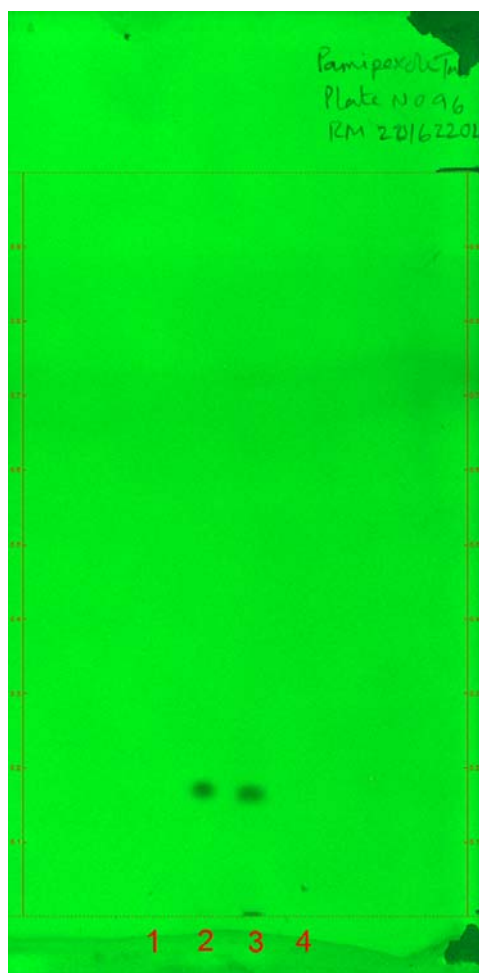




Pramipexole Prolonged-Release Tablets – BP 2018

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 Pramipexole Prolonged-release Tablets by Thin Layer Chromatography as published in BP 2018.



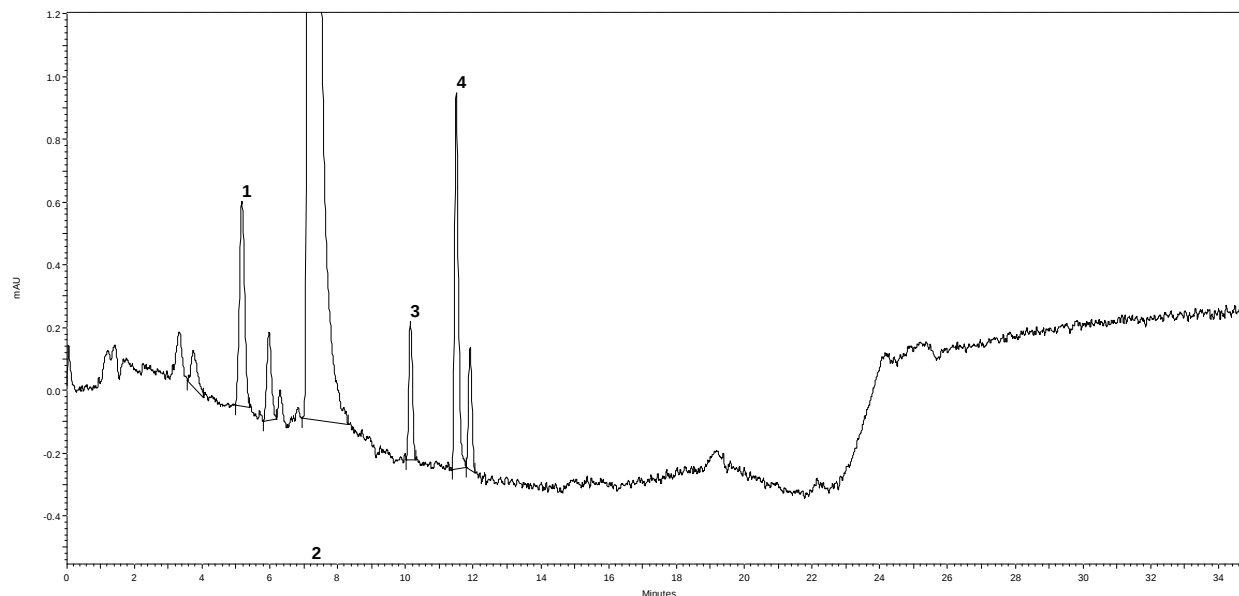
- | | |
|---|---|
| 1 | Blank |
| 2 | 0.010 % w/v pramipexole standard |
| 3 | Prolonged-release tablet 0.010 % w/v solution |
| 4 | Blank |



TLC plate	Merck TLC silica gel 60 F254 Plate, 10 cm × 20 cm
Plate preconditioning	N/A
Diluent	Methanol
Mobile Phase	18 M ammonia : methanol : toluene : ethyl acetate (6:5:15:80, v/v/v/v)
Mobile Phase volume	100 mL
Band application	3 mm band size with a spotting volume of 20 µL
Chamber saturation	Minimum 60 minutes at room temperature
Development	150 mm
Development time	35 minutes
Drying time	10 minutes in air
Derivatisation	N/A
Visualisation	UV light (254 nm)



Typical chromatogram for solution (3) in the Related Substances test for Pramipexole Prolonged-Release Tablets as published in BP 2018.



Peak ID: 1: Impurity A; 2: Pramipexole; 3: Impurity B; 4: Impurity C

Column : HiChrom Inertsil ODS2 (125 mm x 4.6 mm, 5 μ m)
Mobile Phase A : 5 g/L of sodium octanesulfonate monohydrate and 9.1 g/L of potassium dihydrogen orthophosphate, adjusted to pH 3.0 with orthophosphoric acid
Mobile Phase B : Acetonitrile: mobile phase A (50:50, v/v)

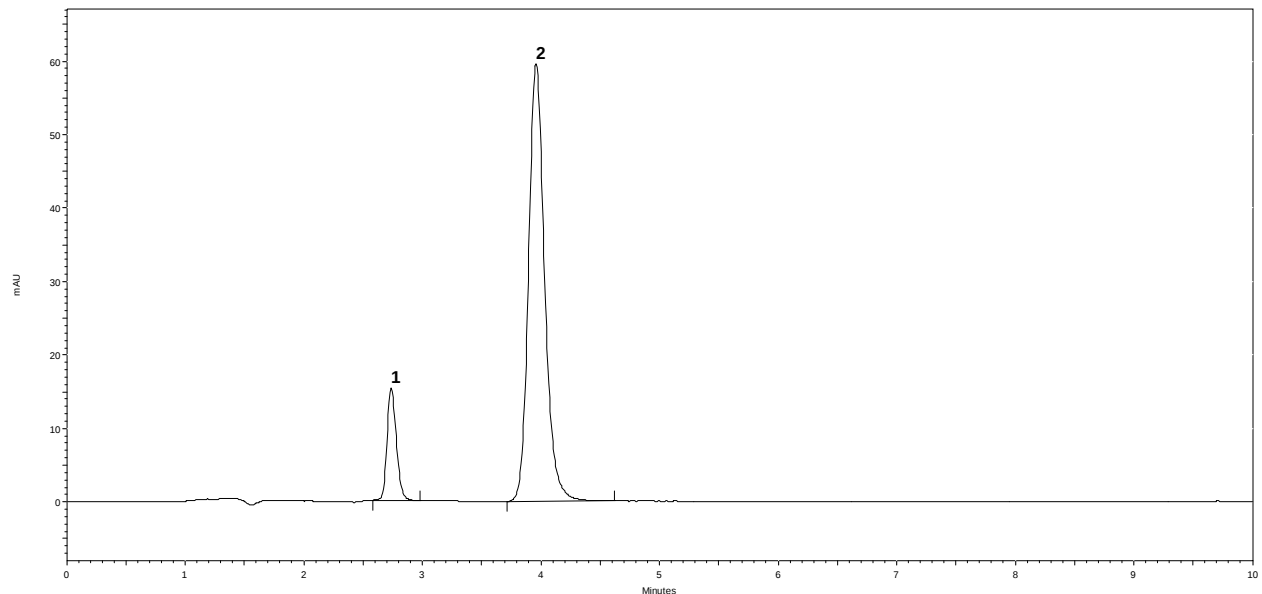
Gradient

Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
0-1	60	40
1-16	60-20	40-80
16-20	20	80
20-22	20-60	80-40
22-35	60	40

Diluent : Methanol: mobile phase A (40:60, v/v)
Flow Rate : 1.5 mL/min
Column Temp : 40°C
Auto-sampler Temp : Ambient
Injection Volume : 200 μ L
Detection : UV, 264 nm



Typical chromatogram for solution (3) in the Assay/Uniformity of Content test for Pramipexole prolonged-release Tablets as published in BP 2018.



Peak ID: 1: Impurity A; 2: Pramipexole

Column	: HiChrom Inertsil ODS2 (125 mm x 4.6 mm, 5 μ m)
Buffer	: 5 g sodium octanesulfonate monohydrate and 9.1 g potassium dihydrogen orthophosphate dissolved in 900 mL of water, adjusted to pH 3.0 with orthophosphoric acid and diluted to 1000 mL with water.
Mobile Phase	: Acetonitrile: buffer (25:75, v/v)
Diluent	: Acetonitrile: buffer (20:80, v/v)
Flow Rate	: 1.5 mL/min
Column Temp	: 40°C
Auto-sampler Temp	: Ambient
Injection Volume	: 200 μ L
Detection	: UV, 264 nm