

Chromservis HPLC columns corresponding to Pharmacopoeia methods

USP Code	Description	Corresponding column
L1	Octadecyl silane chemically bonded to porous or nonporous silica particles or superficially porous particles or ceramic micro-particles, 1.5–10 µm in diameter, or a monolithic rod.	ARION® Plus C18 ARION® Polar C18 ASTRA® C18-AQ ASTRA® C18-BDS ASTRA® C18-HE CHROMSHELL® C18 Plus CHROMSHELL® C18-XB CHROMSHELL® C18 Polar
L3	Porous silica particles or superficially porous particles, 1.5–10 µm in diameter, or a monolithic rod.	ARION® HILIC Plus ARION® Si ASTRA® Si
L7	Octylsilane chemically bonded to totally porous or superficially porous silica particles 1.5–10 µm in diameter, or a monolithic rod.	ARION® C8 ASTRA® C8-HE ASTRA® C8-BDS
L8	An essentially monomolecular layer of aminopropylsilane chemically bonded to totally porous silica gel support, 1.5–10 µm in diameter, or a monolithic silica rod.	ARION® NH ₂
L10	Nitrile groups chemically bonded to porous silica particles or superficially porous particles, 1.5–10 µm in diameter, or a monolithic silica rod.	ARION® CN
L11	Phenyl groups chemically bonded to porous or superficially porous silica particles, 1.5–10 µm in diameter, or a monolithic silica rod.	ARION® Biphenyl ARION® Phenyl-Butyl ASTRA® Phenyl-Hexyl-HE
L14	Silica gel having a chemically bonded, strongly basic quaternary ammonium anion-exchange coating, 5–10 µm in diameter.	ARION® SAX
L17	Strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the hydrogen form, 6–12 µm in diameter.	ASTRA® Sugar H(S)
L19	Strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the calcium form, 5–15 µm in diameter.	ASTRA® Sugar Ca(S)
L20	Dihydropropane groups chemically bonded to porous silica particles, 1.5–10 µm in diameter, or a monolithic silica rod.	ASTRA® Diol
L43	Pentafluorophenyl groups chemically bonded to porous or superficially porous silica particles by a propyl spacer, 1.5–10 µm in diameter.	ARION® PFP
L50	Multifunction resin with reversed-phase retention and strong anion-exchange functionalities. The resin consists of ethylvinylbenzene, 55 % cross-linked with divinylbenzene copolymer, 3–15 µm in diameter, and a surface area not less than 350 m ² per g. Substrate is coated with quaternary ammonium functionalized latex particles consisting of styrene cross-linked with divinylbenzene.	ARION® SCX



Allowable Adjustments to HPLC Methods in the United States Pharmacopeia (USP)⁽¹⁾ and European Pharmacopoeia (Ph.Eur.)⁽²⁾

Parameter	Isocratic Elution	Gradient Elution
pH	±0.2	±0.2
Buffer concentration	±10 %	±10 %
Mobile phase / Gradient volume	Solvent ratio up to the lesser of ±30 % relative or ±10 % absolute for minor components	Gradient segments adjusted according to the equation: $tG_2 = tG_1 \times (F_1/F_2) [(L_2 \times dc_2) / (L_1 \times dc_1)]$
UV wavelength	No changes allowed	No changes allowed
Column dimensions	L (length) / dp (particle diameter) = -25 % to +50 % Adjustments from totally porous (TPP) to superficially porous particles (SPP): $(t_R/W_h)^2 = -25 \% \text{ to } +50 \%$ The system suitability criteria are fulfilled, selectivity and elution order of the specified impurities are demonstrated to be equivalent.	L (length) / dp (particle diameter) = -25 % to +50 % Adjustments from totally porous (TPP) to superficially porous particles (SPP): $(t_R/W_h)^2 = -25 \% \text{ to } +50 \%$ The system suitability criteria are fulfilled, selectivity and elution order of the specified impurities are demonstrated to be equivalent.
Stationary phase	No change of the identity of the substituent; the other physicochemical characteristics of the stationary phase. A change from TPP to SPP is allowed provided the above-mentioned requirements are met.	No change of the identity of the substituent; the other physicochemical characteristics of the stationary phase. A change from TPP to SPP is allowed provided the above-mentioned requirements are met.
Internal diameter	In absence of a change in particle size and/or length, the internal diameter may be adjusted.	In absence of a change in particle size and/or length, the internal diameter may be adjusted.
Flow rate	Allowed if column efficiency does not reduce by > 20 % Adjustment according to the equation: $F_2 = F_1 \times [(dc_2^2 \times dp_1) / (dc_1^2 \times dp_2)]$	Adjustment according to the equation: $F_2 = F_1 \times [(dc_2^2 \times dp_1) / (dc_1^2 \times dp_2)]$
Injection volume	Allowed if system suitability, limit of detection and repeatability are within specified limits. Adjustment according to the equation: $V_{inj2} = V_{inj1} (L_2 dc_2^2) / (L_1 dc_1^2)$	Allowed if system suitability, limit of detection and repeatability are within specified limits. Adjustment according to the equation: $V_{inj2} = V_{inj1} (L_2 dc_2^2) / (L_1 dc_1^2)$
Column temp.	±10 °C	±5 °C
Dwell volume		The length of the isocratic step may be adapted. Adapted time points according to the equation: $t_c = t - [(D - D_0)/F]$

References

- (1) United States Pharmacopeia (USP), General Chapter <621>
- (2) European Pharmacopoeia (Ph. Eur.), Chapter 2.2.46