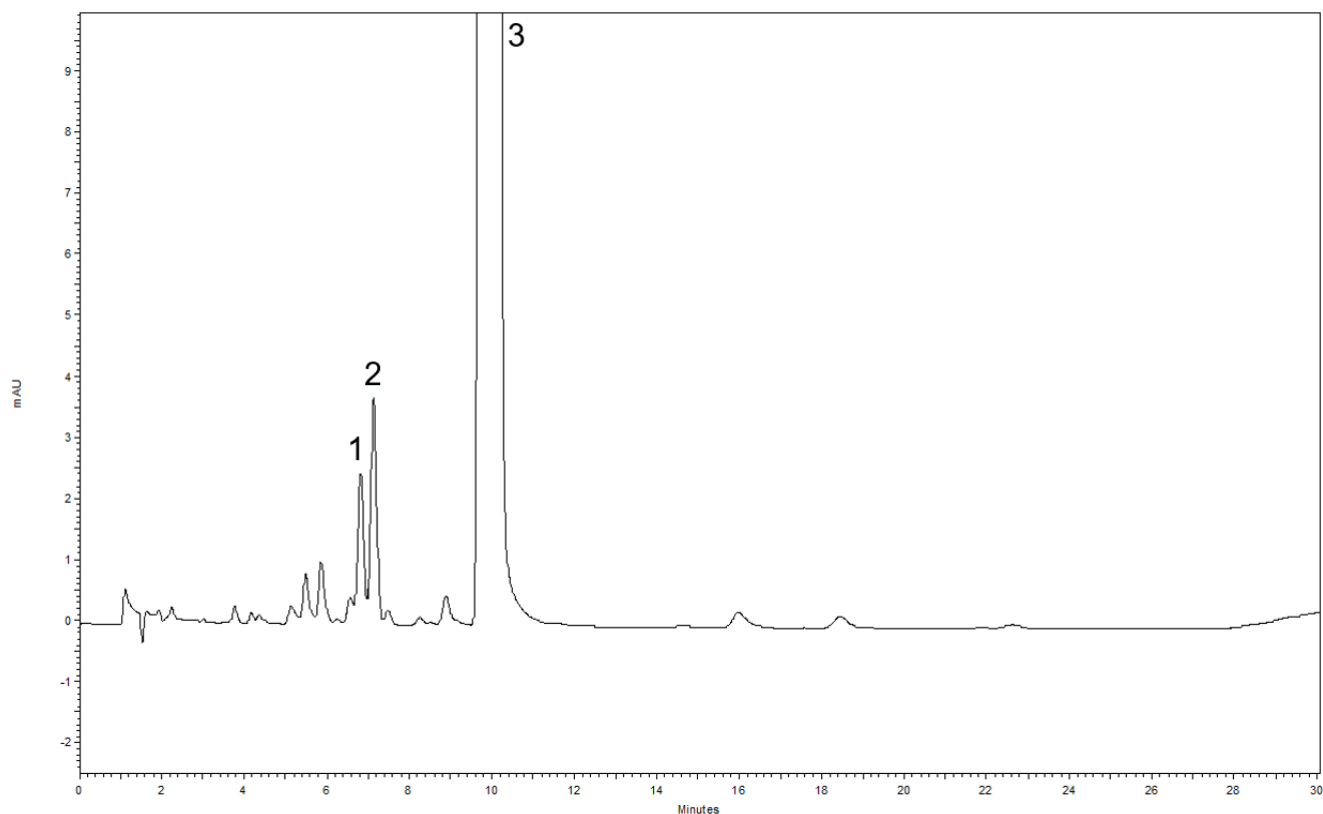




Eplerenone Tablets – BP 2024

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 and Assay tests for Eplerenone Tablets as published in BP 2024.

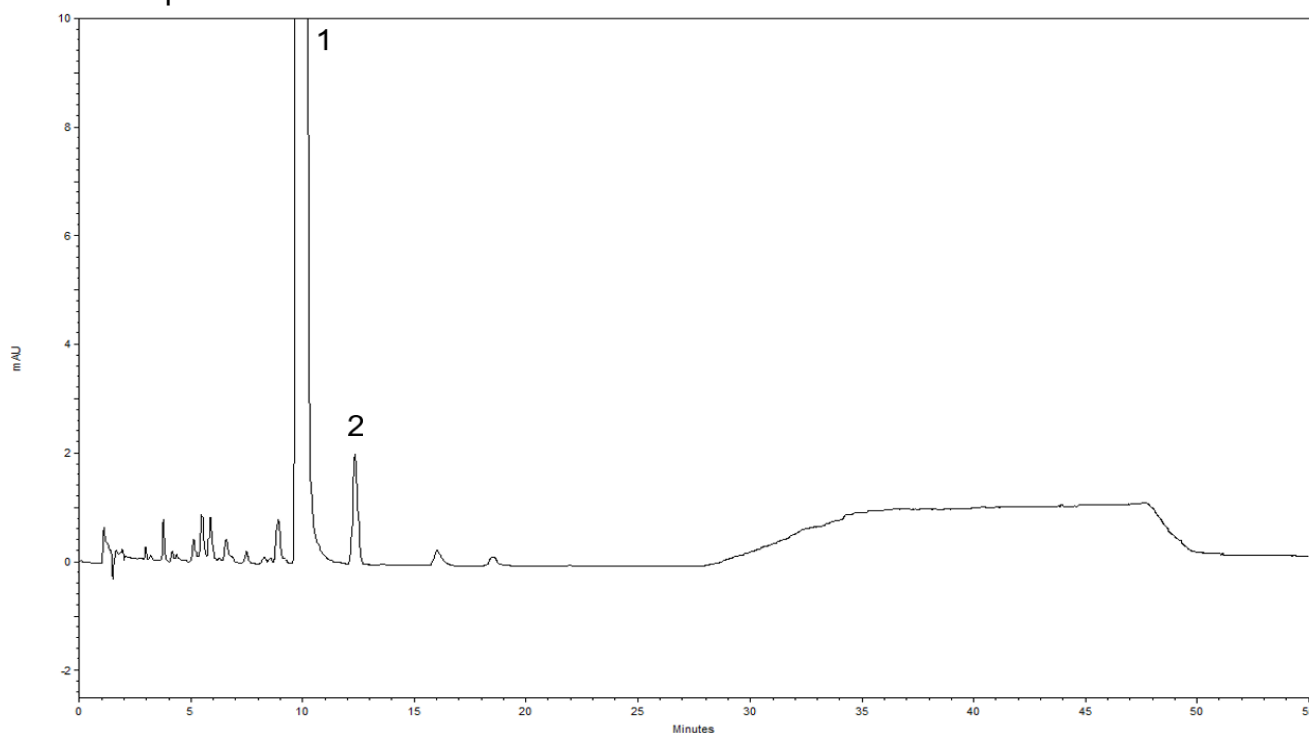


Peak ID: 1: Impurity D. 2: Impurity A. 3: Eplerenone.

Column	Inertsil ODS-3 (150 mm x 4.6 mm, 3 µm)
Method Ref.	Related Substances and Assay for the Eplerenone Tablets monograph from BP 2024
Mobile Phase A	0.1% v/v orthophosphoric acid
Mobile Phase B	Orthophosphoric acid: acetonitrile: methanol (0.1:40:60, v/v/v)

Diluent (Solution B)	Acetonitrile: methanol: water (25:25:50, v/v/v)		
Flow rate	1.0 mL/min		
Column Temp	30°C		
Injection Volume	20 µL		
Detection	240 nm		
Gradient			
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0 – 25	54	46	isocratic
25 – 32	54 → 40	46 → 60	linear gradient
32 – 45	40	60	isocratic
45 – 46	40 → 54	60 → 46	linear gradient
46 - 55	54	46	re-equilibration

Typical chromatogram for solution (4) from the Related Substances test for Eplerenone Tablets as published in BP 2024.



Peak ID: 1: Eplerenone. 2: Impurity B.

Column	Inertsil ODS-3 (150 mm x 4.6 mm, 3 μm)		
Method Ref.	Related Substances and Assay for the Eplerenone Tablets monograph from BP 2024		
Mobile Phase A	0.1% v/v orthophosphoric acid		
Mobile Phase B	Orthophosphoric acid: acetonitrile: methanol (0.1:40:60, v/v/v)		
Diluent (Solution B)	Acetonitrile: methanol: water (25:25:50, v/v/v)		
Flow rate	1.0 mL/min		
Column Temp	30°C		
Injection Volume	20 μL		
Detection	240 nm		
Gradient			
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0 – 25	54	46	isocratic
25 – 32	54 → 40	46 → 60	linear gradient
32 – 45	40	60	isocratic
45 – 46	40 → 54	60 → 46	linear gradient
46 - 55	54	46	re-equilibration