

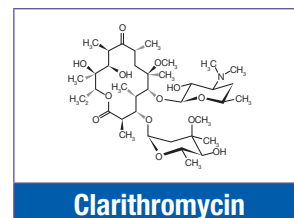
APPLICATION

Clarithromycin and Related Substances

Ph. Eur. monograph 1651

Overview

The Ph. Eur. Monograph 1651 outlines the separation of Clarithromycin from impurities. This method was studied and improvements were made to provide faster separations within allowable adjustments.



Ph. Eur. Monograph 1651 Details

Reference Solution (d) Dissolve 15 mg of Clarithromycin for peak identification CRS* in 5 mL of acetonitrile and dilute to 10 mL with water

Column

Size	100 x 4.6 mm	
Stationary Phase	Octadecylsilyl silica gel for chromatography R (3.5 μm)	
Temperature	40 °C	
Mobile Phase	A: 4.76 g/L solution of potassium dihydrogen phosphate adjusted to pH 4.4 with dilute phosphoric acid B: Acetonitrile	
Gradient	Time (min)	%B
	0 – 32 min	25 → 60
	32– 34 min	60
Flow Rate	1.1 mL/min	
Detection	Spectrophotometer @ 205 nm	
Injection	10 μL	

Relative Retention with Reference to Clarithromycin (about 11 min)**

Impurity A	about 0.42
Impurity J	about 0.63
Impurity L	about 0.74
Impurity B	about 0.79
Impurity M	about 0.81
Impurity C	about 0.89
Impurity D	about 0.96
Impurity N	about 1.15
Impurity E	about 1.27
Impurity F	about 1.33
Impurity P	about 1.35
Impurity O	about 1.41
Impurity K	about 1.59
Impurity G	about 1.59
Impurity H	about 1.82

System Suitability

Peak-to-Valley Ratio Minimum 3.0, where H_p = height above the baseline of the peak due to Impurity D and H_v = height above the baseline of the lowest point of the curve separating this peak from the peak due to Clarithromycin in the chromatogram obtained with reference solution D

* Ph. Eur. Standard Clarithromycin for peak identification CRS Y0000321 was purchased from European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe; Postal address: 7 Allée Kastner CS 30026F - 67081 STRASBOURG (France).

** Retention times, relative retentions, and retardation factors are provided for information only and are not mandatory, no deviation allowance is defined.



Achieve improved sensitivity and resolution
using Kinetex Core-Shell Columns

Method 1

Original Method as Described in the Monograph

Column: Kinetex[®] Core-Shell XB-C18 3.5 μ m

Dimensions: 100 x 4.6 mm

Part No.: 00D-4744-E0

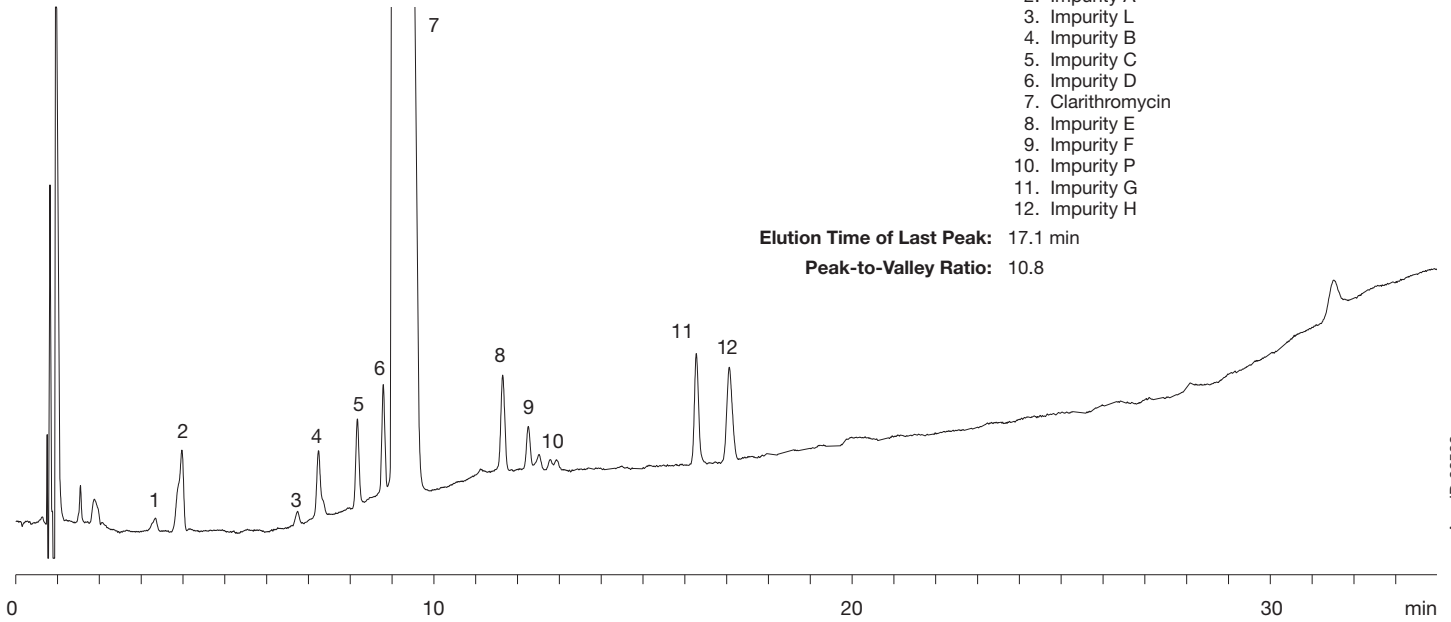
Flow Rate: 1.1 mL/min

Sample:

1. Impurity I
2. Impurity A
3. Impurity L
4. Impurity B
5. Impurity C
6. Impurity D
7. Clarithromycin
8. Impurity E
9. Impurity F
10. Impurity P
11. Impurity G
12. Impurity H

Elution Time of Last Peak: 17.1 min

Peak-to-Valley Ratio: 10.8



App ID 23503

Adjustments for Meeting System Suitability

(European Pharmacopeia 9.0, Chapter 2.2.46. Chromatographic separation techniques)

Method Parameter	Allowed Adjustments (isocratic elution)	Method 1
Mobile Phase pH	± 0.2 units	As specified
Concentration of Salts in Buffer	± 10 %	As specified in Monograph 1651 Details Table
Composition of the Mobile Phase	± 30 % of the minor solvent component relative or 2 % absolute, whichever is the larger. No other component is altered by more than 10 % absolute.	As specified in Monograph 1651 Details Table
Wavelength of Detector	No deviations permitted	205 nm (as specified)
Injection Volume	May be decreased, provided detection and repeatability of the peak(s) to be determined are satisfactory.	1 µL (as specified)
Column Temperature	± 10 °C	40 °C (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)
Column Length	± 70 %	100 mm (as specified)
Column Internal Diameter	± 25 %	4.6 mm (as specified)
Particle Size	-50 %	3.5 µm (as specified)
Flow Rate	± 50 %	1.1 mL/min (as specified)

Kinetex® Ordering Information

3.5 µm Analytical Columns (mm)		SecurityGuard ULTRA Cartridges [†]	
Phases	100 x 4.6	150 x 4.6	3/pk
XB-C18	00D-4744-E0	00F-4744-E0	AJ0-8768
			for 4.6 mm ID



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APPLICATION

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