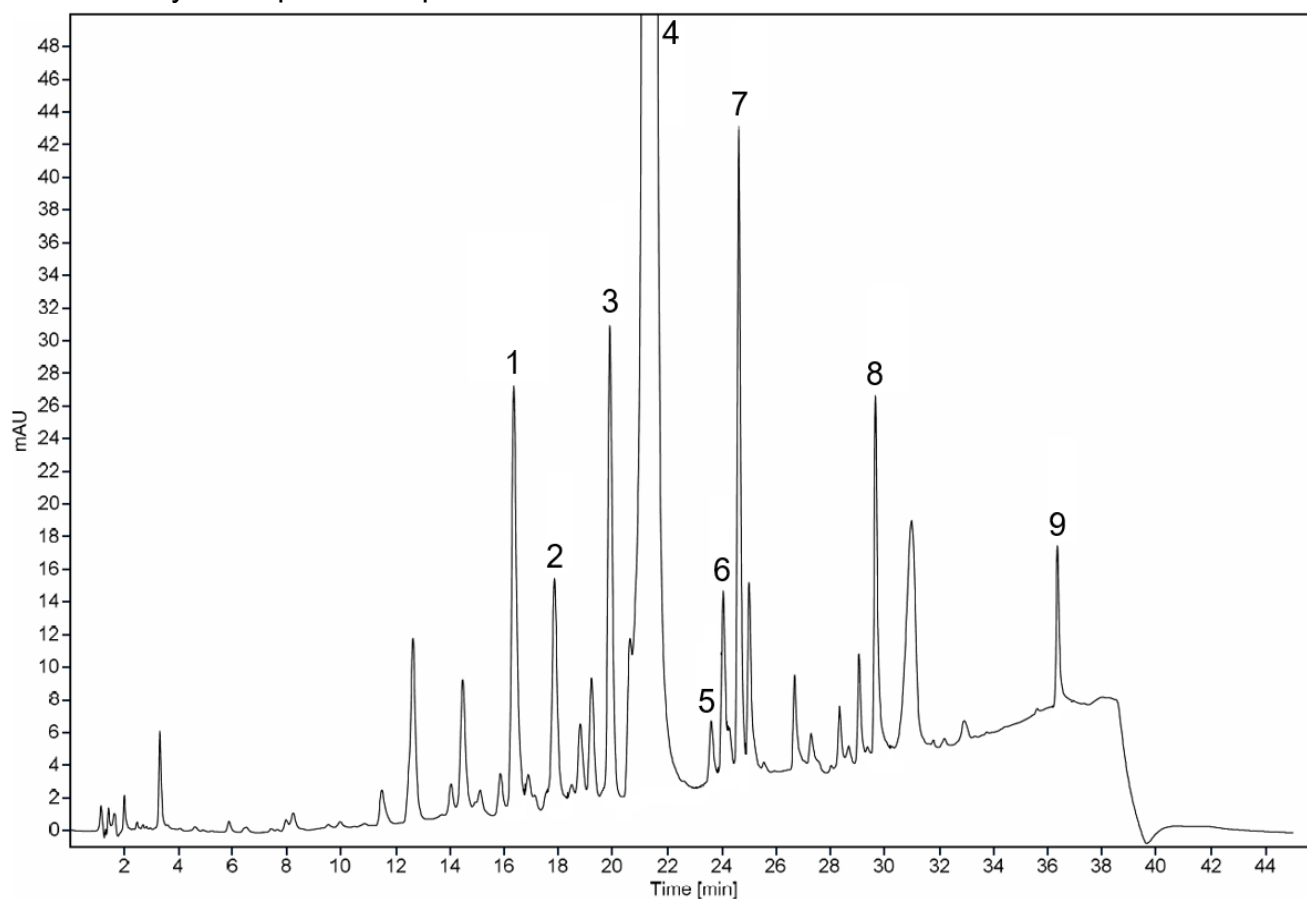




Vancomycin Capsules – BP 2023

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 (2) from the Related Substances and Vancomycin B test for Vancomycin Capsules as published in BP 2023.

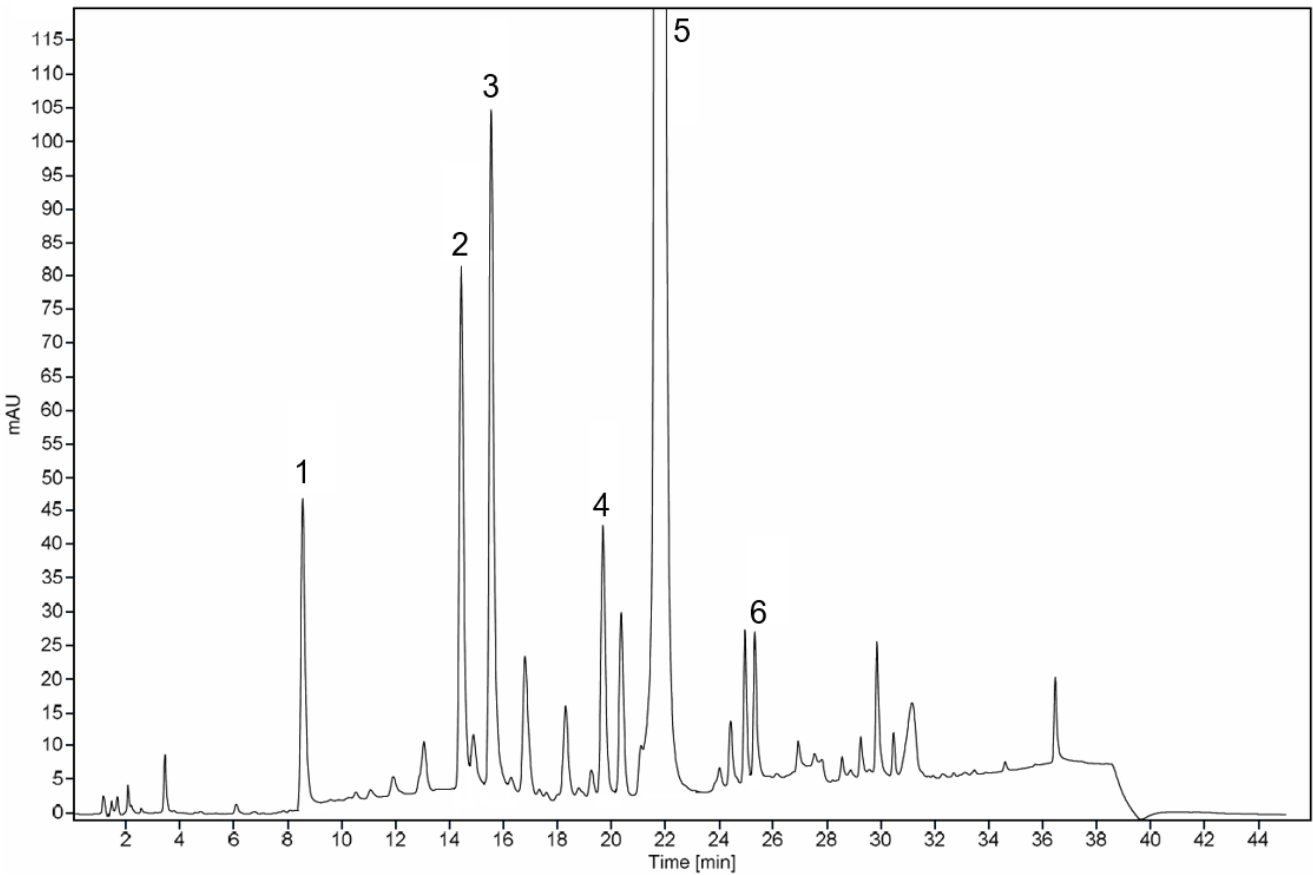


Peak ID: 1: Impurity A; 2: Impurity F; 3: Impurity H; 4: Vancomycin; 5: Impurity M;
6: Impurity I; 7: Impurity J; 8: Impurity K; 9: Impurity C.

Column	Waters Acquity CSH C18 (150 mm x 2.1 mm, 1.7 µm)
Method Ref.	Related substances and Vancomycin B for the Vancomycin Capsules monograph from BP 2023

Solution A	0.7% w/v solution of tris(hydroxymethyl)aminomethane adjusted to pH 8.1 with a 20% v/v solution of glacial acetic acid.		
Mobile Phase A	Acetonitrile: methanol: solution A (3:4:93, v/v/v)		
Mobile Phase B	Acetonitrile: methanol: solution A (10:40:50, v/v/v)		
Diluent (Solution B)	Water		
Flow rate	0.3 mL/min		
Column Temp	40°C		
Injection Volume	2 µL		
Detection	280 nm		
Gradient			
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0 – 7	88	12	isocratic
7 – 21	88 → 75	12 → 25	linear gradient
21 – 35	75 → 25	25 → 75	linear gradient
35 – 37	25	75	isocratic
37 – 38	25 → 88	75 → 12	linear gradient
38 – 45	88	12	re-equilibration

Typical chromatogram for solution (3) from the Related Substances and Vancomycin B test for Vancomycin Capsules as published in BP 2023.

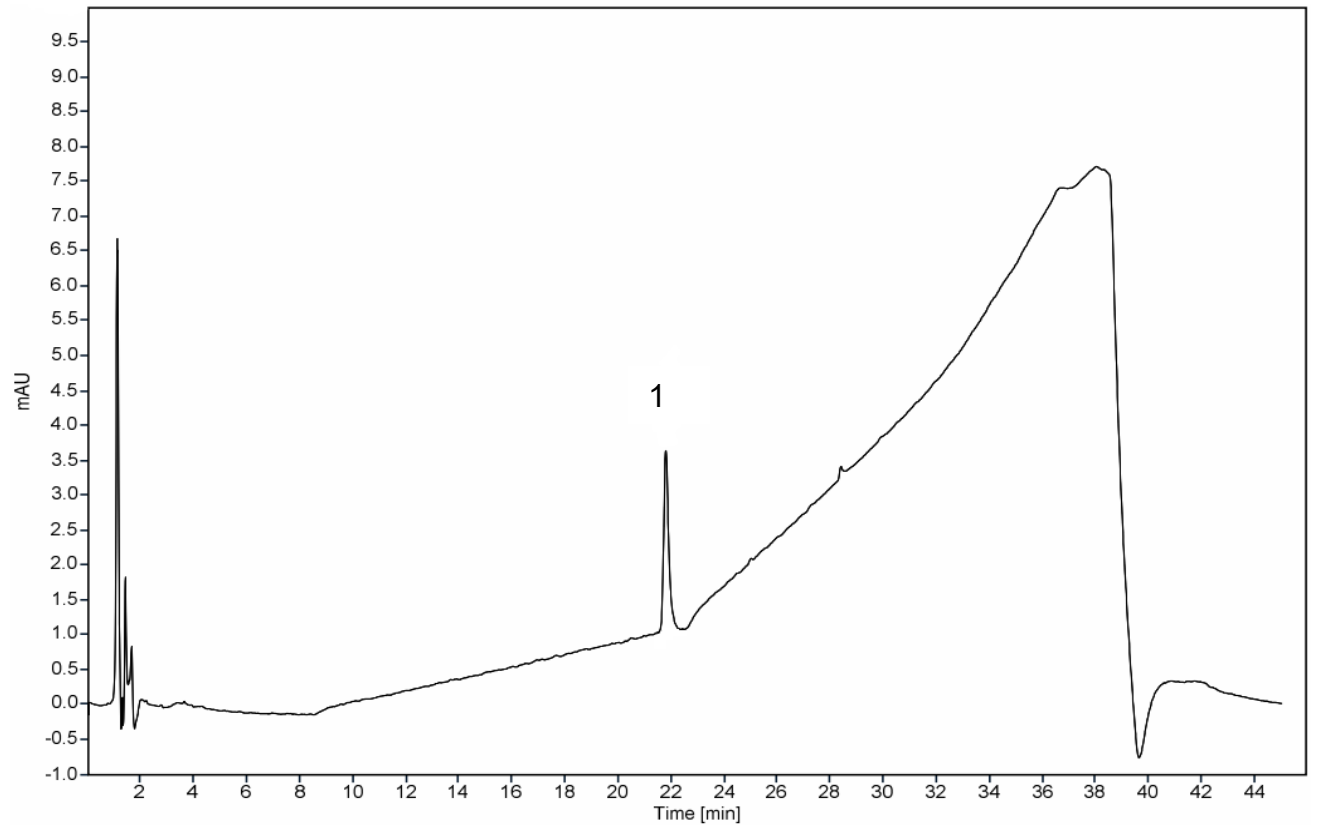


Peak ID: 1: Impurity E; 2: Impurity L; 3: Impurity B; 4: Impurity G; 5: Vancomycin; 6: Impurity D.

Column	Waters Acquity CSH C18 (150 mm x 2.1 mm, 1.7 µm)
Method Ref.	Related substances and Vancomycin B for the Vancomycin Capsules monograph from BP 2023
Solution A	0.7% w/v solution of tris(hydroxymethyl)aminomethane adjusted to pH 8.1 with a 20% v/v solution of glacial acetic acid.
Mobile Phase A	Acetonitrile: methanol: solution A (3:4:93, v/v/v)
Mobile Phase B	Acetonitrile: methanol: solution A (10:40:50, v/v/v)
Diluent (Solution B)	Water
Flow rate	0.3 mL/min
Column Temp	40°C
Injection Volume	2 µL

Detection	280 nm		
Gradient			
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0 – 7	88	12	isocratic
7 – 21	88 → 75	12 → 25	linear gradient
21 – 35	75 → 25	25 → 75	linear gradient
35 – 37	25	75	isocratic
37 – 38	25 → 88	75 → 12	linear gradient
38 – 45	88	12	re-equilibration

Typical chromatogram for solution (4) from the Related Substances and Vancomycin B test for Vancomycin Capsules as published in BP 2023.



Peak ID: 1: Vancomycin

Column	Waters Acquity CSH C18 (150 mm x 2.1 mm, 1.7 µm)
Method Ref.	Related substances and Vancomycin B for the Vancomycin Capsules monograph from BP 2023
Solution A	0.7% w/v solution of tris(hydroxymethyl)aminomethane adjusted to pH 8.1 with a 20% v/v solution of glacial acetic acid.
Mobile Phase A	Acetonitrile: methanol: solution A (3:4:93, v/v/v)
Mobile Phase B	Acetonitrile: methanol: solution A (10:40:50, v/v/v)
Diluent (Solution B)	Water
Flow rate	0.3 mL/min
Column Temp	40°C
Injection Volume	2 µL
Detection	280 nm

Gradient			
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0 – 7	88	12	isocratic
7 – 21	88 → 75	12 → 25	linear gradient
21 – 35	75 → 25	25 → 75	linear gradient
35 – 37	25	75	isocratic
37 – 38	25 → 88	75 → 12	linear gradient
38 – 45	88	12	re-equilibration