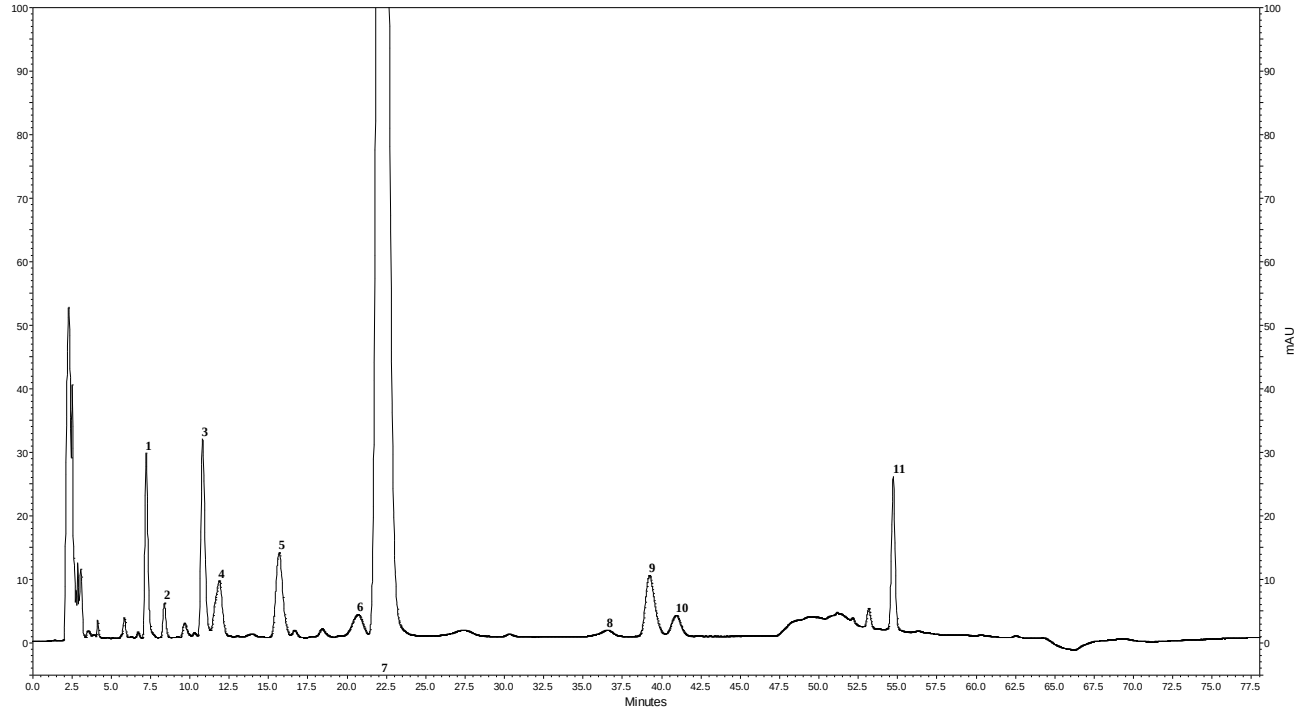
Erythromycin Stearate Tablets – BP 2021

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 Erythromycin Stearate Tablets as published in BP 2021.



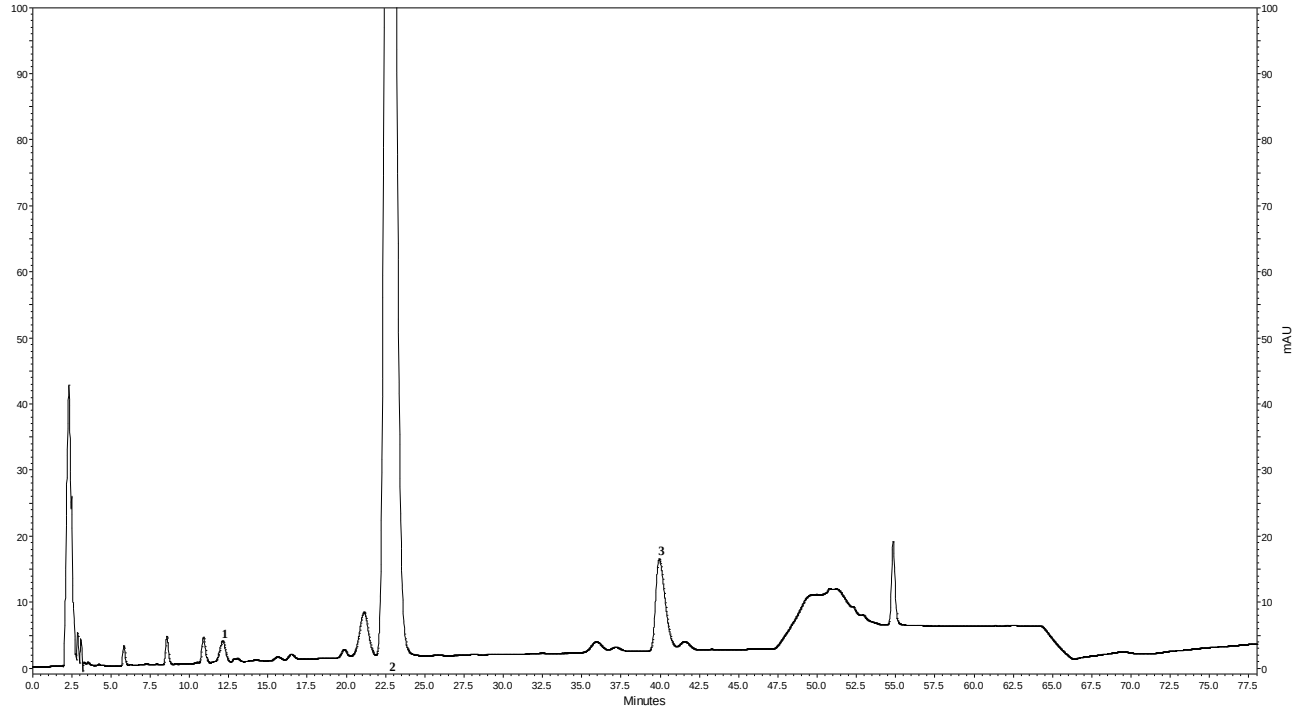
Peak ID: 1: Impurity H; 2: Impurity A: 3: Impurity B; 4: Erythromycin C; 5: Impurity L; 6: Impurity C; 7: Erythromycin A; 8: Impurity D; 9: Erythromycin B; 10: Impurity F; 11: Impurity E

Column	:	XTerra RP18 (250 mm x 4.6 mm, 3.5 µm)
Method Ref.	:	Related Substances for the Erythromycin Stearate Tablets 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	:	

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
63-78	100	0

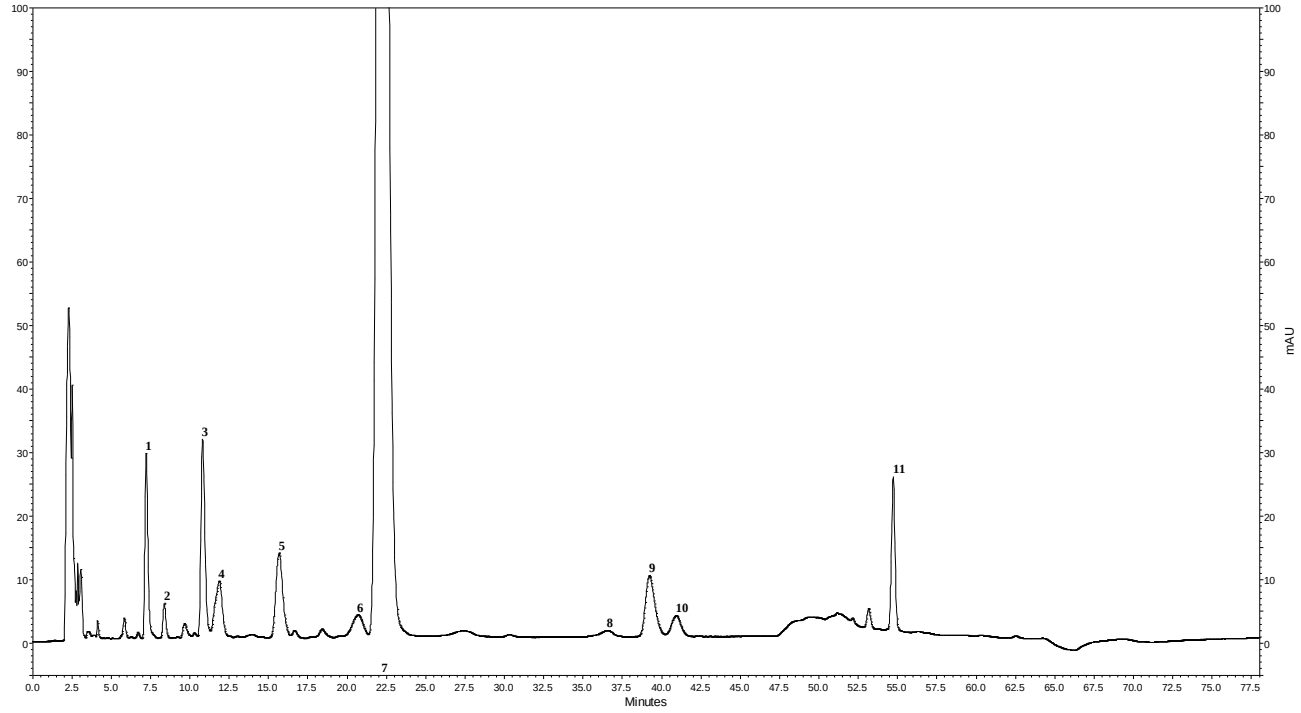
Flow rate	:	1.0 mL/min
Column Temp	:	65 °C
Injection Volume	:	100 µL
Detection	:	210 nm

Typical chromatogram for solution (2) in the Assay test for Erythromycin Stearate Tablets 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 Stearate Tablets 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 µm)
Method Ref. : Assay for the Erythromycin Stearate Tablets 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 :

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
63-78	100	0

Flow rate : 1.0 mL/min
Column Temp : 65 °C
Injection Volume : 100 µL
Detection : 210 nm