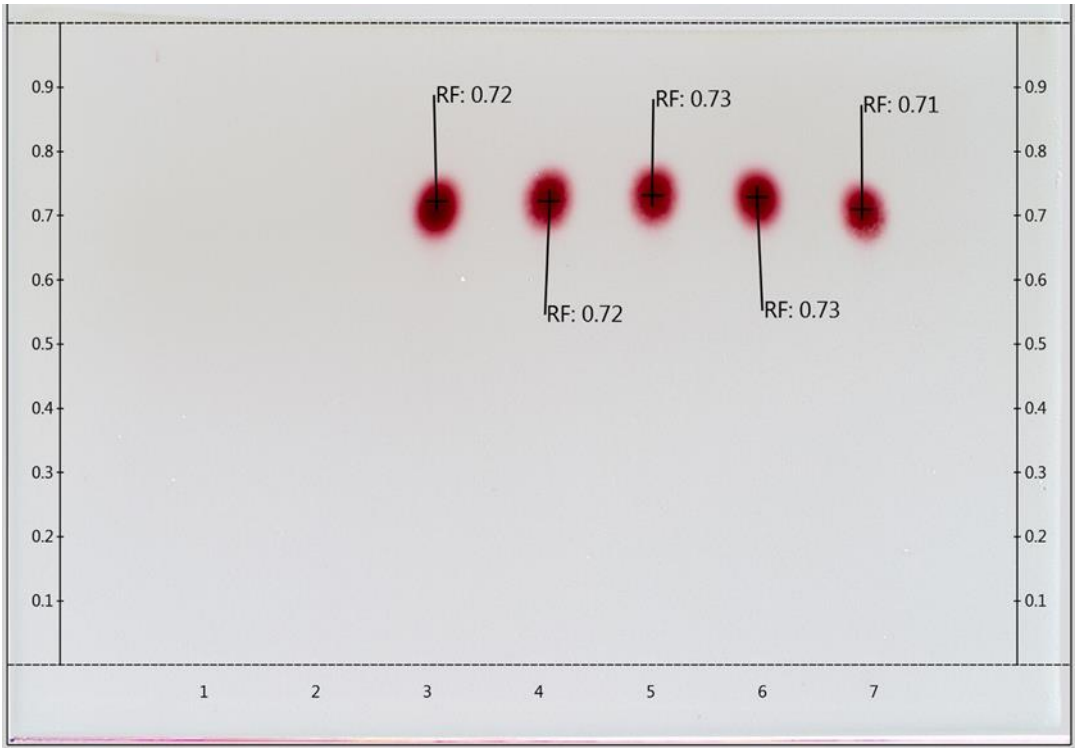
British Pharmacopoeia

**Pregabalin Oral Solution – 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 Oral Solution by Thin Layer Chromatography as published in BP 2022.




| | |
|---|---|
| 1-2 | Blank |
| 3-4 | 0.5 % w/v pregabalin standard solution |
| 5-6 | Oral solution sample 0.5 % w/v solutions |
| 7 | 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 | 63 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 |

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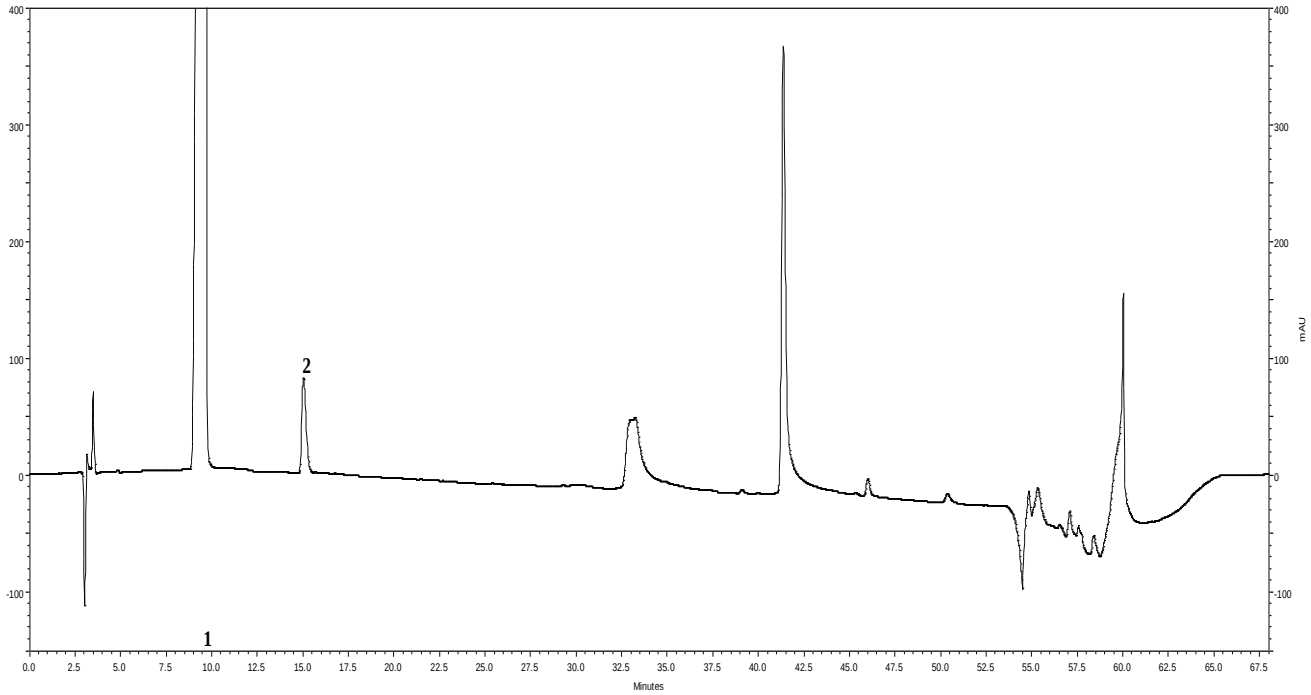
Typical chromatogram for solution (4) in the Related Substances test for Pregabalin Oral Solution as published in BP 2022.



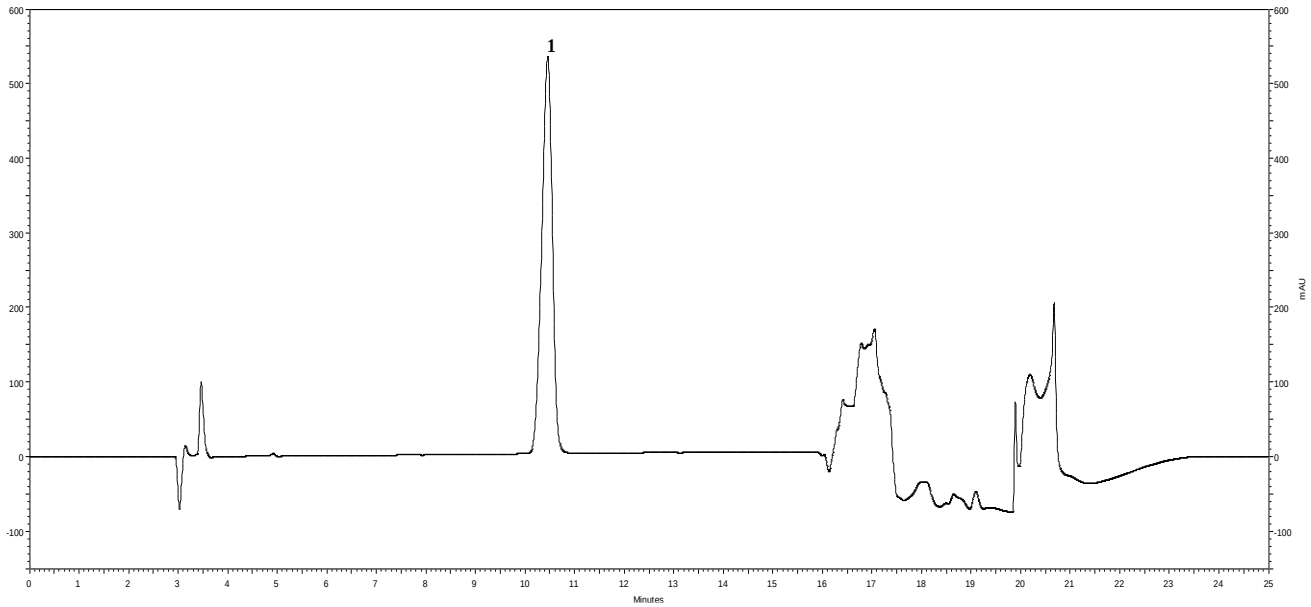

Peak ID: 1: Pregabalin; 2: Impurity 1

Column : Inertsil ODS3 C18 (250 mm x 4.6 mm, 5 µm)
Method Ref. : Related substances for the Pregabalin Oral Solution monograph from BP 2022
Mobile Phase A : Acetonitrile R1: methanol R1: buffer (5: 11: 84, v/v/v)
Mobile phase B : Acetonitrile R1
Gradient :

| Time (minutes) | Mobile phase A (% v/v) | Mobile phase B (% v/v) |
|---|---|---|
| 0 – 6 | 100 | 0 |
| 6 – 45 | 100 → 76 | 0 → 24 |
| 45 – 50 | 76 | 24 |
| 50 – 51 | 76 → 30 | 24 → 70 |
| 51 – 55 | 30 | 70 |
| 55 – 59 | 30 → 100 | 70 → 0 |
| 59 – 68 | 100 | 0 |

Buffer : 0.04 M diammonium hydrogen orthophosphate adjusted to pH 6.6 with orthophosphoric acid
Diluent : Acetonitrile R1: methanol R1: water (10: 10: 80, v/v/v)
Flow rate : 0.8 mL/min
Column Temp : 30 °C
Injection Volume : 50 µL
Detection : 210 nm

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




Peak ID: 1: Pregabalin

Column : Inertsil ODS3 C18 (250 mm x 4.6 mm, 5 µm)
Method Ref. : Assay for the Pregabalin Oral Solution monograph from BP 2022
Mobile Phase A : Acetonitrile R1 : methanol R1: buffer (4: 11: 85, v/v/v)
Mobile Phase B : Acetonitrile R1
Gradient :

| Time (minutes) | Mobile phase A (% v/v) | Mobile phase B (% v/v) |
|---|---|---|
| 0 – 12 | 100 | 0 |
| 12 – 12.1 | 100 → 20 | 0 → 80 |
| 12.1 – 16 | 20 | 80 |
| 16 – 17 | 20 → 100 | 80 → 0 |
| 17 – 25 | 100 | 0 |

Buffer : 0.04 M diammonium hydrogen orthophosphate adjusted to pH 6.6 with orthophosphoric acid
Diluent : Acetonitrile R1: methanol R1: water (10: 10: 80, v/v/v)
Flow rate : 0.8 mL/min
Column Temp : 30 °C
Injection Volume : 25 µL
Detection : 210 nm