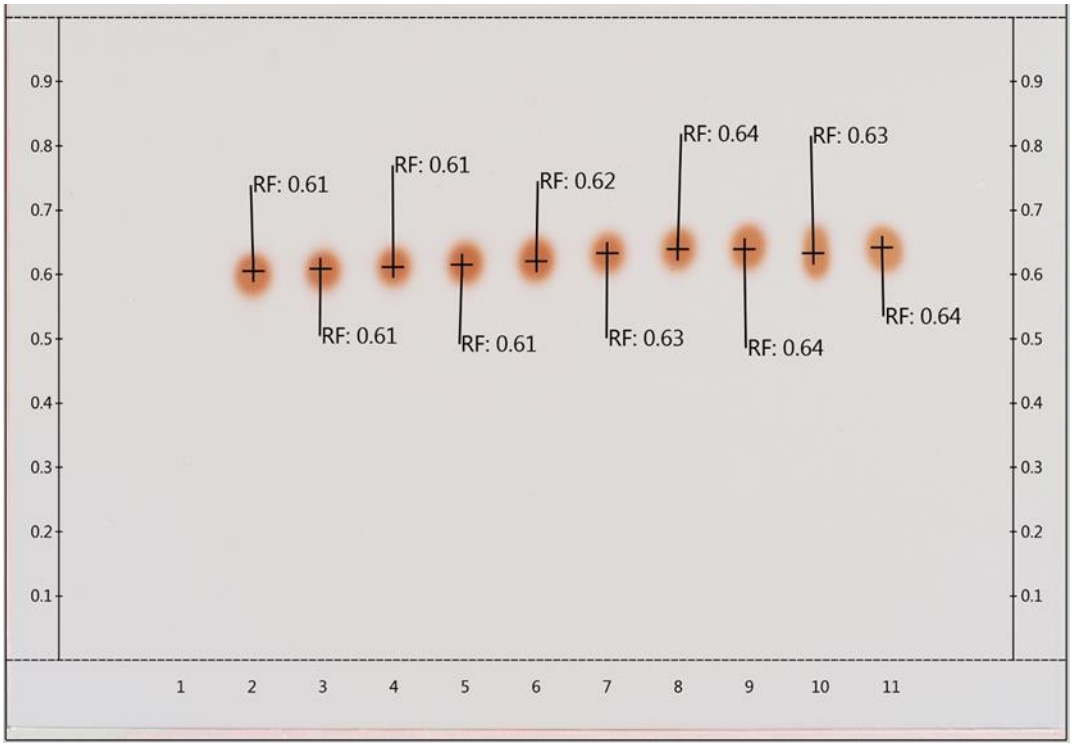
Pregabalin Capsules – BP 2022

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 Pregabalin Capsules by Thin Layer Chromatography as published in BP 2022.

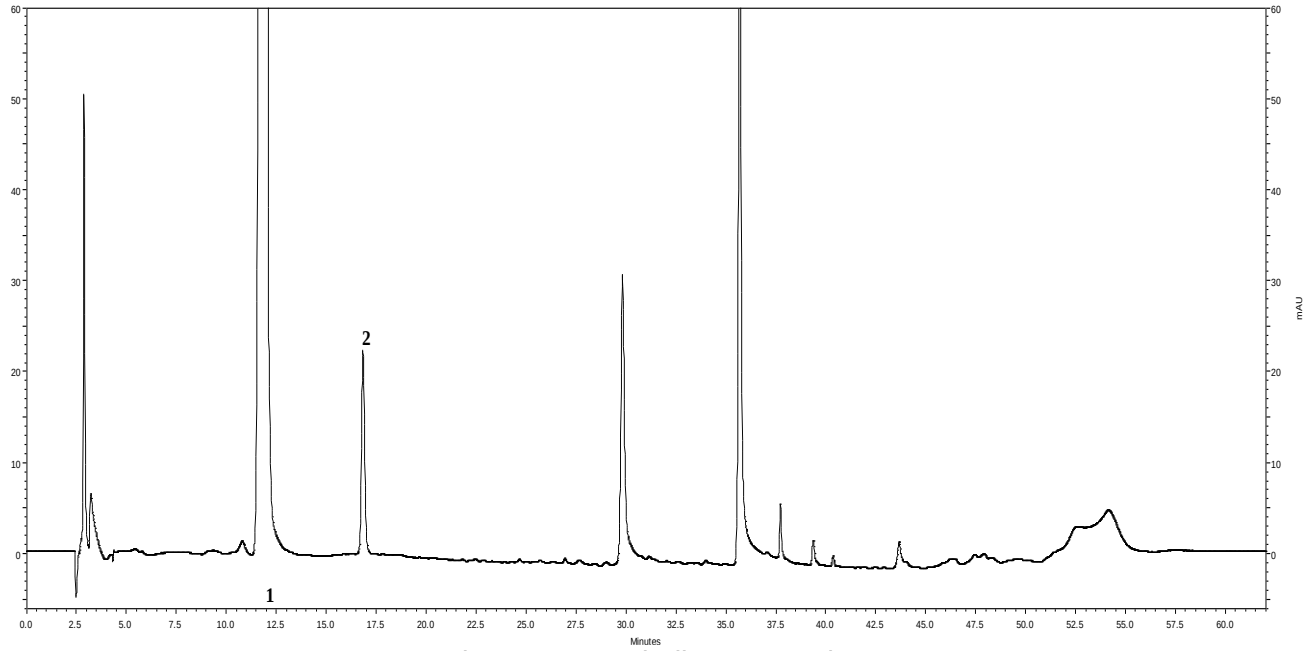


1	Blank
2	0.5 % w/v pregabalin standard solution
3-10	Capsule sample 0.5 % w/v solutions
11	0.5 % w/v pregabalin standard solution

TLC plate	Merck TLC silica gel 60 (20 cm × 20 cm)
Plate preconditioning	N/A
Diluent	Methanol: water (50: 50, v/v)
Mobile Phase	Glacial acetic acid: methanol: chloroform (20: 50: 60, v/v/v)
Mobile Phase volume	100 mL
Band application	3 mm band size with a spotting volume of 4 µL
Chamber saturation	Minimum 60 minutes at room temperature
Development	120 mm
Development time	58 minutes
Drying time	5 minutes in a current of warm air
Derivatisation	Sprayed with ninhydrin solution then heated at 90 °C for 2 minutes
Visualisation	Derivatised plates were visualised under white light

British Pharmacopoeia

Typical chromatogram for solution (4) in the Related Substances test for Pregabalin Capsules as published in BP 2022.



Peak ID: 1: Pregabalin; 2: Impurity 1

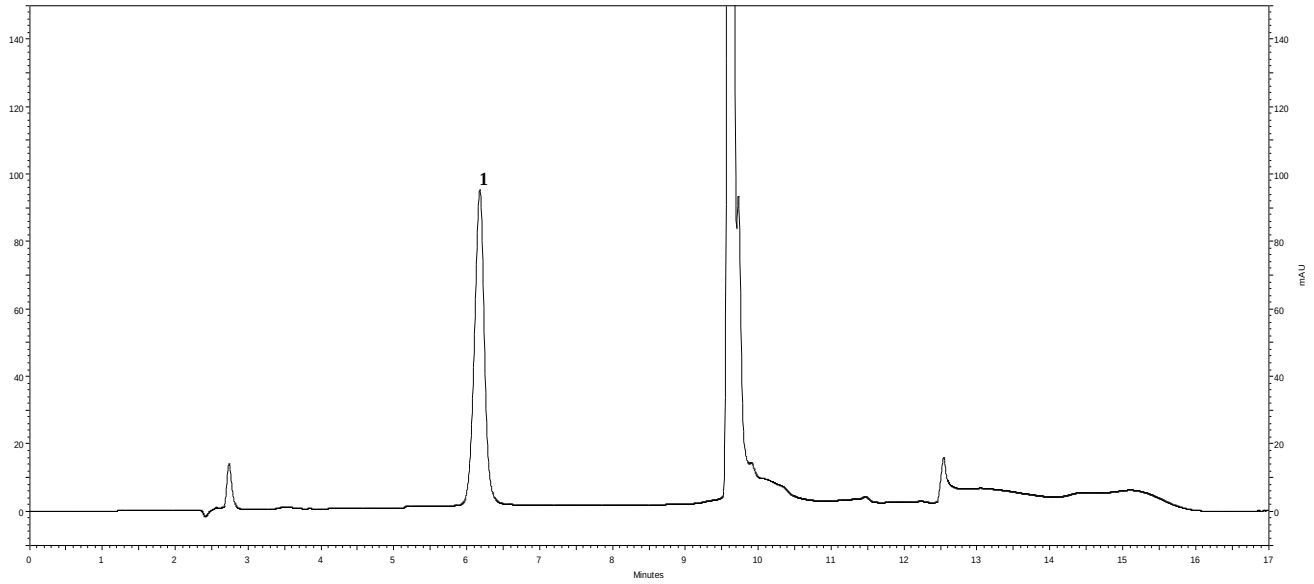
Column	:	HiChrom Inertsil ODS-3V C18 (250 mm x 4.6 mm, 5.0 µm)
Method Ref.	:	Related substances for the Pregabalin Capsules monograph from BP 2022
Mobile Phase A	:	Acetonitrile R1: buffer (2: 100, v/v)
Mobile Phase B	:	Acetonitrile R1
Gradient	:	

Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0 – 3	98	2
3 – 31	98 → 75	2 → 25
31 – 43	75 → 45	25 → 55
43 – 48	45	55
48 – 50	45 → 98	55 → 2
50 – 63	98	2

Buffer	:	0.272 % w/v potassium dihydrogen orthophosphate adjusted to pH 5.9 with 1 M sodium hydroxide
Diluent	:	Water
Flow rate	:	1.0 mL/min
Column Temp	:	40 °C
Injection Volume	:	50 µL
Detection	:	210 nm

MHRA

Typical chromatogram for solution (2) in the Assay test for Pregabalin Capsules as published in BP 2022.



Peak ID: 1: Pregabalin

Column	:	HiChrom Inertsil ODS-3V C18 (250 mm x 4.6 mm, 5.0 µm)
Method Ref.	:	Assay for the Pregabalin Capsules monograph from BP 2022
Mobile Phase A	:	Acetonitrile R1: buffer (10: 90, v/v)
Mobile phase B	:	Acetonitrile R1
Gradient	:	

Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0 – 5	100	0
5 – 6	100 → 60	0 → 40
6 – 10	60	40
10 – 11	60 → 100	40 → 0
11 – 17	100	0

Buffer	:	0.272 % w/v potassium dihydrogen orthophosphate adjusted to pH 5.9 with 1 M sodium hydroxide
Diluent	:	Acetonitrile R1: Water (10: 90, v/v)
Flow rate	:	1.0 mL/min
Column Temp	:	40 °C
Injection Volume	:	20 µL
Detection	:	210 nm