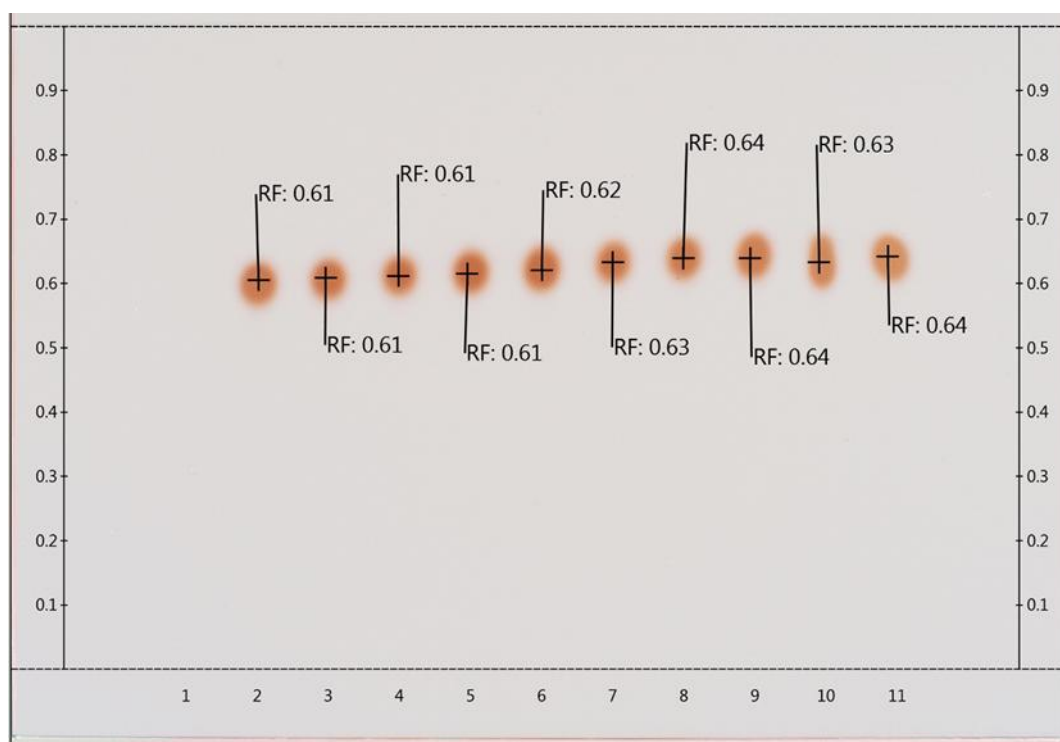




Pregabalin Capsules – BP 2022

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.

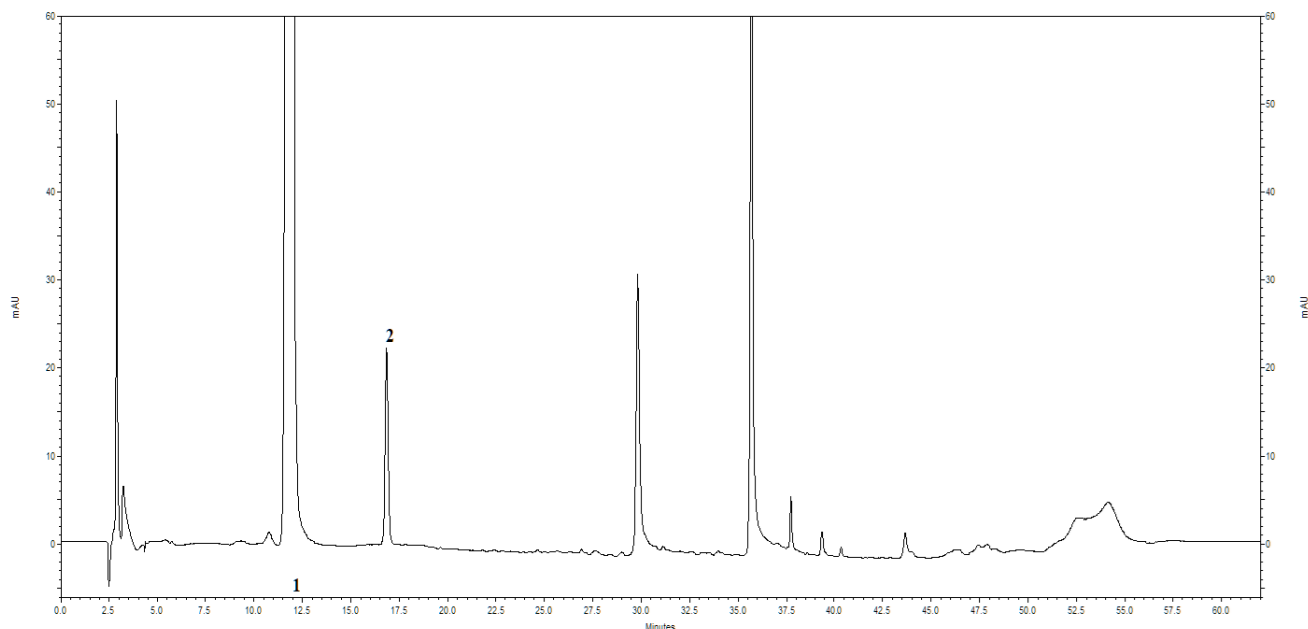


- | | |
|------|--|
| 1 | Blank |
| 2 | 0.5 % w/v pregabalin standard solution |
| 3-10 | Capsule sample 0.5 % w/v solutions |
| 11 | 0.5 % w/v pregabalin standard solution |

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

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



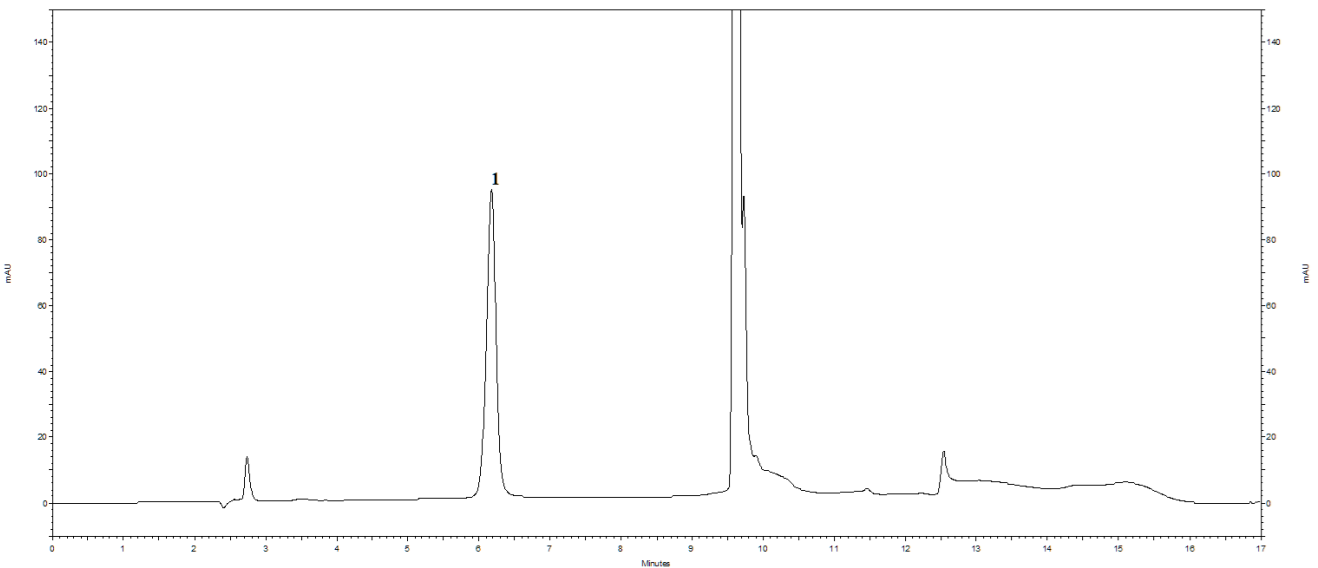
Peak ID: 1: Pregabalin; 2: Impurity 1

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

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