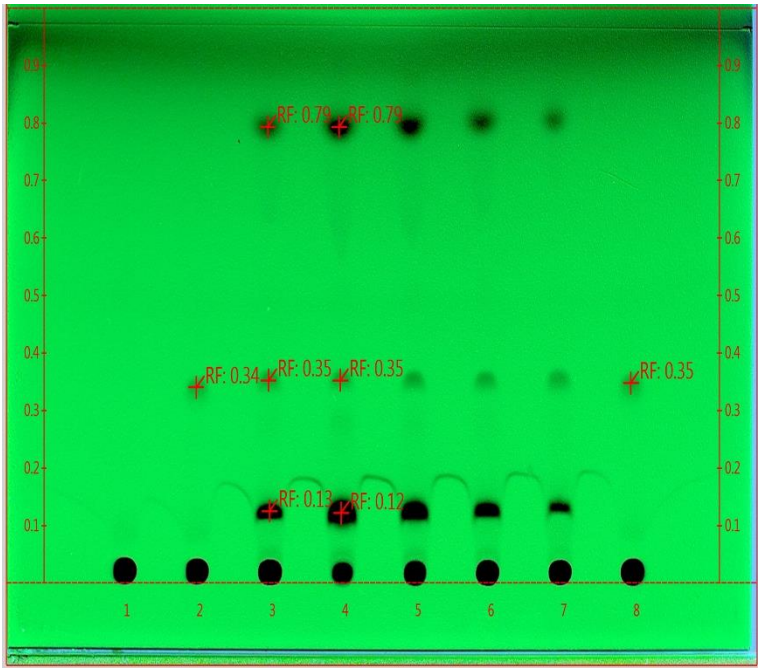
British Pharmacopoeia

Nadolol Oral Suspension – 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 Nadolol Oral Suspension by Thin Layer Chromatography as published in BP 2021.



1	Blank
2 & 8	0.1 % w/v nadolol standard solution
3	System suitability solution
4-7	Oral suspension 0.1 % w/v solution

TLC plate	Merck TLC silica gel 60 F254 plate (20 cm × 20 cm)
Plate preconditioning	N/A
Diluent	0.1 M hydrochloric acid
Mobile Phase	2 M ammonium hydroxide : dichloromethane : acetone (1:1:8, v/v/v)
Mobile Phase volume	100 mL
Band application	3 mm band size with a spotting volume of 25 µL
Chamber saturation	Minimum 60 minutes at room temperature
Development	100 mm
Development time	24 minutes
Drying time	10 minutes in air
Derivatisation	N/A
Visualisation	Developed plate examined under UV light (254 nm)

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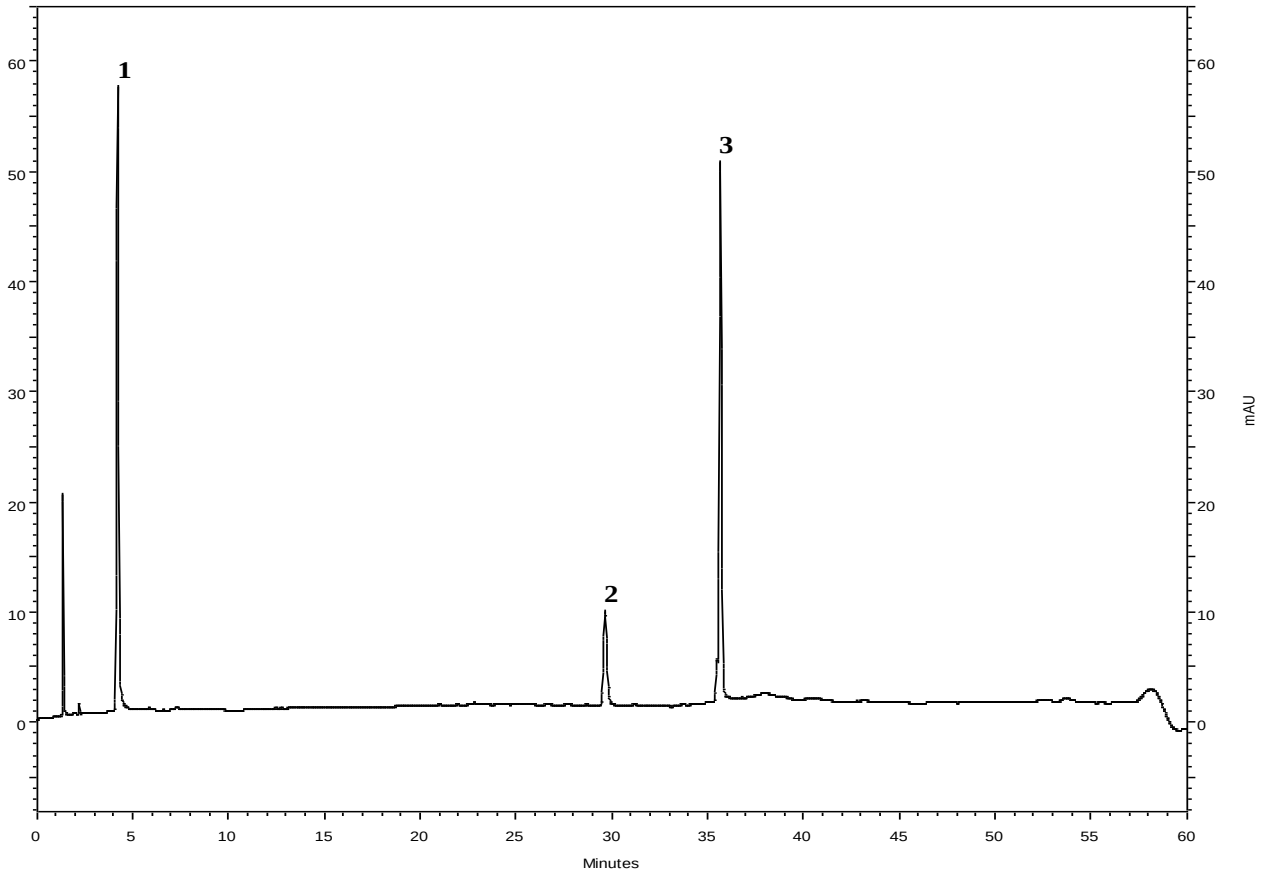
Typical chromatogram for solution (3) in the Related Substances test for Nadolol Oral Suspension as published in BP 2021.



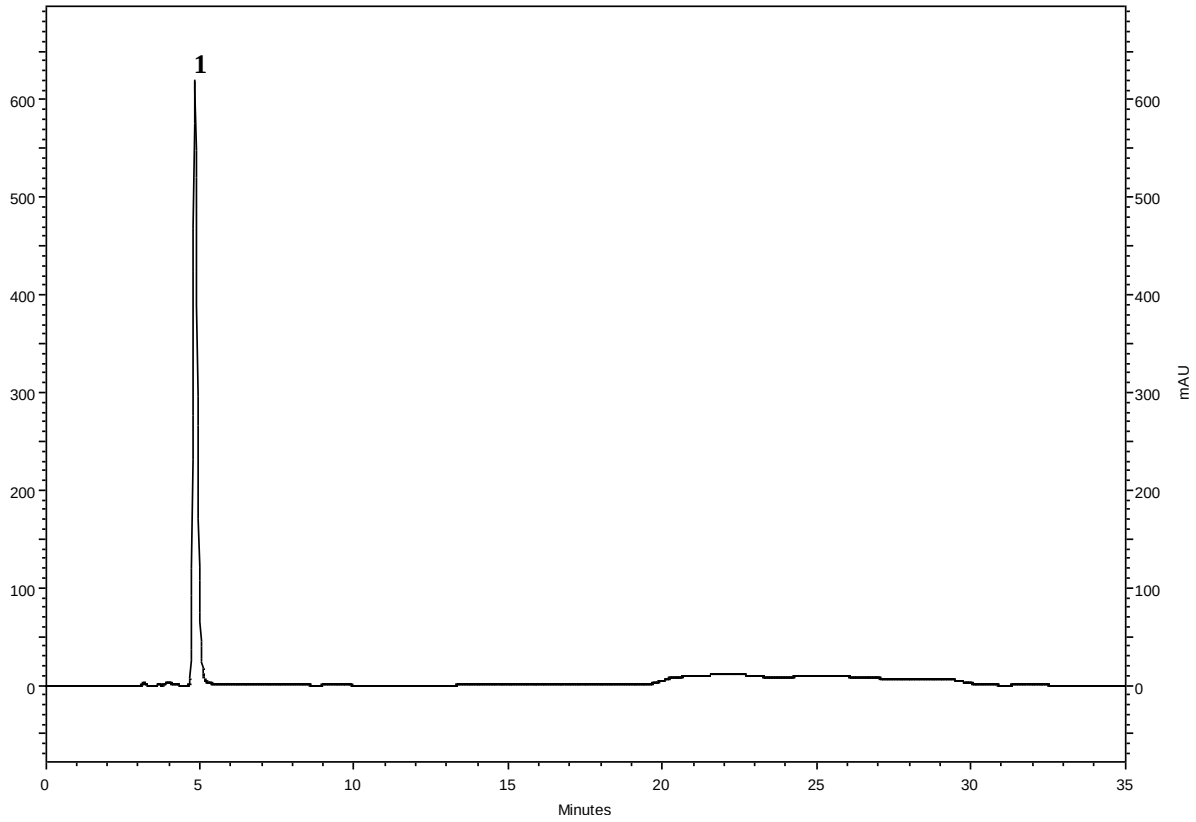
Peak ID: 1: Impurity A; 2: Nadolol; 3: Impurity D

Column	:	Lichrospher, 100 RP 18, (250 x 4.0 mm, 5 µm)
Method Ref.	:	Related Substances for the Nadolol Oral Suspension monograph from BP 2021
Mobile Phase A	:	0.56 % w/v of sodium octanesulfonate, adjusted to pH 3.5 with a 30 % w/v solution of orthophosphoric acid
Mobile Phase B	:	Acetonitrile
Gradient	:	

Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0 – 7	84	16
7 – 30	84 → 72	16 → 28
30 – 35	72 → 62	28 → 38
35 – 55	62	38
55 - 56	62 → 84	38 → 16
56 - 60	84	16

Diluent	:	Acetonitrile: water (20: 80, v/v)
Flow rate	:	1.0 mL/min
Column Temp	:	40 °C
Injection Volume	:	20 µL
Detection	:	206 nm

Typical chromatogram for solution (2) in the Assay test for Nadolol Oral Suspension as published in BP 2021.



Peak ID: 1: Nadolol

Column	:	HiChrom Nucleosil C2 (250 mm x 4.6 mm, 7.0 µm)
Method Ref.	:	Assay for the Nadolol Oral Suspension monograph from BP 2021
Buffer	:	4.49 g/L of sodium chloride and 0.77 mL/L of 0.1 N hydrochloric acid
Mobile Phase A	:	Methanol: buffer (25: 75, v/v)
Mobile Phase B		Buffer
Mobile Phase C	:	Methanol
Diluent	:	Mobile Phase A
Gradient	:	

Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Mobile phase C (% v/v)
0 - 15	100	0	0
15 - 16	100 - 0	0 - 50	0 - 50
16 - 25	0	50	50
25 - 26	0 - 100	0	0
26 - 35	100	0	0
0 - 15	100	0	0

Flow rate	:	1.0 mL/min
Column Temp	:	25 °C
Injection Volume	:	20 µL
Detection	:	220 nm