-1	Spherical
L57	A chiral-recognition protein, ovomucoid, chemically bonded to silica particles, about 5 µm in diameter, with a pore size of 120 Å.	Ultron® ES-OVM	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 Yarra SEC-X150 Yarra SEC-X300	Spherical Spherical Spherical Spherical Spherical Spherical
L62	C30 silane bonded phase on a fully porous spherical silica, 3 to 15 µm in diameter.	Develosil® Combi-RP Develosil RP-Aqueous Develosil RP-Aqueous-AR	Spherical Spherical Spherical
L67	Porous vinyl alcohol copolymer with a C18 alkyl group attached to the hydroxyl group of the polymer, 2 to 10 µm in diameter.	Asahipak® ODP-50	Spherical
L71	A rigid, spherical polymethacrylate 4 to 6 µm in diameter.	Shodex RSpak DE-413 Shodex RSpak DE-613	Spherical Spherical
L72	(S)-phenylglycine and 3,5-dinitroaniline urea linkage covalently bonded to silica.	Chirex™ 3012	Spherical
L80	Cellulose tris(4-methylbenzoate)-coated, porous, spherical, silica particles, 5 to 20 µm in diameter.	Lux Cellulose-3	Spherical
L82	Polyamine chemically bonded to cross-linked polyvinyl alcohol polymer, 4 to 5 µm in diameter	Asahipak® NH2P-50	Spherical
L87	Dodecyl silane chemically bonded to porous silica particles, 1.5 to 10 µm in diameter.	Synergi™ Max-RP Jupiter Proteo	Spherical Spherical
L93	Cellulose tris (3,5-dimethylphenylcarbamate) reversed phase chiral stationary phase coated on 3 or 5 µm silica gel particles.	Lux Cellulose-1	Spherical
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 to 10 µm in diameter.	Kinetex Polar C18 Kinetex EVO C18 Luna Omega Polar C18 Luna Omega PS C18 Synergi Hydro-RP	Spherical Spherical Spherical Spherical Spherical
L99	Amylose tris-(3,5-dimethylphenylcarbamate), immobilized on porous, spherical, silica particles, 3 to 5 µm in diameter.	Lux i-Amylose-1	Spherical
L107	Cellulose tris(4-methylbenzoate)-coated porous spherical particles, 3 to 5 µm in diameter, for use with reversed phase mobile phases.	Lux Cellulose-3	Spherical