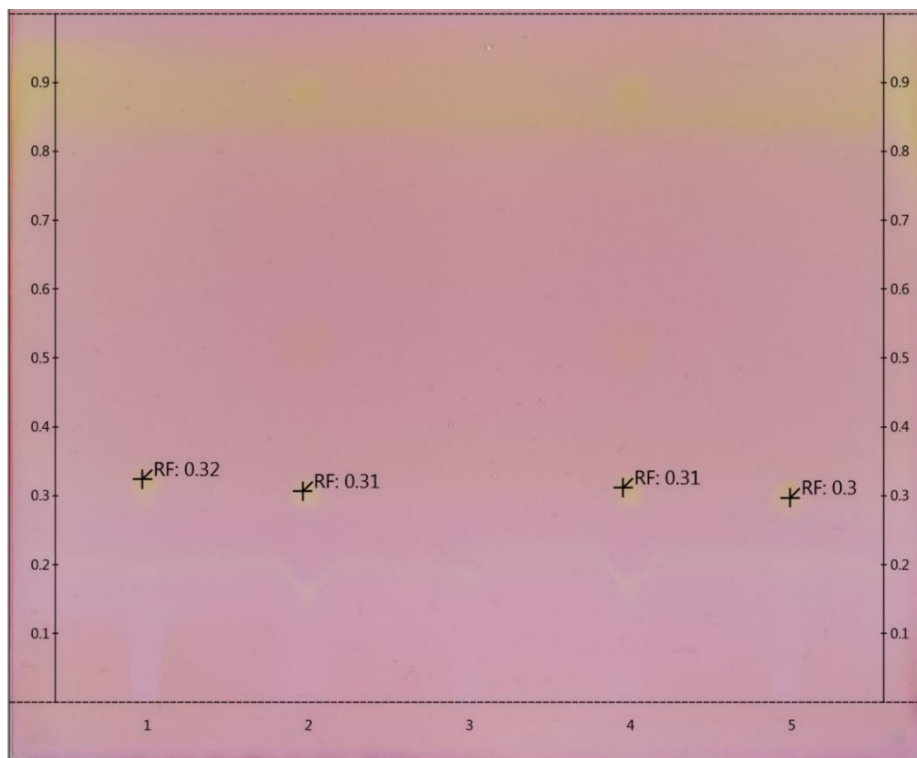




Clindamycin Lotion – BP 2021

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 Lotion by Thin Layer Chromatography as published in BP 2021.



1 & 5 0.12 % w/v of clindamycin phosphate

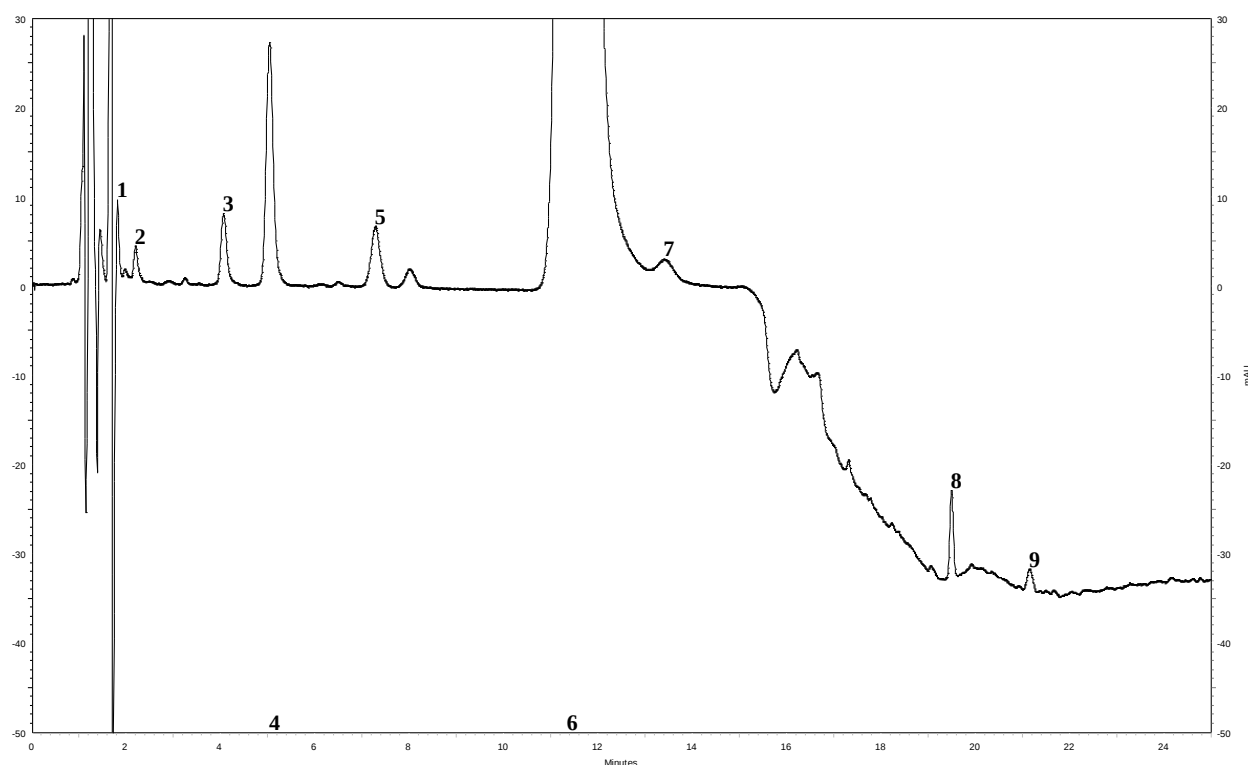
2 & 4 Lotion 0.1 % w/v solution

3 Blank

TLC plate	Merck TLC silica gel 60 plate (20 cm × 20 cm)
Plate preconditioning	N/A
Diluent	Acetonitrile: 1M potassium dihydrogen phosphate, previously adjusted to pH 2.5 using orthophosphoric acid. (45: 155, v/v)
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 100° C to 105° 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 Lotion 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 μ m)
Method Ref. : Related substances for the Clindamycin Lotion 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 adjusted to pH 6.0 with a 45% w/v solution of potassium hydroxide

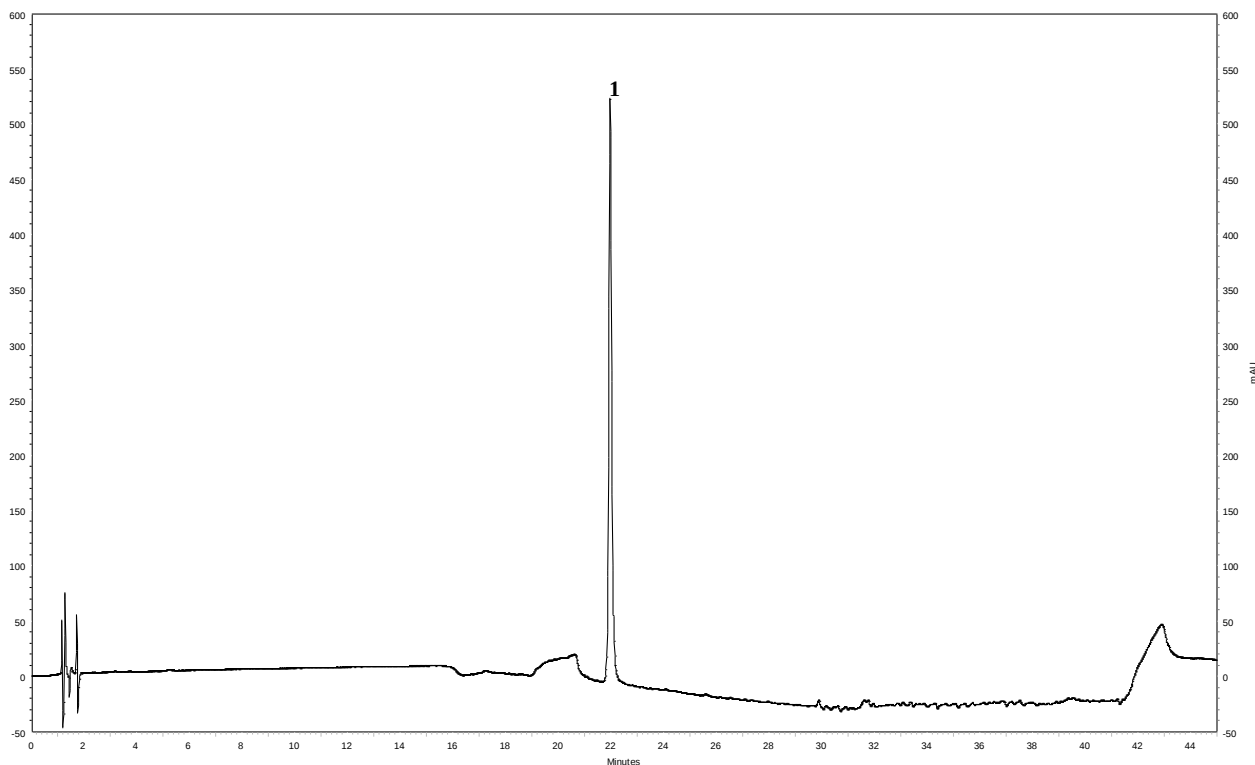
Gradient :

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 - 45	50 - 100	50 - 0
45 - 50	100	0

Diluent : Acetonitrile : water, previously adjusted to pH 2.0 with orthophosphoric acid (15 : 85, v/v)
Flow rate : 1.1 mL/min
Column Temp : 30 $^{\circ}$ C
Autosampler Temp : 4 $^{\circ}$ C
Injection Volume : 20 μ L
Detection : 210 nm



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



Peak ID: 1: Clindamycin phosphate

Column : Waters, Symmetry C18 (150 mm x 4.6 mm, 5 μ m)
Method Ref. : Assay for the Clindamycin Lotion monograph from BP 2021
Mobile Phase A : Acetonitrile: Buffer (15: 85, v/v)
Mobile Phase B : Buffer : acetonitrile (40:60, v/v)
Buffer : 1M potassium dihydrogen phosphate adjusted to pH 6.0 with a 45% w/v solution of potassium hydroxide
Diluent : Acetonitrile : water, previously adjusted to pH 2.0 with orthophosphoric acid (15 : 85 v/v)

Gradient :

Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0 - 13	100	0
13 - 30	100 - 44	0 - 56
30 - 40	44	56
40 - 41	44 - 100	56 - 0
41 - 45	100	0

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