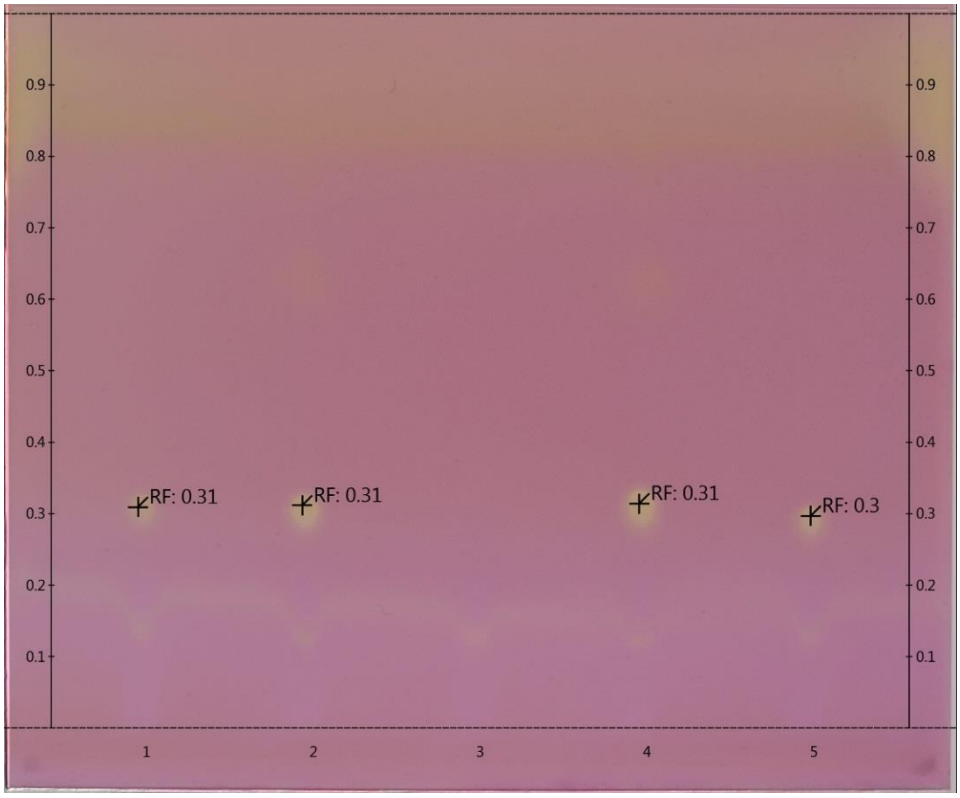
Clindamycin Gel – BP 2021

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.

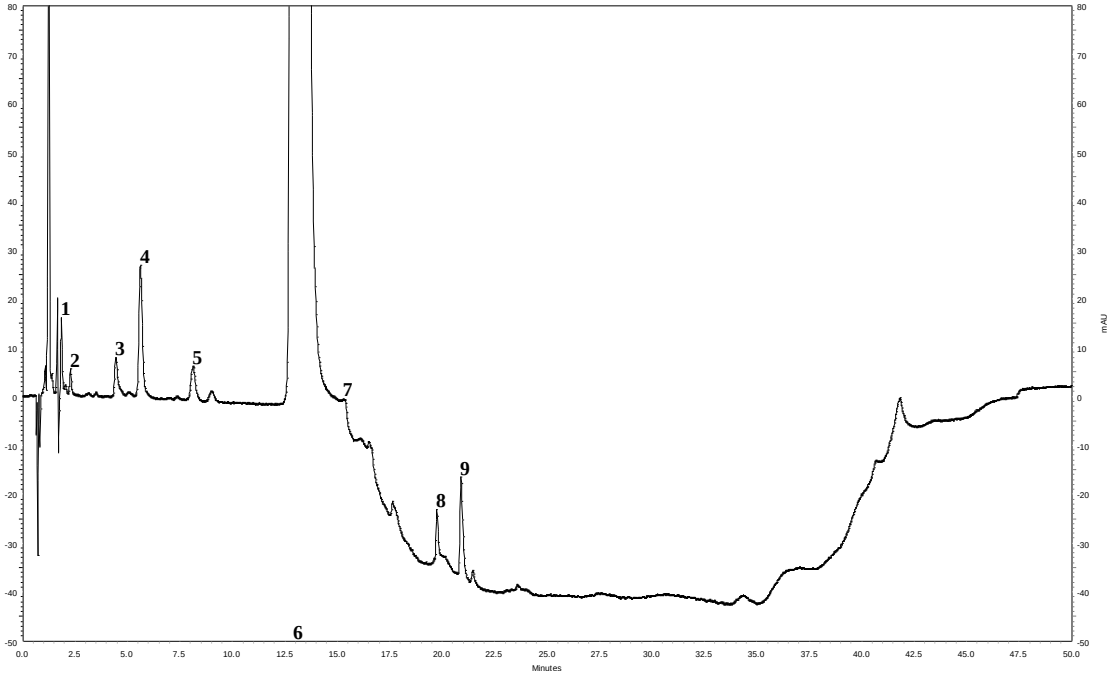
Typical chromatogram for the Identification test for Clindamycin Gel by Thin Layer Chromatography as published in BP 2021.



1 & 5	0.12 % w/v of clindamycin phosphate
2 & 4	Gel sample 0.1 % w/v of solution
3	Blank

TLC plate	Merck TLC silica gel 60 plate (20 cm × 20 cm)
Plate preconditioning	N/A
Diluent	Acetonitrile: buffer (22.5: 77.5, v/v)
Buffer	1M potassium phosphate solution adjusted to pH 2.5
Mobile Phase	Water : glacial acetic acid: 1-butanol (20: 20: 60, v/v/v)
Mobile Phase volume	100 mL
Band application	3 mm band size with a spotting volume of 10 µL
Chamber saturation	Minimum 60 minutes at room temperature
Development	150 mm
Development time	268 minutes
Drying time	Dried at 100º C to 105º C for 30 minutes.
Derivatisation	Allowed to cool down and sprayed with 0.1 % w/v solution of potassium permanganate
Visualisation	Developed plate examined under day light.

Typical chromatogram for solution (3) in the Related Substances test for Clindamycin Gel as published in BP 2021.



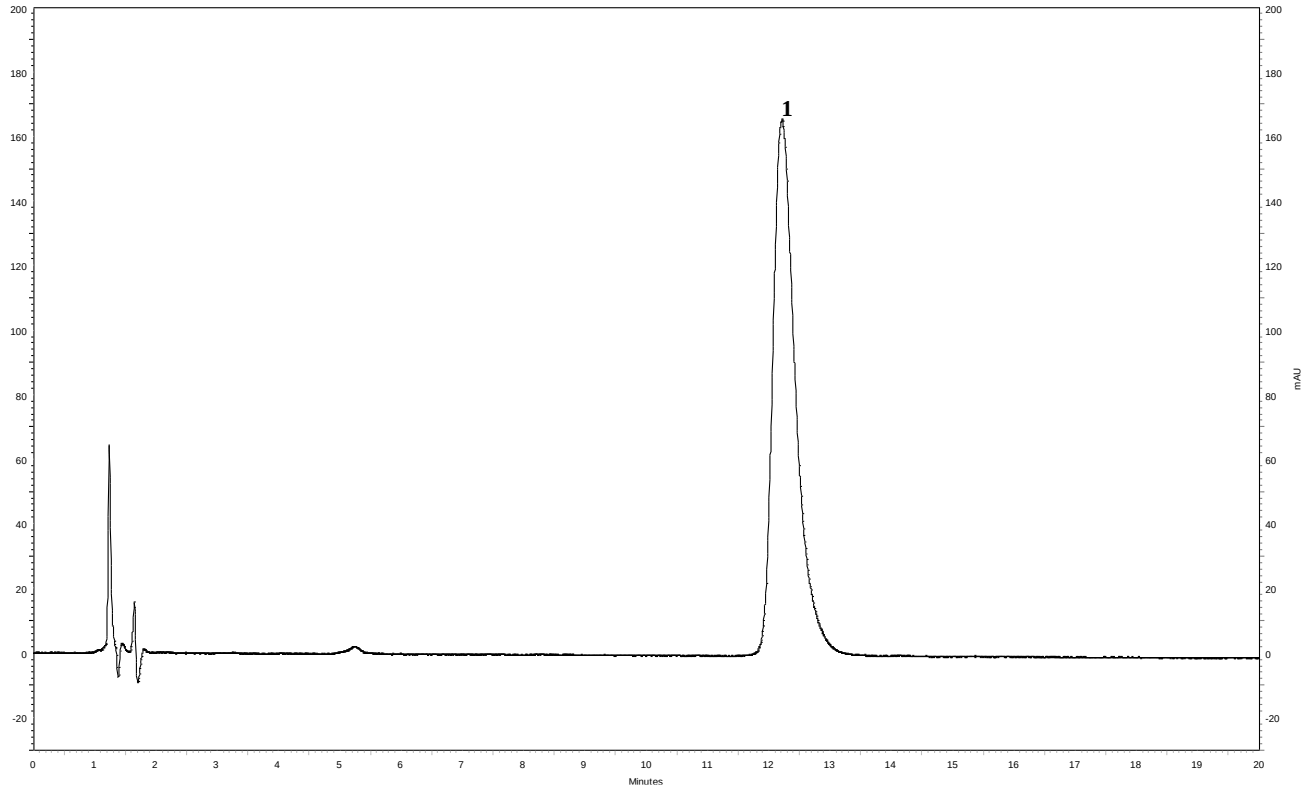
Peak ID: 1: Impurity F; 2: Impurity G; 3: Impurity I; 4: Impurity B; 5: Impurity L; 6: Clindamycin phosphate; 7: Impurity J; 8: Impurity E; 9: Impurity K

Column	:	Waters, Symmetry C18 (150 mm x 4.6 mm, 5 µm)
Method Ref.	:	Related substances for the Clindamycin Gel monograph from BP 2021
Mobile Phase A	:	Acetonitrile : Buffer (21:79, v/v)
Mobile Phase B	:	Buffer : acetonitrile (40:60, v/v)
Buffer	:	1M potassium dihydrogen phosphate, previously adjusted to pH 6.0 with a 45% w/v solution of potassium hydroxide
Diluent	:	Mobile phase A
Gradient	:	

Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0 - 13	100	0
13 - 18	100 - 50	0 - 50
18 - 39	50	50
39 - 40	50 - 100	50 - 0
40 - 50	100	0

Flow rate	:	1.1 mL/min
Column Temp	:	30 °C
Autosampler Temp		4 °C
Injection Volume	:	20 µL
Detection	:	210 nm

Typical chromatogram for solution (2) in the Assay test for Clindamycin Gel as published in BP 2021.



Peak ID: 1: Clindamycin phosphate

Column	:	Waters, Symmetry C18 (150 mm x 4.6 mm, 5 µm)
Method Ref.	:	Assay for the Clindamycin Gel monograph from BP 2021
Mobile Phase A	:	Acetonitrile : buffer (21:79, v/v)
Buffer	:	1M potassium dihydrogen phosphate, previously adjusted to pH 6.0 with a 45% w/v solution of potassium hydroxide
Diluent	:	Mobile phase A
Flow rate	:	1.1 mL/min
Column Temp	:	30 °C
Autosampler Temp		4 °C
Injection Volume	:	20 µL
Detection	:	210 nm