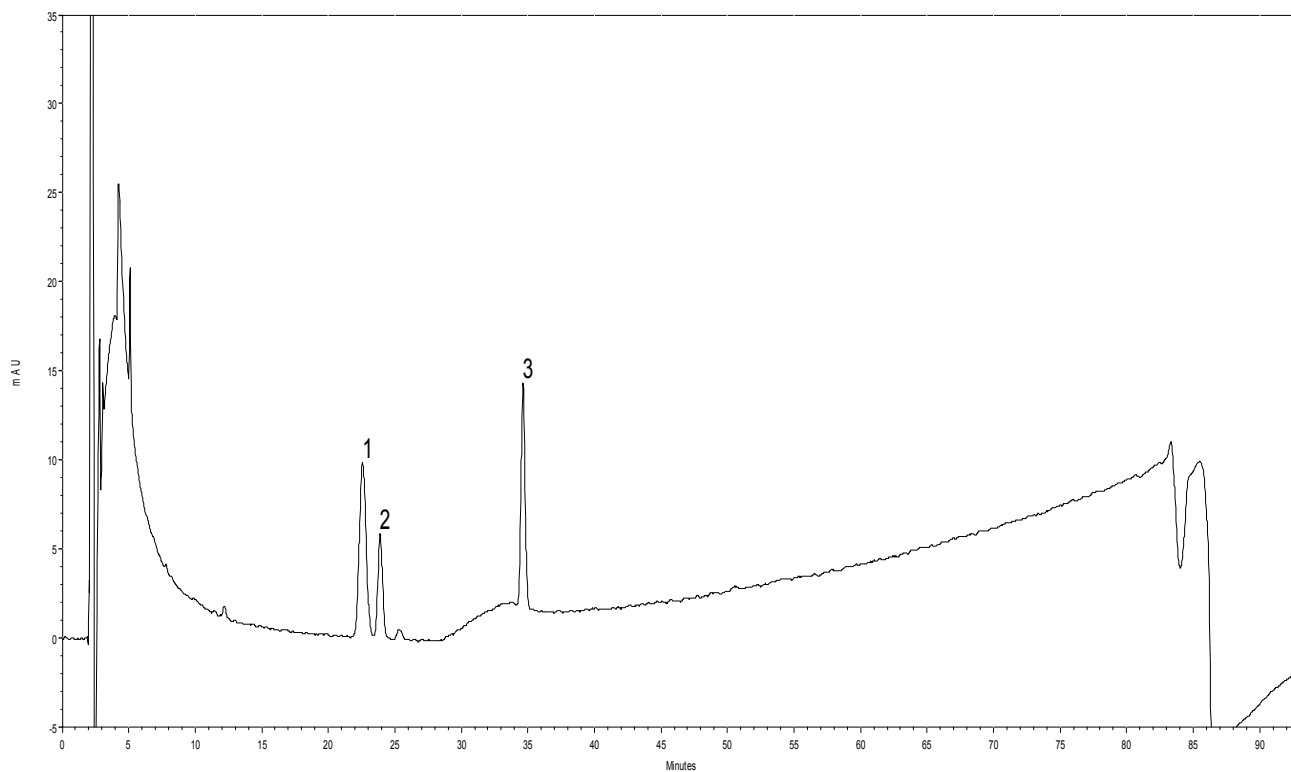


Azithromycin Capsules – BP 2018

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.

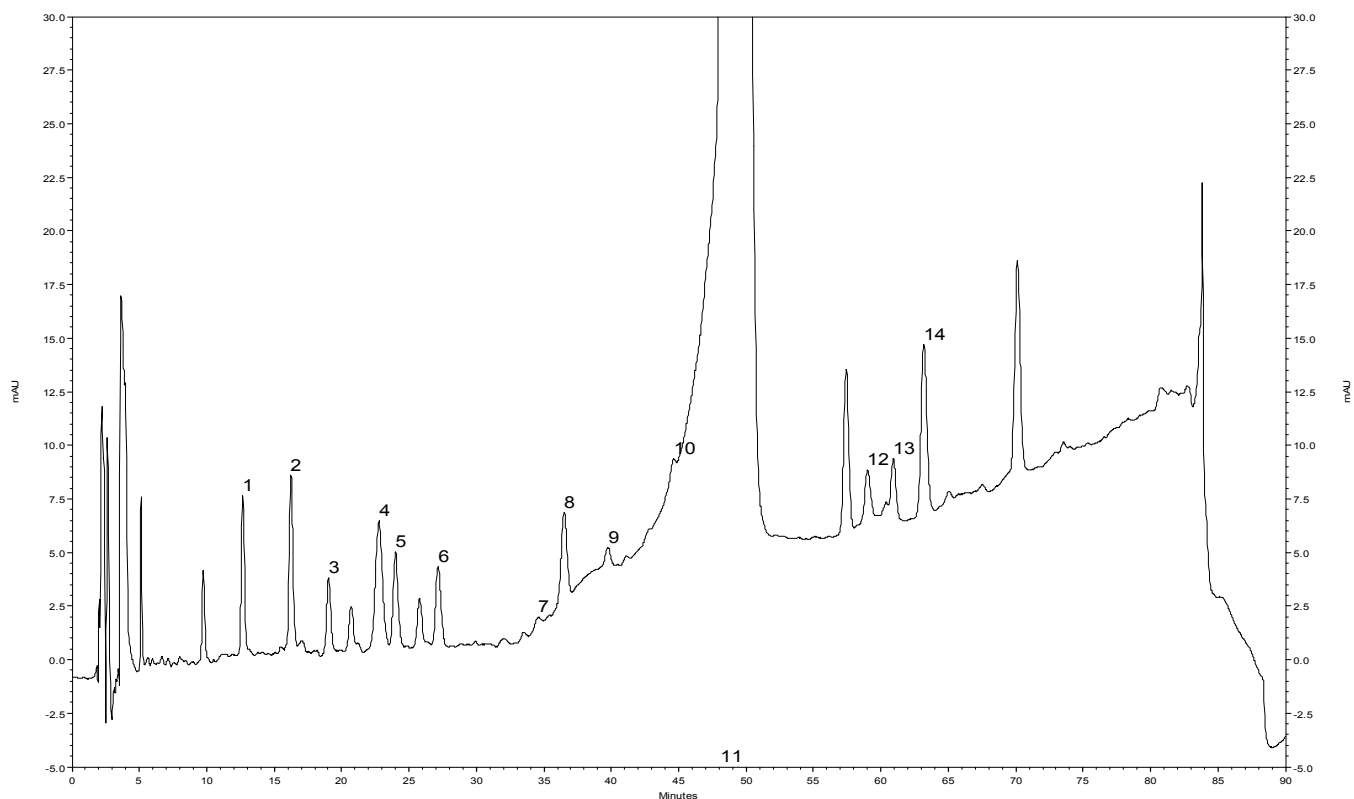
Typical chromatogram for solution (3) in the Related Substances test for Azithromycin Capsules as published in BP 2018.



Peak ID: 1: Impurity F, 2: Impurity J, 3: Impurity H



Typical chromatogram for solution (4) in the Related Substances test for Azithromycin Capsules as published in BP 2018.



Peak ID: 1: Impurity L; 2: Impurity M; 3: Impurity E; 4: Impurity F; 5: Impurity J; 6: Impurity I; 7: Impurity N; 8: Impurity A; 9: Impurity P; 10: Azithromycin; 11: Impurity O; 12: Impurity G; 13: Impurity B



Column : Waters, C18 Xterra MS (250 mm x 4.6 mm, 5 µm)
Method Ref. : Related substances for the Azithromycin Capsules monograph from BP 2018
Mobile Phase A : 0.180 % w/v solution of anhydrous disodium hydrogen orthophosphate adjusted to pH 8.9 with dilute orthophosphoric acid or with dilute sodium hydroxide solution.

Mobile phase B : Methanol: acetonitrile (25:75 v/v)

Gradient: :

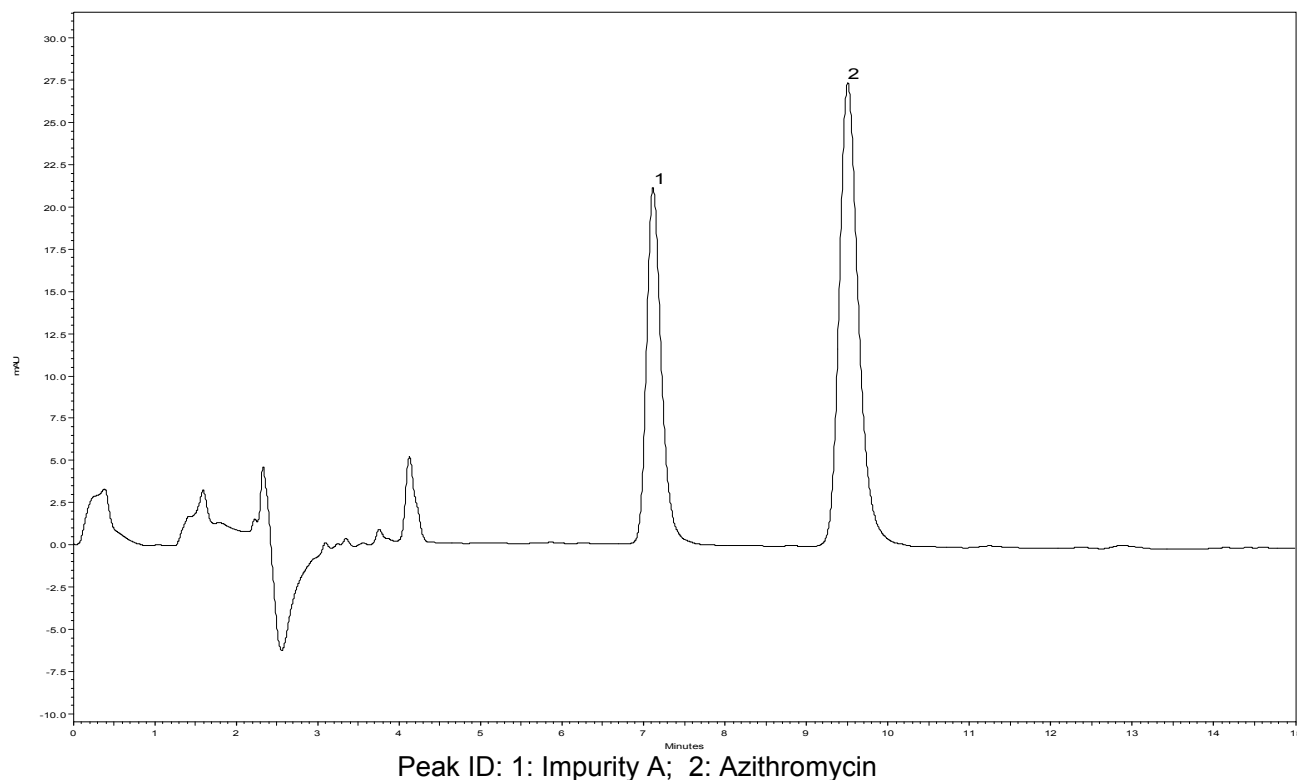
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0 – 30	50 → 45	50 → 55
30 – 35	45 → 40	55 → 60
35 – 80	40 → 25	60 → 75
80 – 81	25 → 50	75 → 50
81 – 93	50	50

Diluent: Solvent A (35 volumes of 0.173 % w/v solution of ammonium dihydrogen orthophosphate adjusted to pH 10.0 with ammonia, 35 volumes of methanol and 30 volumes of acetonitrile).

Flow Rate : 1.0 mL/min
Column Temp : 60 °C
Injection Volume : 50 µL
Detection : UV, 210 nm



Typical chromatogram for solution (3) in the Assay test for Azithromycin Capsules as published in BP 2018.



Column : Shodex, Asahipak ODP-50 (250 mm x 4.6 mm, 5 μ m)
Method Ref. : Assay for the Azithromycin Capsules monograph from BP 2018
Mobile Phase : Acetonitrile: buffer (60:40, v/v)
Diluent : Solvent A (40 volumes of 0.67 % w/v solution of dipotassium hydrogen orthophosphate adjusted to pH 8.0 with orthophosphoric acid and 60 volumes of acetonitrile)
Flow Rate : 1.0 mL/min
Column Temp : 40 $^{\circ}$ C
Injection Volume : 10 μ L
Detection : UV, 210 nm