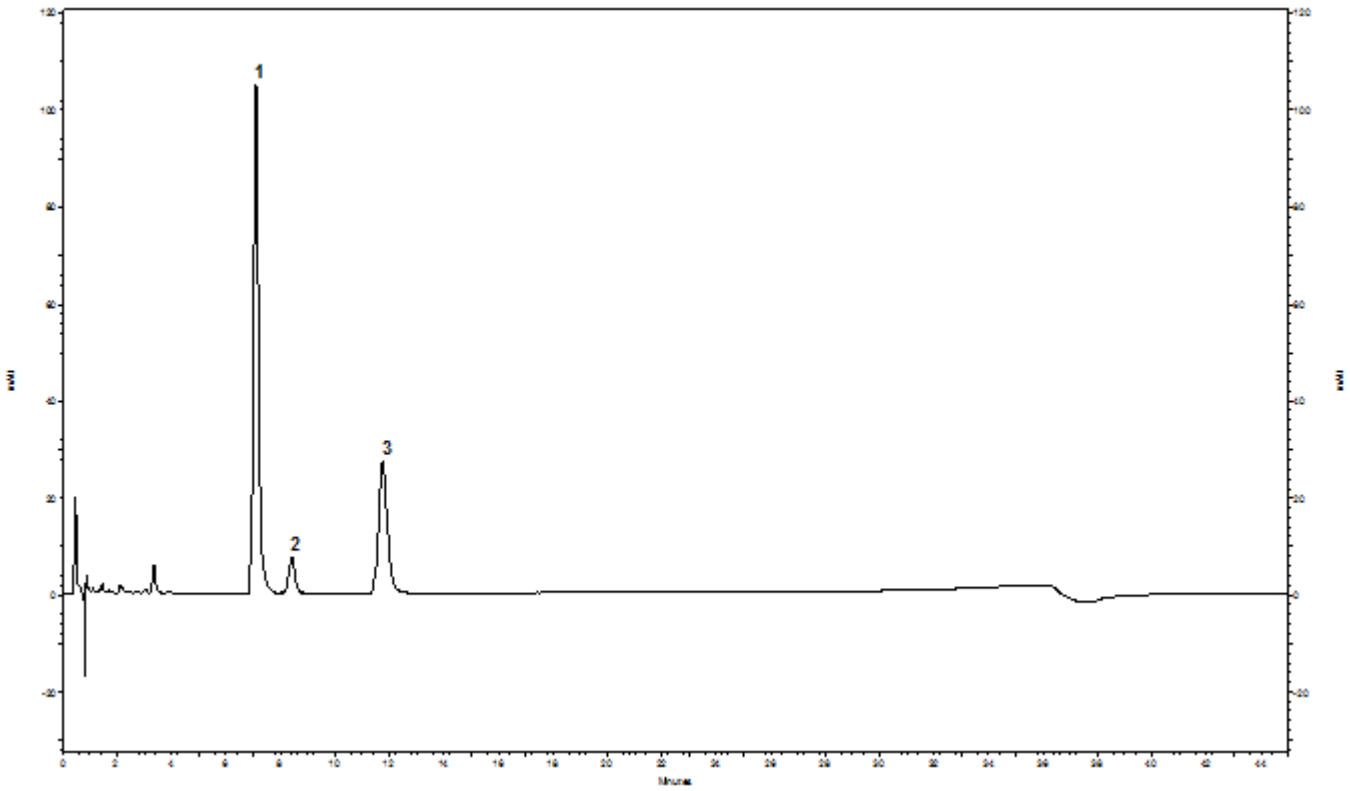
Methylphenidate Prolonged-release Capsules – BP 2021

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 solution (3) in the Related Substances test for Methylphenidate Prolonged-release Capsules as published in BP 2021.



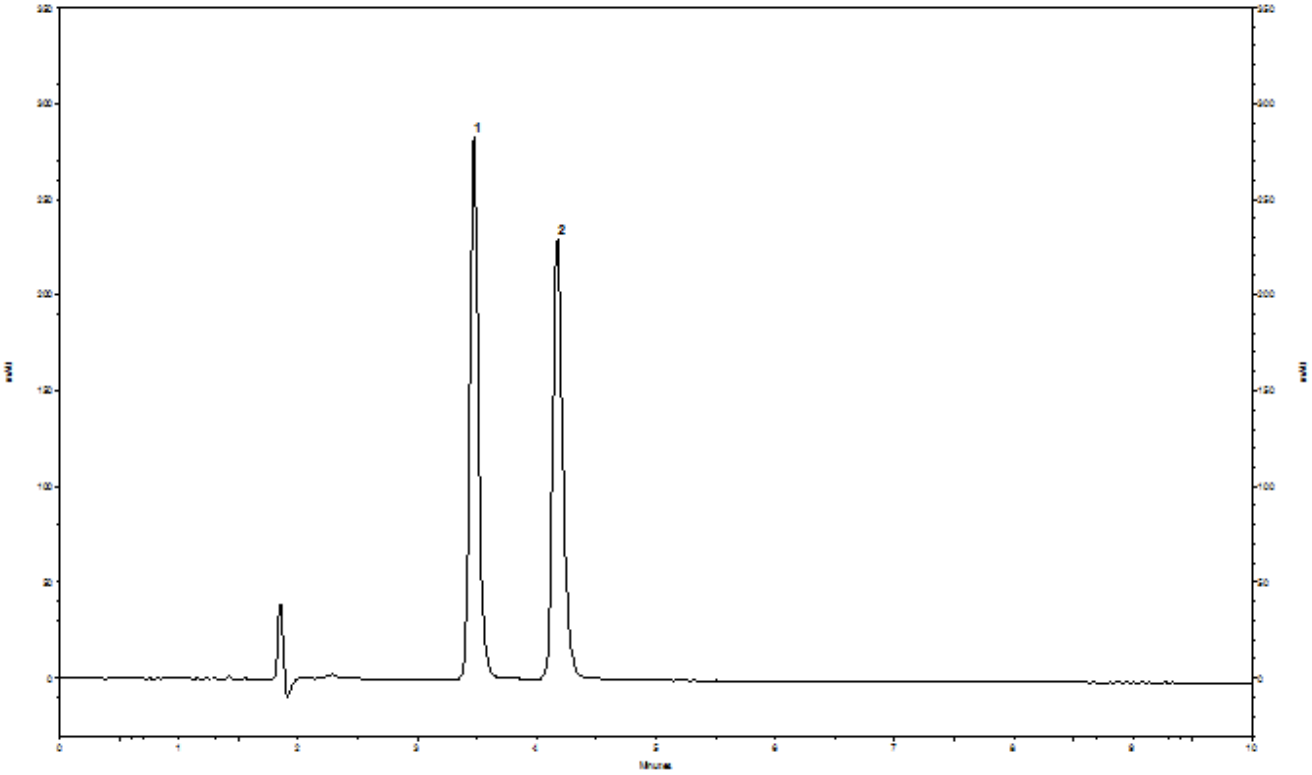
Peak ID: 1: Impurity A; 2: Impurity C; 3: Impurity B

Column	:	Waters Symmetry C18 (75 mm x 4.6 mm, 3.5 µm)
Method Ref.	:	Related Substances for the Methylphenidate Prolonged-release Capsules monograph from BP 2021
Mobile Phase A	:	0.216 % w/v sodium octanesulfonate containing 1 mL of trimethylamine, adjusted to pH 2.7 with orthophosphoric acid
Mobile Phase B	:	Acetonitrile
Gradient		

Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
0-15	80	20
15-35	80-60	20-40
35-36	60-80	40-20
36-45	80	20

Diluent	:	Solution A
Flow rate	:	1.3 mL/min
Column Temp	:	40 °C
Injection Volume	:	100 µL
Detection	:	215 nm

Typical chromatogram for solution (3) in the Assay test for Methylphenidate Prolonged-release Capsules as published in BP 2021.



Peak ID: 1: Phenylephrine; 2: Methylphenidate

Column	:	Spherisorb CN (250 mm x 4.6 mm, 5 µm)
Method Ref.	:	Assay for the Methylphenidate Prolonged-release Capsules monograph from BP 2021
Mobile Phase	:	Buffer: acetonitrile: methanol (300: 300: 400, v/v/v)
Buffer	:	0.16 % w/v solution of anhydrous sodium acetate adjusted to pH 4.0 with glacial acetic acid.
Diluent	:	Mobile phase
Flow rate	:	1.5 mL/min
Column Temp	:	25 °C
Injection Volume	:	10 µL
Detection	:	210 nm