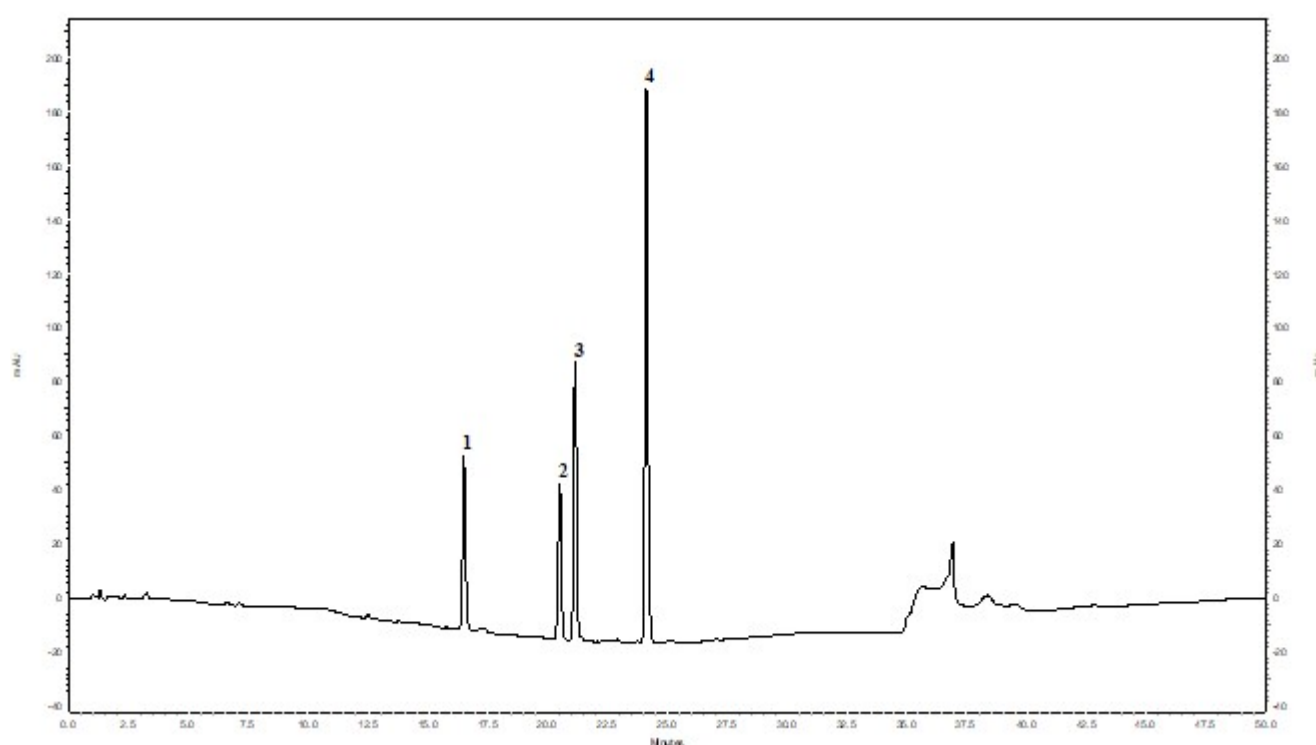


Sodium Fusidate Tablets – BP 2021

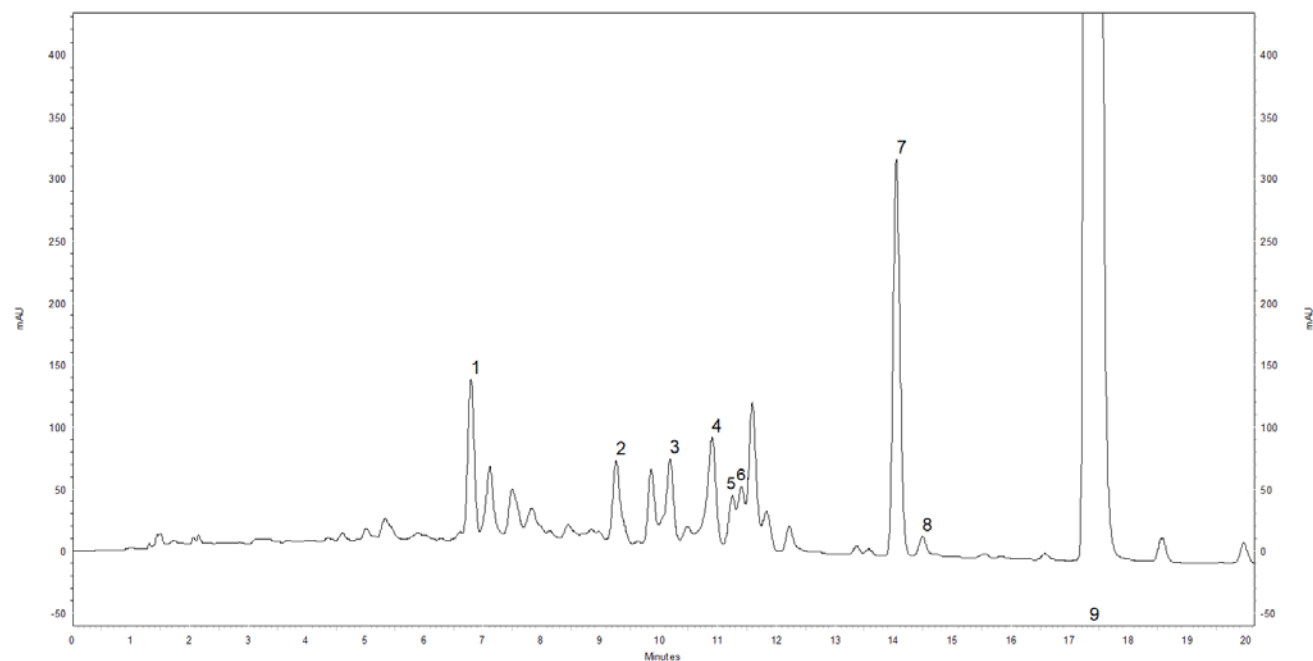
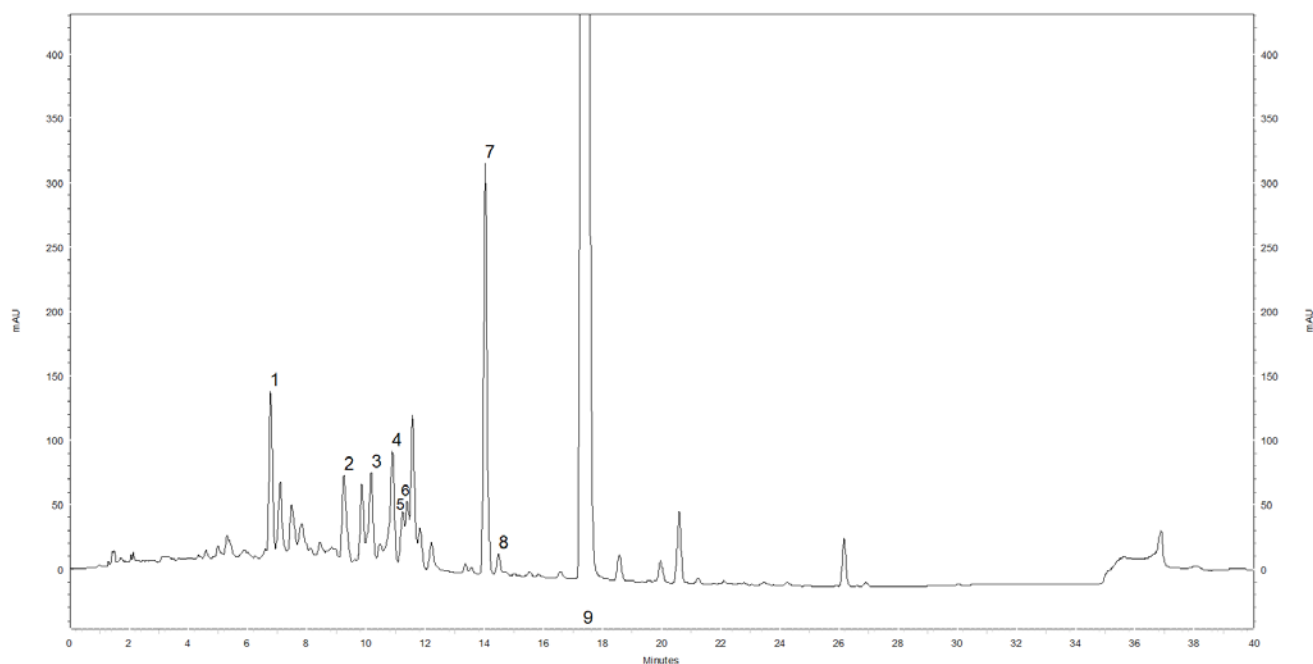
These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for solution (3) in the Related Substances test for Sodium Fusidate Tablets as published in BP 2021.



Peak ID: 1: Impurity I; 2: Impurity K; 3: Impurity L; 4: Impurity M

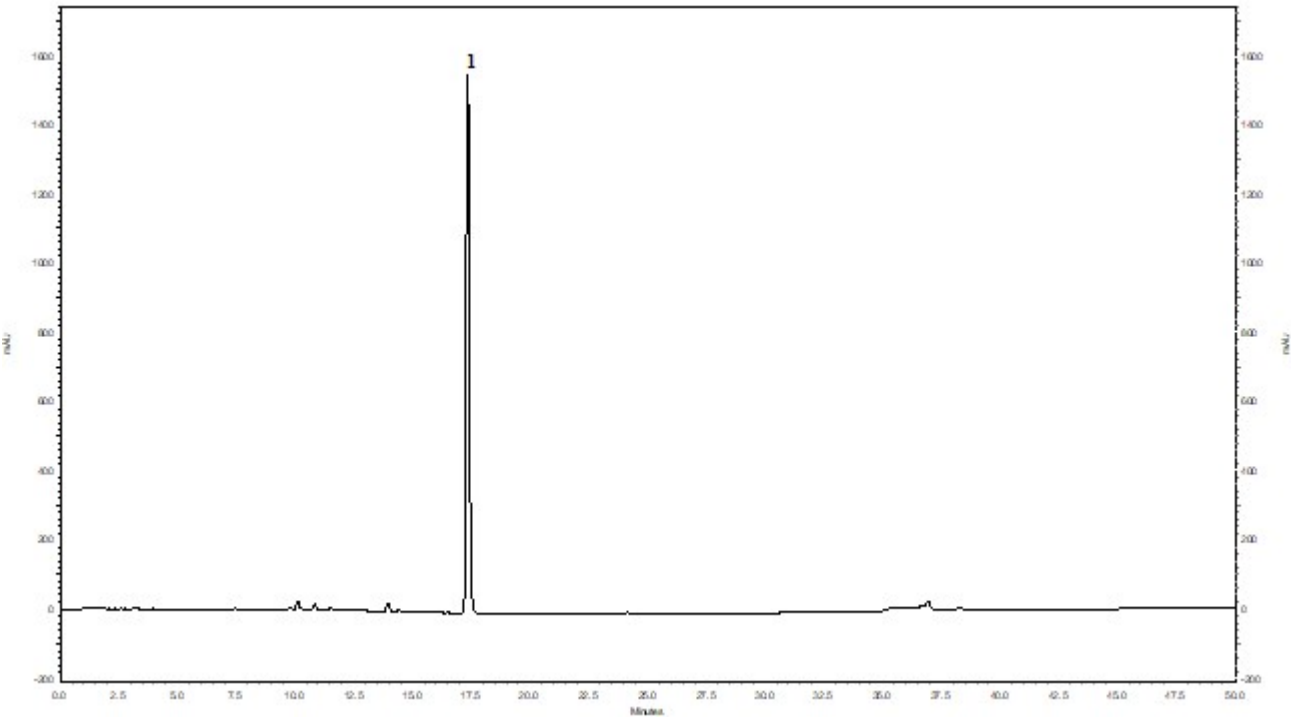
Typical chromatogram for solution (4) in the Related Substances test for Sodium Fusidate Tablets as published in BP 2021.



Peak ID: 1: Impurity A; 2: Impurity B; 3: Impurity C; 4: Impurity D; 5: Impurity N; 6: Impurity F;
7: Impurity G; 8: Impurity H and 9: Fusidic acid

Column	Waters, Symmetry C18 (150 mm x 4.6 mm, 3.5 µm)		
Method Ref.	Related Substances for the Sodium Fusidate Tablets monograph from BP 2021		
Mobile Phase A	Methanol: 5 g/L solution of orthophosphoric acid: acetonitrile (20: 40: 40, v/v/v)		
Mobile Phase B	5 g/L solution of orthophosphoric acid: methanol: acetonitrile (10: 20: 70, v/v/v)		
Gradient	Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
	0 - 3	100	0
	3 - 28	100 - 0	0 - 100
	28 - 33	0	100
	33 - 34	0 - 100	100 - 0
	34 - 40	100	0
Diluent	Methanol: 5 g/L solution of orthophosphoric acid: acetonitrile (10: 40: 50, v/v/v)		
Flow rate	1.0 mL/min		
Column Temp	30 °C		
Injection Volume	20 µL		
Detection	235 nm		

Typical chromatogram for solution (2) in the Assay test for Sodium Fusidate Tablets as published in BP 2021.



Peak ID: 1: Fusidic acid

Column	Waters, Symmetry C18 (150 mm x 4.6 mm, 3.5 µm)		
Method Ref.	Assay for the Sodium Fusidate Tablets monograph from BP 2021		
Mobile Phase A	Methanol: 5 g/L solution of orthophosphoric acid: acetonitrile (20: 40: 40, v/v/v)		
Mobile Phase B	5 g/L solution of orthophosphoric acid: methanol: acetonitrile (10: 20: 70, v/v/v)		
Gradient	Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
	0 - 3	100	0
	3 - 28	100 - 0	0 - 100
	28 - 33	0	100
	33 - 34	0 - 100	100 - 0
	34 - 40	100	0
Diluent	Methanol: 5 g/L solution of orthophosphoric acid: acetonitrile (10: 40: 50, v/v/v)		
Flow rate	1.0 mL/min		
Column Temp	30 °C		
Injection Volume	20 µL		
Detection	235 nm		