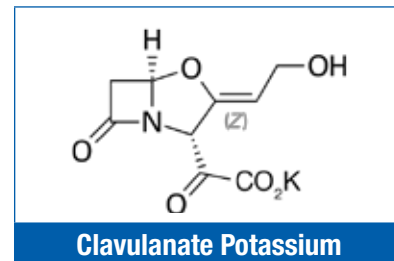


APPLICATION

Clavulanate Potassium and Related Substances *USP*

Overview

The related substances test of the USP monograph outlines the separation of all relevant impurities from Clavulanate Potassium. This method was studied and improvements were made to provide higher resolution (Rs) and a faster separation time within allowable adjustments.



USP Monograph: Clavulanate Potassium Details

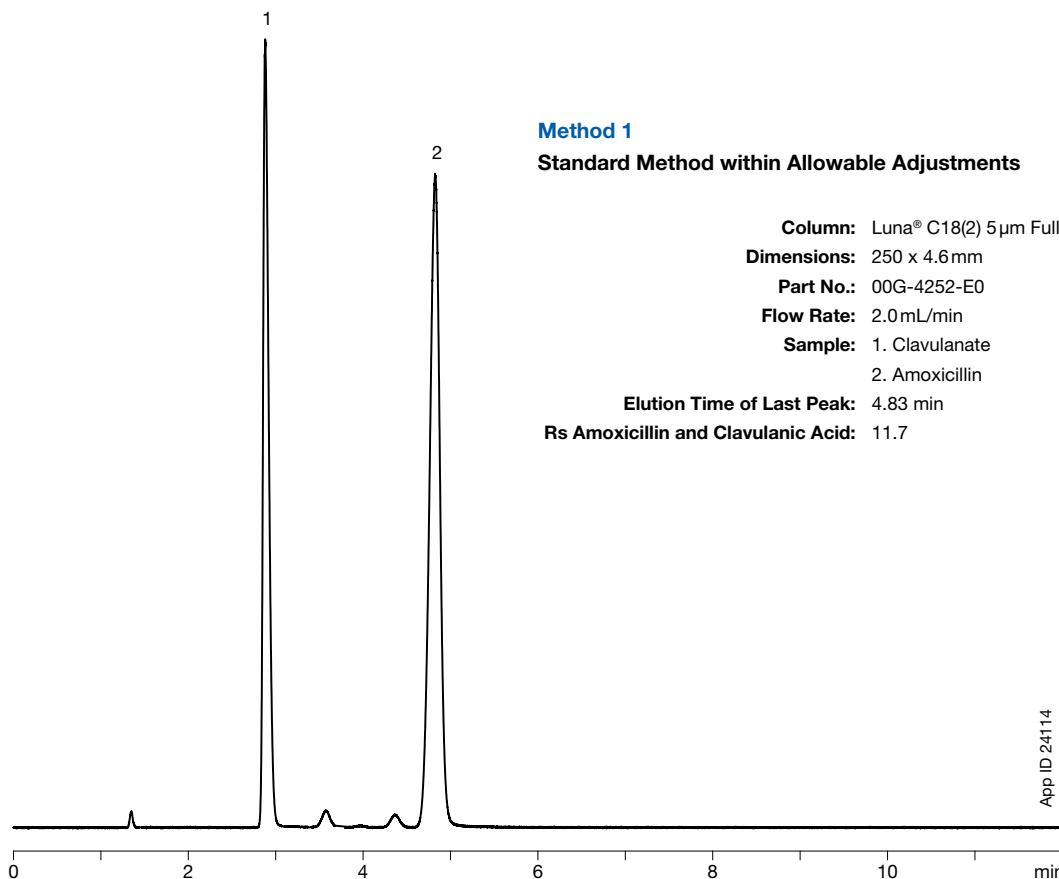
| | |
|------------------------------------|--|
| Solution A | 7.8 mg/mL of monobasic sodium phosphate in water. Adjust with phosphoric acid or 10 N sodium hydroxide to a pH of 4.4 ± 0.1 before final dilution. |
| Standard Solution | 0.25 mg/mL of USP Clavulanate Lithium RS in water |
| System Suitability Solution | 0.5 mg/ml of Amoxicillin dissolved in Standard Solution |
| Sample Solution | 0.25 mg/mL of Clavulanate Potassium in water |

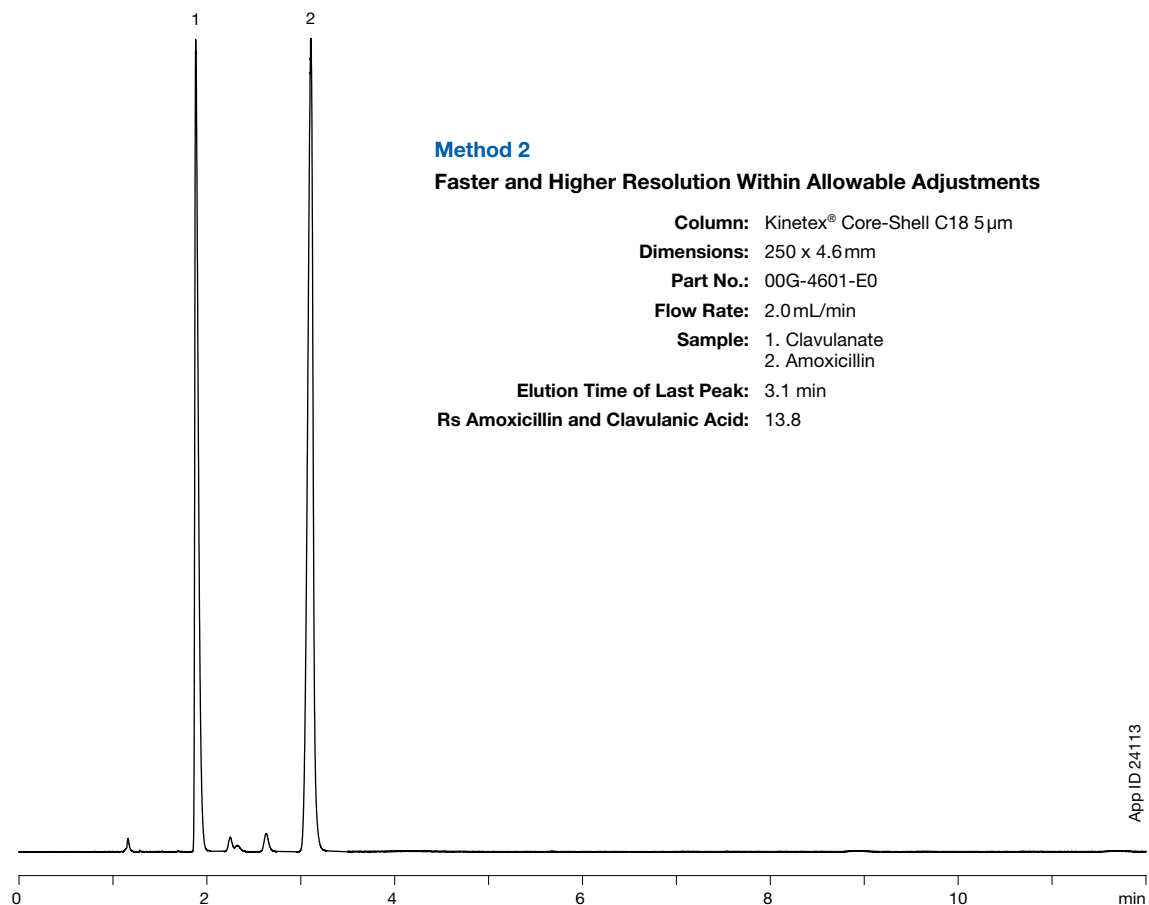
Column

| | |
|-------------------------|--|
| Size | 30 x 4.0 mm |
| Stationary Phase | 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 |
| Mobile Phase | Methanol and Solution A (1:19) |
| Flow Rate | 2.0 mL/min |
| Detection | Spectrophotometer @ 220 nm |
| Injection | 20 µL |

System Suitability

Minimum resolution of 3.5 between Amoxicillin and Clavulanic Acid





Adjustments for Meeting System Suitability

| Method Parameter | Allowed Adjustments (isocratic elution) | Method 1 | Method 2 |
|----------------------------------|---|---|----------------|
| Mobile Phase pH | ± 0.2 units | As specified | As specified |
| Concentration of Salts in Buffer | ± 10 % | As specified in Monograph Details Table | As specified |
| Composition of the Mobile Phase | ± 30 % Relative; cannot exceed ± 10 % Absolute change; cannot be reduced to zero | As specified in Monograph Details Table | As specified |
| Wavelength of Detector | No deviations permitted | 220 nm (as specified) | As specified |
| Injection Volume | Can be adjusted as much as needed; must be consistent with linearity, precision, and detection requirements | 20 µL (as specified) | As specified |
| Column Temperature | ± 10 °C | Ambient (as specified) | As specified |
| Stationary Phase | No change of the identity of the substituent permitted (e.g. no replacement of C18 by C8) | L1 (as specified) | As specified |
| Column Length | Column length (L) to particle size diameter (dp) ratio can be adjusted between -25 % and +50 %* | 250 mm (-17 %) | 250 mm (-17 %) |
| Column Internal Diameter | Can be adjusted so long as linear velocity is maintained | 4.6 mm (+15 %) | 4.6 mm (+15 %) |
| Particle Size | Column length (L) to particle size diameter (dp) ratio can be adjusted between -25 % and +50 %* | 5 µm (as specified) | As specified |
| Flow Rate | ± 50 % (at given ID) | 2.0 mL/min (as specified) | As specified |

*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 %

Kinetex® Ordering Information

| 5 µm Minibore Columns (mm) | | | | | SecurityGuard™ ULTRA Cartridges [‡] |
|----------------------------|-------------|-------------|-------------|-------------|--|
| Phases | 30 x 2.1 | 50 x 2.1 | 100 x 2.1 | 150 x 2.1 | 3/pk |
| C18 | 00A-4601-AN | 00B-4601-AN | 00D-4601-AN | 00F-4601-AN | AJO-8782 for 2.1 mm ID |

| 5 µm MidBore™ Columns (mm) | | | | SecurityGuard ULTRA Cartridges [‡] |
|----------------------------|-------------|-------------|-------------|---|
| Phases | 50 x 3.0 | 100 x 3.0 | 150 x 3.0 | 3/pk |
| C18 | 00B-4601-YO | 00D-4601-YO | 00F-4601-YO | AJO-8775 for 3.0 mm ID |

| 5 µm Analytical Columns (mm) | | | | | SecurityGuard ULTRA Cartridges [‡] |
|------------------------------|-------------|-------------|-------------|-------------|---|
| Phases | 50 x 4.6 | 100 x 4.6 | 150 x 4.6 | 250 x 4.6 | 3/pk |
| C18 | 00B-4601-E0 | 00D-4601-E0 | 00F-4601-E0 | 00G-4601-E0 | AJO-8768 for 4.6 mm ID |

| 5 µm Semi-Preparative Columns (mm) | | | SecurityGuard SemiPrep Cartridges ^{***} |
|------------------------------------|-------------|-------------|--|
| Phases | 150 x 10 | 250 x 10 | 3/pk |
| C18 | 00F-4601-N0 | 00G-4601-N0 | AJO-9278 for 9-16 mm ID |

[‡]SecurityGuard ULTRA Cartridges require holder, Part No.: AJO-9000

Luna® Ordering Information

| 5 µm Microbore and Minibore Columns (mm) | | | | | | | | SecurityGuard™ Cartridges (mm) |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|---|
| Phases | 50 x 1.0 | 150 x 1.0 | 250 x 1.0 | 30 x 2.0 | 50 x 2.0 | 150 x 2.0 | 250 x 2.0 | 4 x 2.0* |
| C18(2) | 00B-4252-A0 | 00F-4252-A0 | 00G-4252-A0 | 00A-4252-B0 | 00B-4252-B0 | 00F-4252-B0 | 00G-4252-B0 | /10pk AJO-4286 for ID: 2.0-3.0 mm |

| 5 µm MidBore and Analytical Columns (mm) | | | | | | | | SecurityGuard™ Cartridges (mm) | |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|---|---------------------------------|
| Phases | 30 x 3.0 | 50 x 3.0 | 150 x 3.0 | 250 x 3.0 | 30 x 4.6 | 50 x 4.6 | 75 x 4.6 | 4 x 2.0* | 4 x 3.0* |
| C18(2) | 00A-4252-Y0 | 00B-4252-Y0 | 00F-4252-Y0 | 00G-4252-Y0 | 00A-4252-E0 | 00B-4252-E0 | 00C-4252-E0 | /10pk AJO-4286 for ID: 2.0-3.0 mm | /10pk AJO-4287 3.2-8.0 mm |

| 5 µm Analytical and Semi-Prep Columns (mm) | | | | | SecurityGuard™ Cartridges (mm) | |
|--|-------------|-------------|-------------|-------------|---|-----------------------------|
| Phases | 100 x 4.6 | 150 x 4.6 | 250 x 4.6 | 250 x 10 | 4 x 3.0* | 10 x 10 [‡] |
| C18(2) | 00D-4252-E0 | 00F-4252-E0 | 00G-4252-E0 | 00G-4252-N0 | /10pk AJO-4287 for ID: 3.2-8.0 mm | /3pk AJO-7221 9-16 mm |

*SecurityGuard™ Analytical Cartridges require holder, Part No.: KJO-4282

[‡]SemiPrep SecurityGuard Cartridges require holder, Part No.: AJO-9281



If Phenomenex products in this technical note do not provide at least an equivalent separation as compared to a competing product of the same particle size, similar phase and dimensions, return the product with comparative data within 45 days for a FULL REFUND.



APPLICATION

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