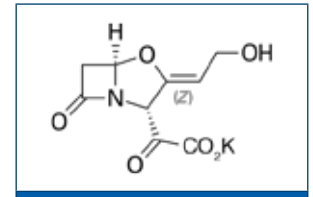


# APPLICATIONS

## Potassium Clavulanate and Related Substances

Ph. Eur. monograph 1140



Potassium Clavulanate

### Overview

The Ph. Eur. Monograph 1140 outlines the separation of Potassium Clavulanate from Amoxicillin. This method was studied and improvements were made to provide faster separations within allowable adjustments.

### Ph. Eur. Monograph 1140 Details

**Reference Solution (b)** Dissolve 10 mg of Lithium Clavulanate CRS\* and 10 mg of Amoxicillin Trihydrate CRS\* in mobile phase A and dilute to 100 mL with mobile phase A

### Column

**Size** 100 x 4.6 mm

**Stationary Phase** Octadecylsilyl silica gel for chromatography R (5 µm)

**Temperature** 40 °C

**Mobile Phase**  
A: 7.8 g/L solution of sodium hydrogen phosphate R adjusted to pH 4.0 with phosphoric acid R  
B: Mixture of equal volumes of methanol R and mobile phase A

**Gradient**

Time (min)	%B
0 – 4	0
4 – 15	0 → 50
15 – 18	50

**Flow Rate** 1.0 mL/min

**Detection** Spectrophotometer @ 230 nm

**Injection** 20 µL

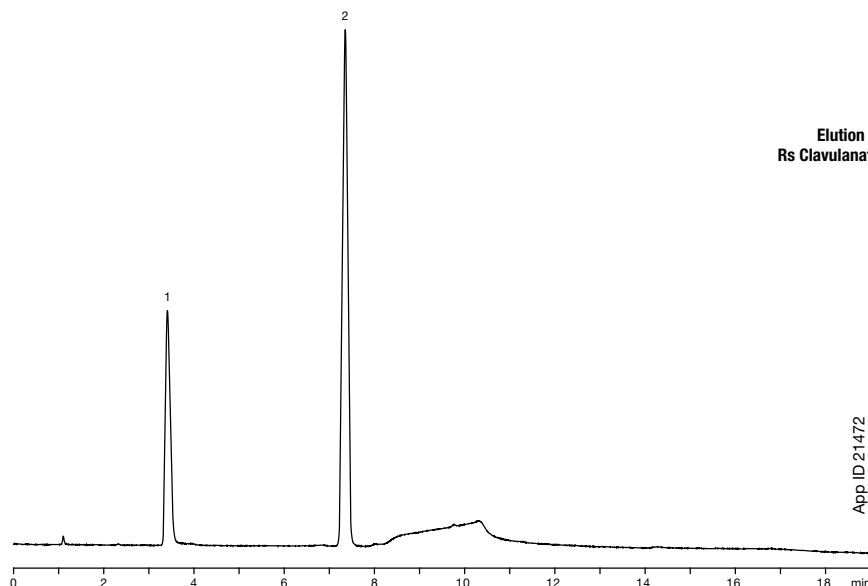
### System Suitability

**Reference Solution (b)** Minimum resolution of 13 between peaks due to Clavulanate (1st peak) and Amoxicillin (2nd peak)

\* Amoxicillin Trihydrate CRS (A0800000) and Lithium Clavulanate CRS (L0720000) were purchased from European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe; Postal address: 7 Allée Kastner CS 30026F - 67081 STRASBOURG (France).

### Method 1

Original Method as Described in the Monograph



**Column:** Gemini® NX-C18 5 µm Fully Porous

**Dimensions:** 100 x 4.6 mm

**Part No.:** 00D-4454-E0

**Flow Rate:** 1 mL/min

**Sample:** 1. Clavulanate

2. Amoxicillin

**Elution Time of Last Peak:** 7.3 min

**Rs Clavulanate and Amoxicillin:** 20.94

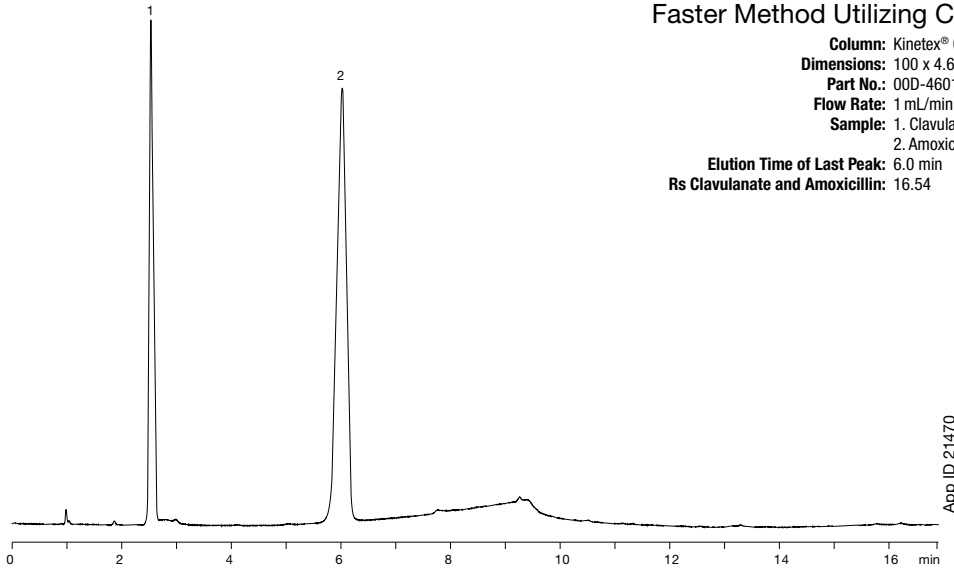
App ID 21472

## Method 2

### Faster Method Utilizing Core-Shell Technology

Column: Kinetex<sup>®</sup> Core-Shell C18 5  $\mu$ m  
 Dimensions: 100 x 4.6 mm  
 Part No.: 00D-4601-E0  
 Flow Rate: 1 mL/min  
 Sample: 1. Clavulanate  
 2. Amoxicillin

Elution Time of Last Peak: 6.0 min  
 Rs Clavulanate and Amoxicillin: 16.54



### Adjustments for Meeting System Suitability (European Pharmacopeia 9.0, Chapter 2.2.46. Chromatographic separation techniques)

Method Parameter	Allowed Adjustments (gradient elution)	Method 1	Method 2
Mobile Phase pH	No adjustment permitted	4 (as specified)	As specified
Concentration of Salts in Buffer	No adjustment permitted	As specified in Monograph 1140 Details Table	As specified
Composition of the Mobile Phase	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 in elution power than the prescribed composition	As specified in Monograph 1140 Details Table	As specified
Wavelength of Detector	No deviations permitted	230 nm (as specified)	As specified
Injection Volume	May be decreased, provided detection and repeatability of the peak(s) to be determined are satisfactory.	20 $\mu$ L (as specified)	As specified
Column Temperature	$\pm 5^\circ\text{C}$	40 $^\circ\text{C}$ (as specified)	As specified
Stationary Phase	No change of the identity of the substituent permitted (e.g. no replacement of C18 by C8)	Octadecylsilyl silica gel for chromatography (as specified)	As specified
Column Length	May be decreased, $\pm 70\%$	100 mm (as specified)	As specified
Column Internal Diameter	$\pm 25\%$	4.6 mm (as specified)	As specified
Particle Size	No adjustment permitted	5 $\mu$ m (as specified)	As specified
Flow Rate	Acceptable when changing the column dimensions	1 mL/min (as specified)	As specified

# APPLICATIONS

## Kinetex<sup>®</sup> Ordering Information

5 µm Minibore Columns (mm)					SecurityGuard <sup>™</sup> ULTRA Cartridges <sup>‡</sup>
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 <sup>™</sup> Columns (mm)				SecurityGuard <sup>™</sup> ULTRA Cartridges <sup>‡</sup>
Phases	50 x 3.0	100 x 3.0	150 x 3.0	3/pk
C18	00B-4601-YO	00D-4601-YO	00F-4601-WYO	AJO-8775 for 3.0 mm ID

5 µm Analytical Columns (mm)					SecurityGuard <sup>™</sup> ULTRA Cartridges <sup>‡</sup>
Phases	50 x 4.6	100 x 4.6	150 x 4.6	250 x 4.6	3/pk
C18	00B-4601-EO	00D-4601-EO	00F-4601-EO	00G-4601-EO	AJO-8768 for 4.6 mm ID

5 µm Semi-Preparative Columns (mm)			SecurityGuard <sup>™</sup> SemiPrep Cartridges <sup>***</sup>
Phases	150 x 10	250 x 10	3/pk
C18	00F-4601-NO	00G-4601-NO	AJO-9278 for 9-16 mm ID

<sup>‡</sup>SecurityGuard ULTRA Cartridges require holder, Part No.: AJO-9000

<sup>\*\*\*</sup>SemiPrep SecurityGuard Cartridges require holder, Part No.: AJO-9281

## Gemini<sup>®</sup> Ordering Information

5 µm Minibore and MidBore Columns (mm)								SecurityGuard <sup>™</sup> Cartridges (mm)	
Phases	30 x 2.0	50 x 2.0	150 x 2.0	250 x 2.0	50 x 3.0	100 x 3.0	150 x 3.0	250 x 3.0	4 x 2.0*
NX-C18	00A-4454-BO	00B-4454-BO	00F-4454-BO	—	00B-4454-YO	00D-4454-YO	00F-4454-YO	00G-4454-YO	AJO-8367 for ID: 2.0-3.0 mm

5 µm Analytical Columns (mm)						SecurityGuard <sup>™</sup> Cartridges (mm)
Phases	30 x 4.6	50 x 4.6	100 x 4.6	150 x 4.6	250 x 4.6	4 x 3.0*
NX-C18	—	00B-4454-EO	00D-4454-EO	00F-4454-EO	00G-4454-EO	AJO-8368 for ID: 3.2-8.0 mm

5 µm Semi-Prep Columns (mm)			SecurityGuard <sup>™</sup> Cartridges (mm)
Phases	150 x 10	250 x 10	10 x 10 <sup>‡</sup>
NX-C18	00F-4454-NO	00G-4454-NO	AJO-8369 for ID: 9-16 mm

\*SecurityGuard<sup>™</sup> Analytical Cartridges require holder, Part No.: KJO-4282

<sup>‡</sup>SemiPrep SecurityGuard<sup>™</sup> Cartridges require holder, Part No.: AJO-9281



# APPLICATIONS

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