

Luna Column Selection by Ph. Eur. Listings and Tolerances



Description According to Pharm. Eur. 8.3 4.1.1. Reagents 2014	Number	Recommended Phenomenex Column	Indicated Particle Size (µm)	Catalogue Page
Silica gel for chromatography.	1076900	Luna Silica(2)	3 to 10	220
Silica gel for chromatography, cyanosilyl.	1109900	Luna CN (Cyano)	3 to 10	220
Silica gel for chromatography, diol dihydroxypropyl, 100 Å.	1110000	Luna HILIC	5	220
Silica gel for chromatography, hydrophilic surface has been modified to provide hydrophilic characteristics.	1077200	Luna HILIC	3 to 10	220
Silica gel for chromatography, nitrile cyanopropylsilyl.	1077300	Luna CN (Cyano)	3 to 10	220
Silica gel for chromatography, nitrile R1 chemically bonded nitrile groups.	1077400	Luna CN (Cyano)	3 to 10	220
Silica gel for chromatography, nitrile R2 ultrapure silica (<20 ppm metal) with cyanopropylsilyl groups.	1119500	Luna CN (Cyano)	3 to 10	220
Silica gel for chromatography, nitrile, endcapped with cyanopropylsilyl groups.	1174500	Luna CN (Cyano)	3 to 10	220
Silica gel for chromatography, octadecylsilyl.	1077500	Luna C18(2)	3 to 10	220
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)	3 to 10	220
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)	3 to 10	220
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)	3 to 10	220
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		220
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)	3 to 10	220
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)	3 to 10	220
Silica gel for chromatography, octadecylsilyl, extra-dense bonded, endcapped.	1188500	Luna C18(2)		220
Silica gel for chromatography, octylsilyl.	1077700	Luna C8(2)	3 to 10	220
Silica gel for chromatography, octylsilyl R1. Bonding of octylsilyl and methyl groups (double bonded phase).	1077701	Luna C8(2)	3 to 10	220
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	Luna C8(2)	3 to 10	220
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	Luna C8(2)	3 to 10	200
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	Luna C8(2)	3 to 10	220
Silica gel for chromatography, phenylhexylsilyl.	1153900	Luna Phenyl-Hexyl	3 to 10	220
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	Luna Phenyl-Hexyl	3	220
Silica gel for chromatography, phenylsilyl.	1110200	Luna Phenyl-Hexyl	5 to 10	220
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	Luna Phenyl-Hexyl	5 to 10	220
Silica gel for chromatography, strong cation-exchange bonding of sulfonic acid groups.	1161400	Luna SCX	5 to 10	220



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Adjusting Ph. Eur. Methods: LC, Isocratic Elution

1. Composition of the mobile phase: $\pm 30\%$ (relative)

The amount of the minor component can be adjusted by $\pm 30\%$ relative or $\pm 2\%$ absolute, whichever is the larger. However a change in any component cannot exceed $\pm 10\%$ absolute.

ex. 60:40 Acetonitrile/Water could be adjusted to $\pm 12\%$ water (= 30 % of 40), but this exceeds the $\pm 10\%$ maximum absolute change. Therefore the amount of water can range from 30 % to 50 % in this case.

2. Mobile phase pH: ± 0.2 units (or ± 1.0 units for non-ionisable substances)

ex. pH of 7.6 can be adjusted from 7.4 – 7.8

3. Concentration of salts in buffer: $\pm 10\%$

ex. 20 mM Potassium phosphate can be 18 – 22 mM, as long as proper pH is maintained as above

4. Stationary phase: No change of the identity of the substituent permitted

ex. No replacement of C18 by C8

5. Particle size: can be reduced as much as 50 %

ex. 10 μm particles can be switched with 5 μm particles

6. Column length: $\pm 70\%$

ex. A 150 x 4.6 mm column can be varied from 45 – 255 mm in length

7. Column internal diameter: $\pm 25\%$

ex. A 150 x 4.6 mm column can be varied from 3.45 – 5.75 mm in diameter

8. Flow rate: $\pm 50\%$ (larger adjustment OK when changing column dimensions)

ex. 1 mL/min can be varied from 0.5 to 1.5 mL/min

ex. When column dimensions are changed (e.g. 125 x 4.0 mm at 0.8 mL/min to 100 x 4.6 mm), the flow rate may be adjusted using the following equation:

$$F_2 = F_1 \frac{l_2 d_2^2}{l_1 d_1^2} = 0.8 = \frac{100 \times 4.6^2}{125 \times 4.0^2} = 0.85 \text{ mL/min}$$

9. Column temperature: $\pm 10\text{ }^\circ\text{C}$

10. Wavelength of detector: no deviations permitted

11. Injection volume: can be decreased as long as detection and repeatability of the peak(s) to be determined are satisfactory; no increase permitted

Source: European Pharmacopeia 8.0, Chapter 2.2.46.
Chromatographic separation techniques, p. 72-79.

Luna Column Selection by Ph. Eur. Listings and Tolerances



Adjusting Ph. Eur. Methods: LC, Gradient Elution

1. 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.

2. Dwell volume: Gradient time points (t in min) can be adapted to compensate differences in dwell volume between the system used for method development (D_0 in mL) and that actually used (D in mL). The adapted time points (t_c) at the current flow rate (F in mL/min) can be calculated using the following equation:

$$t_c = t - \frac{(D - D_0)}{F}$$

3. Mobile phase pH: No adjustment permitted

4. Concentration of salts in buffer: No adjustment permitted

5. Stationary phase: No change of the identity of the substituent permitted
ex. No replacement of C18 by C8

6. Particle size: No adjustment permitted

7. Column length: $\pm 70\%$

ex. A 150 x 4.6 mm column can be varied from 45 – 255 mm in length

8. Column internal diameter: $\pm 25\%$

ex. A 150 x 4.6 mm column can be varied from 3.45 – 5.75 mm in diameter

9. Flow rate: Adjustment is acceptable when changing the column dimensions

ex. When column dimensions are changed (e.g. 125 x 4.0 mm at 0.8 mL/min to 100 x 4.6 mm), the flow rate may be adjusted using the following equation:

$$F_2 = F_1 \frac{l_2 d_2^2}{l_1 d_1^2} = 0.8 \times \frac{100 \times 4.6^2}{125 \times 4.0^2} = 0.85 \text{ mL/min}$$

10. Column temperature: $\pm 5^\circ\text{C}$

11. Wavelength of detector: No deviations permitted

12. Injection volume: can be decreased as long as detection and repeatability of the peak(s) to be determined are satisfactory; no increase permitted

Source: European Pharmacopeia 8.0, Chapter 2.2.46.
Chromatographic separation techniques, p. 72-79.

Luna Column Selection

Ph. Eur. Listings and Tolerances



Adjusting Ph. Eur. Methods: SFC

1. Composition of the mobile phase: $\pm 30\%$ (for packed columns)

The amount of the minor component can be adjusted by $\pm 30\%$ relative or $\pm 2\%$ absolute, whichever is the larger. No adjustment permitted for capillary columns.

ex. 90:10 CO₂/MeOH (Carbon dioxide / Methanol) can be adjusted in a range from 7 – 13 % MeOH

2. Particle size: Can be reduced as much as 50 % (for packed columns)

ex. 10 μm particles can be switched with 5 μm particles

3. Column length: $\pm 70\%$

ex. A 150 x 4.6 mm column can be varied from 45 – 255 mm in length

4. Column internal diameter: $\pm 25\%$ (for packed columns)
 $\pm 50\%$ (for capillary columns)

ex. A 4.6 mm packed column can be varied from 3.45 – 5.75 mm in diameter

ex. A 0.1 mm capillary column can be varied from 0.05 – 0.15 mm in diameter

5. Flow rate: $\pm 50\%$

ex. 1 mL/min can be varied from 0.5 to 1.5 mL/min

6. Column temperature: $\pm 5\%$

7. Wavelength of detector: No deviations permitted

8. Injection volume: Can be decreased as long as detection and repeatability are satisfactory; no increase permitted

Source: European Pharmacopeia 8.0, Chapter 2.2.46.
Chromatographic separation techniques, p. 72-79.



If Luna analytical columns do not provide at least an equivalent separation as compared to a competing column of the same particle size, similar phase, and dimensions, return the column with comparative data within 45 days for a FULL REFUND.



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