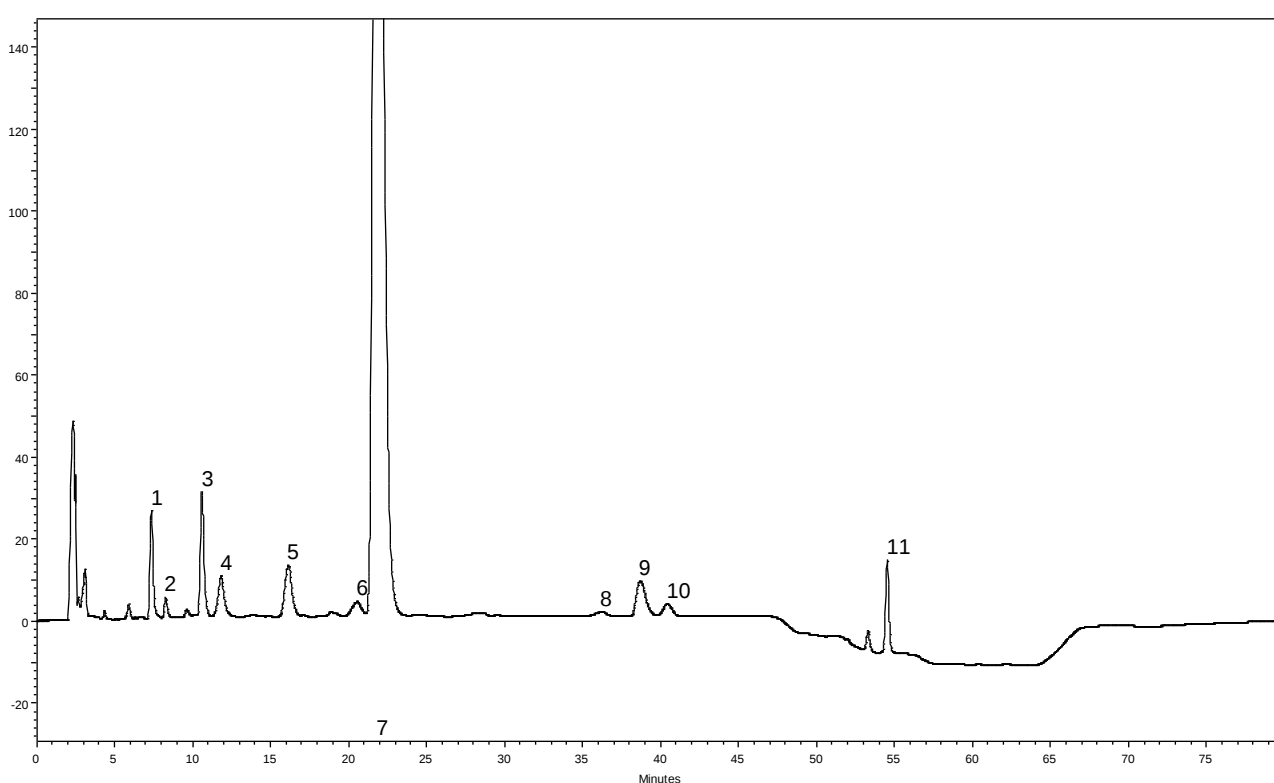




Erythromycin Gastro-resistant Capsules – BP 2021

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.

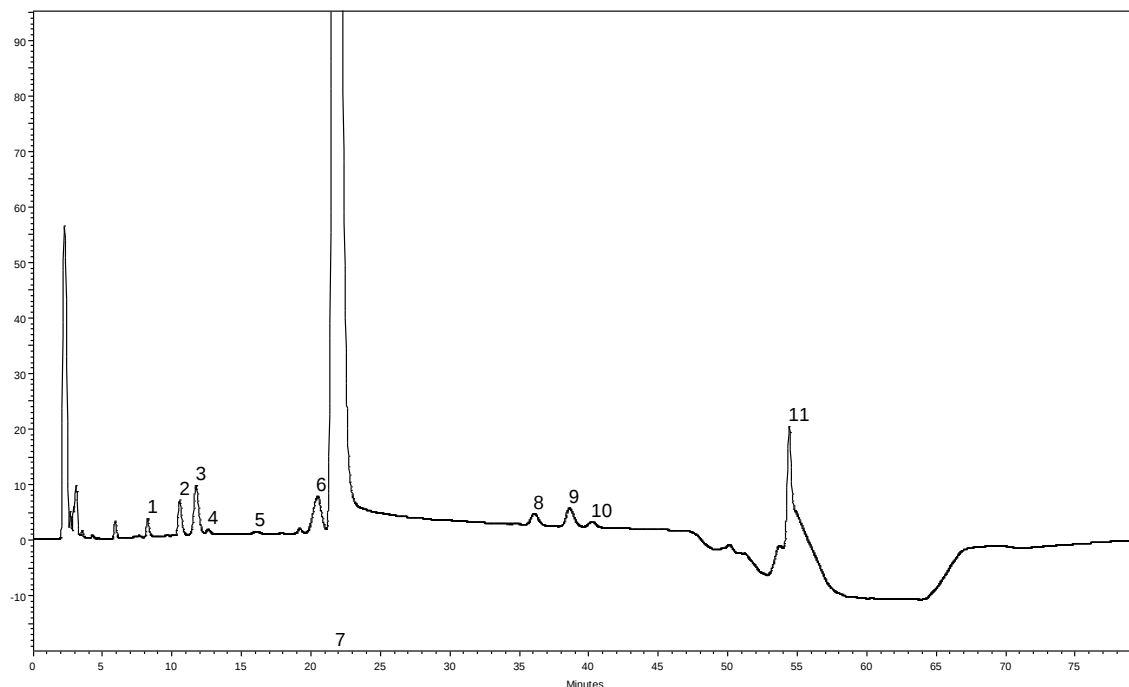
Typical chromatogram for solution (3) in the Related Substances test for Erythromycin Gastro-resistant Capsules as published in BP 2021.



Peak ID: 1: Impurity H; 2: Impurity A; 3: Impurity B; 4: Erythromycin C; 5: Impurity L; 6: Impurity C; 7: Erythromycin A; 8: Impurity D; 9: Erythromycin B; 10: Impurity F; 11: Impurity E

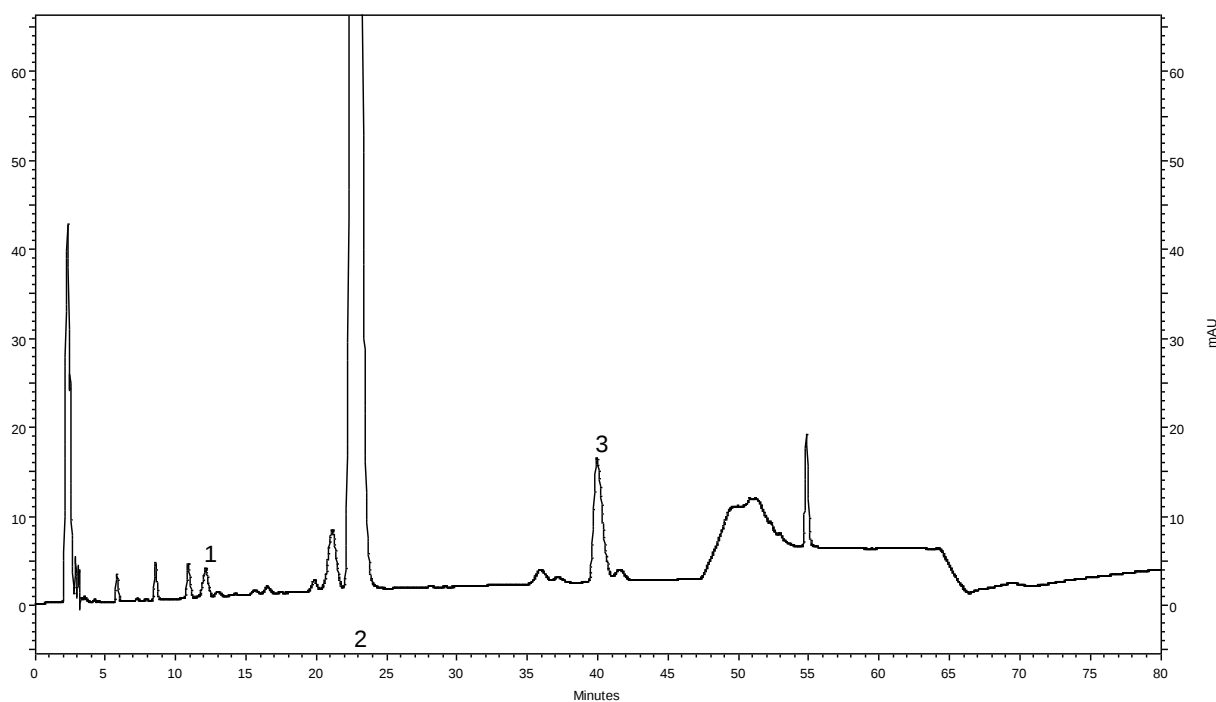


Typical chromatogram for solution (4) in the Related Substances test for Erythromycin Gastro-resistant Capsules as published in BP 2021.



Peak ID: 1: Impurity A; 2: Impurity B; 3: Erythromycin C; 4: Impurity M; 5: Impurity L; 6: Impurity C; 7: Erythromycin A; 8: Impurity D; 9: Erythromycin B; 10: Impurity F; 11: Impurity E

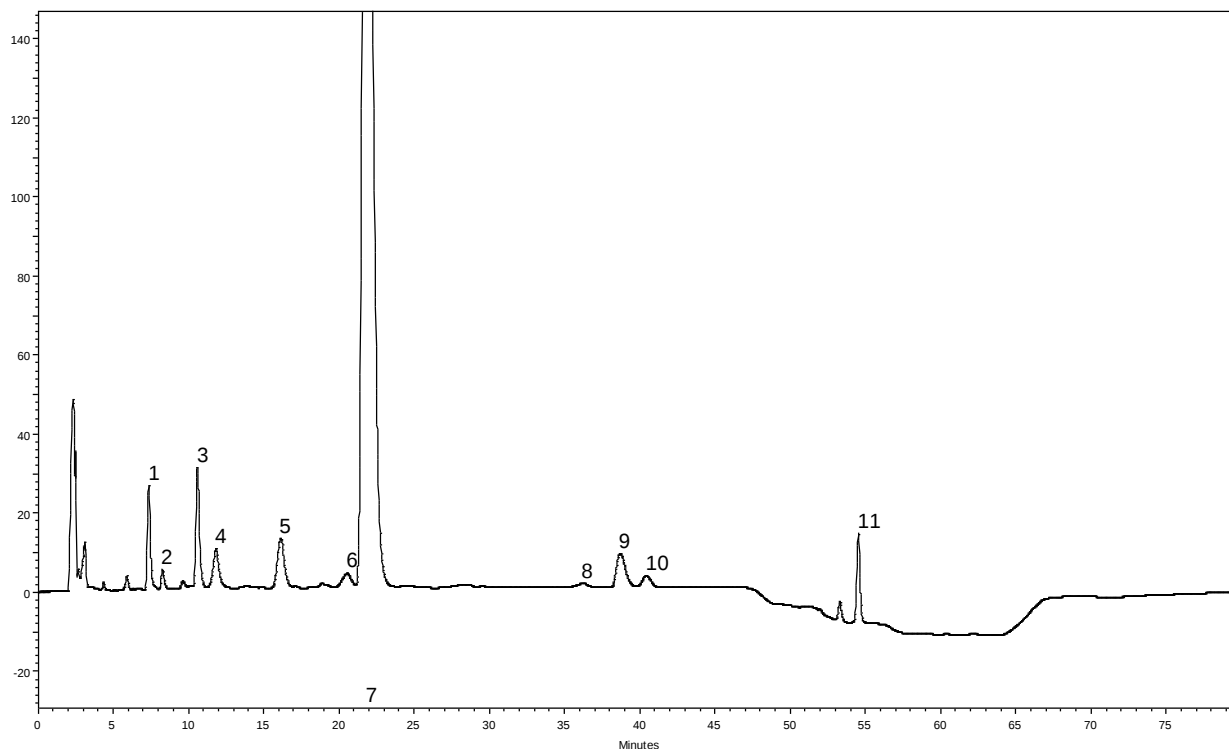
Typical chromatogram for solution (2) in the Assay test for Erythromycin Gastro-resistant Capsules as published in BP 2021.



Peak ID: 1: Erythromycin C; 2: Erythromycin A; 3: Erythromycin B



Typical chromatogram for solution (3) in the Assay test for Erythromycin Gastro-resistant Capsules as published in BP 2021.



Peak ID: 1: Impurity H; 2: Impurity A; 3: Impurity B; 4: Erythromycin C; 5: Impurity L; 6: Impurity C; 7: Erythromycin A; 8: Impurity D; 9: Erythromycin B; 10: Impurity F; 11: Impurity E

Column : XTerra RP18 (250 mm x 4.6 mm, 3.5 μ m)
Method Ref. : Assay for the Erythromycin Gastro-resistant Capsules monograph from BP 2021
Mobile Phase A : Buffer: acetonitrile: water (5: 35: 60, v/v/v)
Mobile Phase B : Buffer: water: acetonitrile (5: 45: 50, v/v/v)
Buffer : 3.5 % w/v dipotassium hydrogen phosphate adjusted to pH 7.0 with dilute phosphoric acid
Diluent : 1.15 % w/v dipotassium hydrogen phosphate adjusted to pH 8.0 with orthophosphoric acid: methanol (40: 60, v/v)

Gradient	:	Orthophosphoric acid-methanol (40:60, v/v)		
		Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
		0-44	100	0
		44-46	100-0	0-100
		46-61	0	100
		61-63	0-100	100-0
		63-80	100	0

Flow rate : 1.0 mL/min
Column Temp : 65 °C
Autosampler Temp : 4 °C
Injection Volume : 100 μ L
Detection : 210 nm