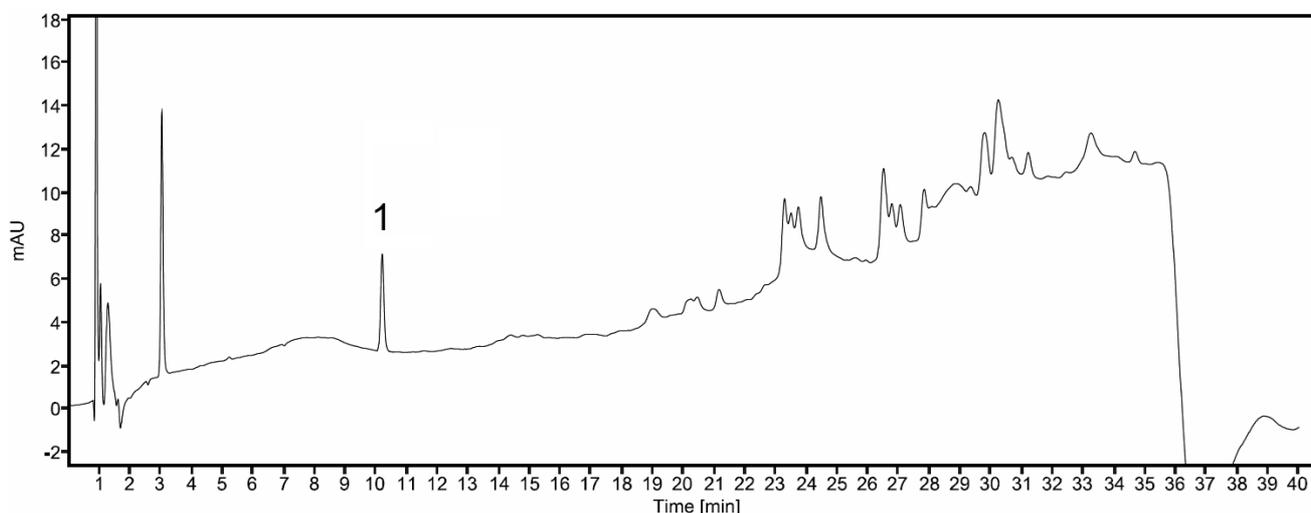




## Clarithromycin Infusion – BP 2025

These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for solution (3) from the Related Substances test for Clarithromycin Infusion as published in BP 2025.

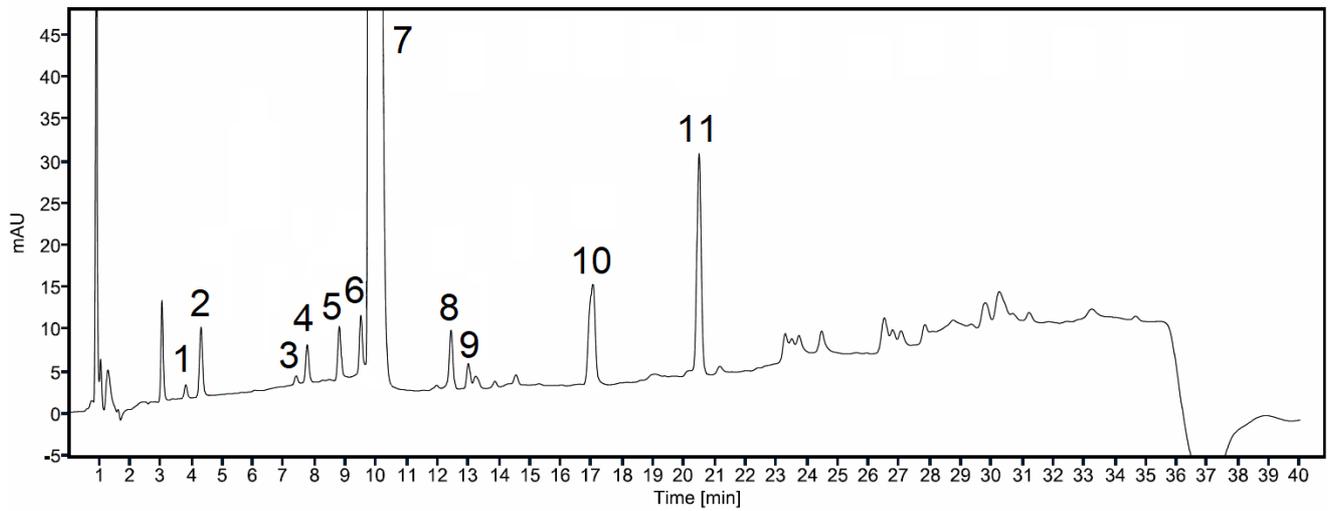


Peak ID: 1: Clarithromycin.

<b>Column</b>	Waters XTerra C18 (100 mm x 4.6 mm, 3.5 µm)
<b>Method Ref.</b>	Related Substances for the Clarithromycin Infusion monograph from BP 2025
<b>Mobile Phase A</b>	A 0.476% w/v solution of potassium dihydrogen orthophosphate, adjusted to pH 4.4 with 2M orthophosphoric acid
<b>Mobile Phase B</b>	Acetonitrile
<b>Diluent (Solution A)</b>	Acetonitrile: Water (1:1, v/v)
<b>Flow rate</b>	Refer to gradient table below
<b>Auto-Sampler Temp</b>	8°C
<b>Column Temp</b>	40°C

<b>Injection Volume</b>	10 $\mu$ L			
<b>Detection</b>	205 nm			
<b>Gradient</b>				
<b>Time (minutes)</b>	<b>Mobile phase A (% v/v)</b>	<b>Mobile phase B (% v/v)</b>	<b>Flow rate (mL/min)</b>	<b>Comment</b>
0 – 32	75 $\rightarrow$ 40	25 $\rightarrow$ 60	1.1	linear gradient
32 – 34	40	60	1.1	isocratic
34 – 35	40 $\rightarrow$ 75	60 $\rightarrow$ 25	1.1	linear gradient
35 – 40	75	25	1.1	re-equilibration

Typical chromatogram for solution (4) from the Related Substances test for Clarithromycin Infusion as published in BP 2025.

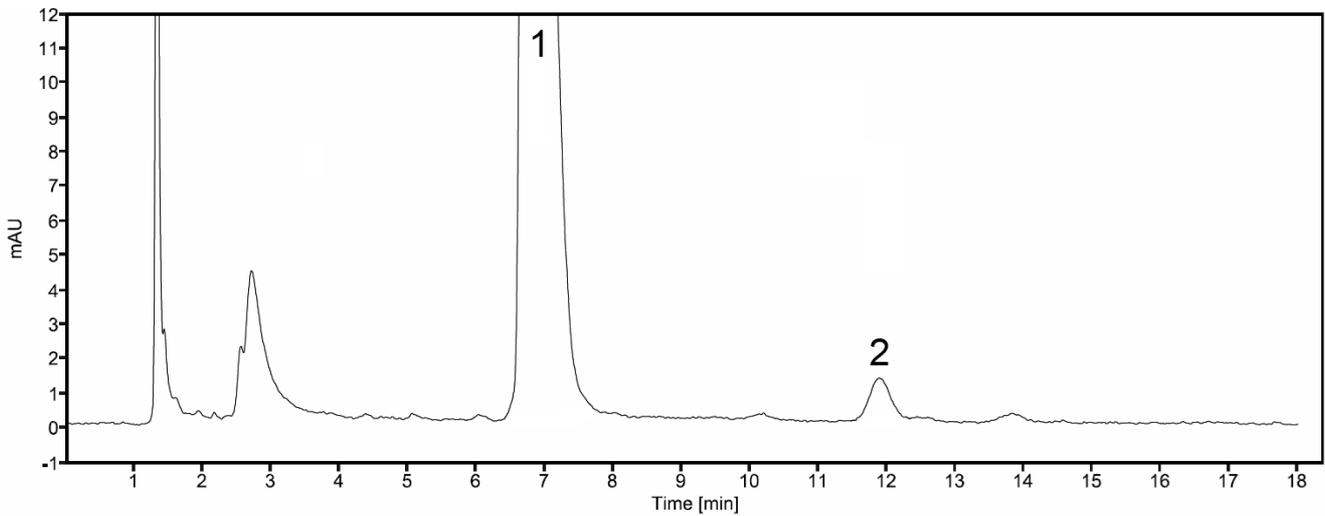


Peak ID: 1: Impurity I. 2: Impurity A. 3: Impurity L. 4: Impurity B. 5: Impurity C. 6: Impurity D. 7: Clarithromycin. 8: Impurity E. 9: Impurity F. 10: Impurity G. 11: Impurity H.

<b>Column</b>	Waters XTerra C18 (100 mm x 4.6 mm, 3.5 µm)			
<b>Method Ref.</b>	Related Substances for the Clarithromycin Infusion monograph from BP 2025			
<b>Mobile Phase A</b>	A 0.476% w/v solution of potassium dihydrogen orthophosphate, adjusted to pH 4.4 with 2M orthophosphoric acid			
<b>Mobile Phase B</b>	Acetonitrile			
<b>Diluent (Solution A)</b>	Acetonitrile: Water (1:1, v/v)			
<b>Flow rate</b>	Refer to gradient table below			
<b>Column Temp</b>	40°C			
<b>Injection Volume</b>	10 µL			
<b>Detection</b>	205 nm			
<b>Gradient</b>				
<b>Time (minutes)</b>	<b>Mobile phase A (% v/v)</b>	<b>Mobile phase B (% v/v)</b>	<b>Flow rate (mL/min)</b>	<b>Comment</b>
0 – 32	75 → 40	25 → 60	1.1	linear gradient
32 – 34	40	60	1.1	isocratic

34 – 35	40 → 75	60 → 25	1.1	linear gradient
35 – 40	75	25	1.1	re-equilibration

Typical chromatogram for solution (3) from the Assay test for Clarithromycin Infusion as published in BP 2025.



Peak ID: 1: Clarithromycin. 2: Impurity E.

<b>Column</b>	Agilent Zorbax Eclipse XDB (150 mm x 4.6 mm, 5 µm)
<b>Method Ref.</b>	Assay for the Clarithromycin Infusion monograph from BP 2025
<b>Mobile Phase</b>	35 volumes of 0.067M potassium dihydrogen orthophosphate and 65 volumes of methanol adjusted to pH 4.0 with orthophosphoric acid
<b>Diluent</b>	Mobile phase
<b>Flow rate</b>	1.5 mL/min
<b>Column Temp</b>	50°C
<b>Injection Volume</b>	25 µL
<b>Detection</b>	210 nm