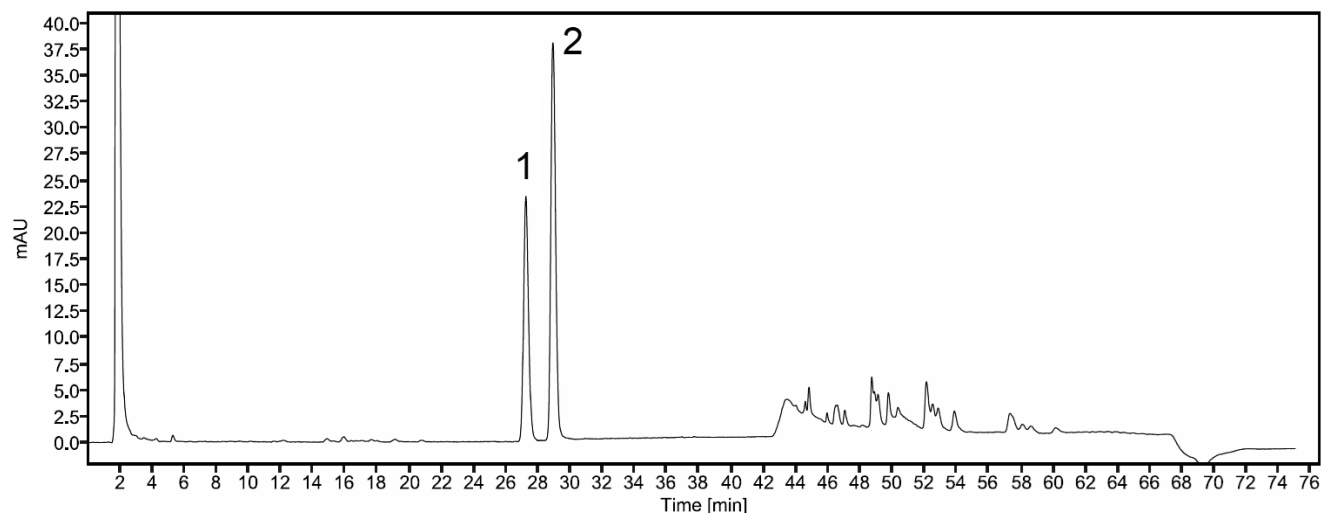




Solifenacin Oral Suspension – BP 2025

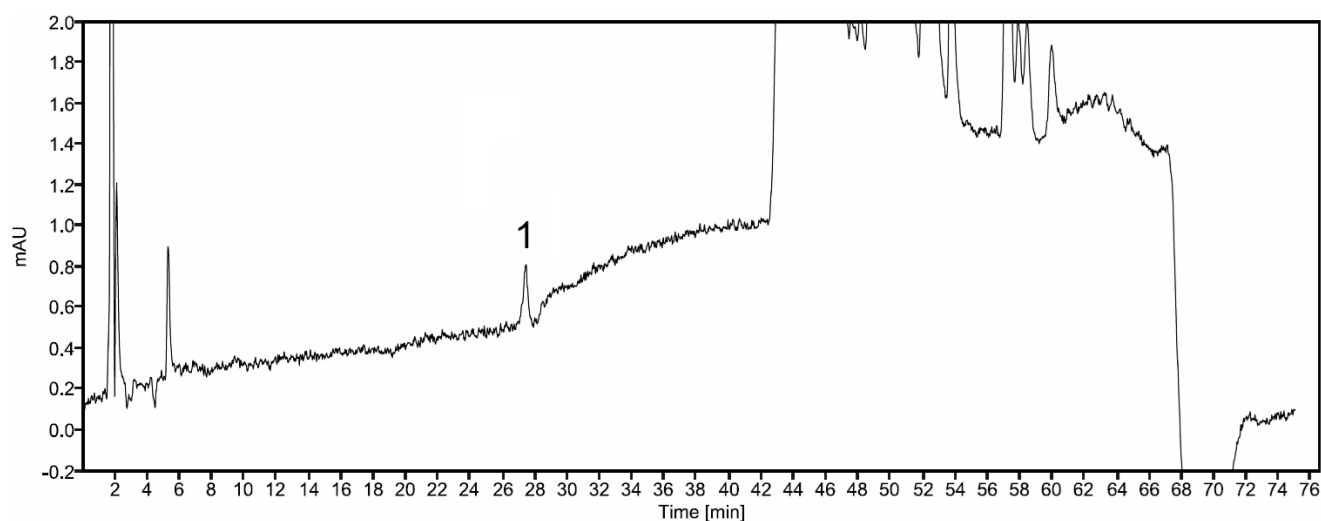
These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for solution (3) from the Related Substances test for Solifenacin Oral Suspension as published in BP 2025.



Peak ID: 1: Solifenacin. 2: Impurity I.

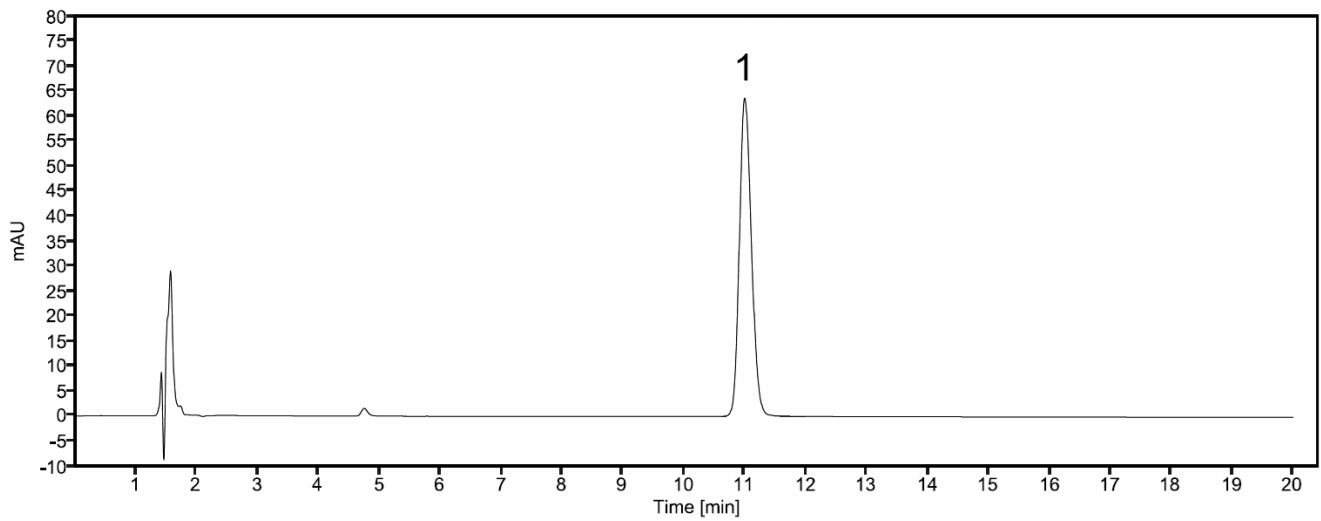
Typical chromatogram for solution (4) from the Related Substances test for Solifenacin Oral Suspension as published in BP 2025.



Peak ID: 1: Solifenacin.

Column	Waters XTerra MS C18 (150 mm x 4.6 mm, 3.5 µm)			
Method Ref.	Related Substances for the Solifenacin Oral Suspension monograph from BP 2025			
Mobile Phase A	1 volume of acetonitrile and 4 volumes of a 0.05M ammonium dihydrogen orthophosphate solution, adjusted to pH 2.4 with orthophosphoric acid			
Mobile Phase B	Acetonitrile			
Diluent (Solution A)	Acetonitrile: 0.1M Hydrochloric acid (2:3, v/v)			
Flow rate	Refer to gradient table below			
Column Temp	40°C			
Autosampler Temp	5°C			
Injection Volume	15 µL			
Detection	210 nm			
Gradient				
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Flow rate (mL/min)	Comment
0 – 25	95 → 90	5 → 10	1.0	linear gradient
25 – 40	90 → 75	10 → 25	1.0	linear gradient
40 – 41	75 → 50	25 → 50	1.0	linear gradient
41 – 65	50	50	1.0	isocratic
65 – 66	50 → 95	50 → 5	1.0	linear gradient
66 – 75	95	5	1.0	re-equilibration

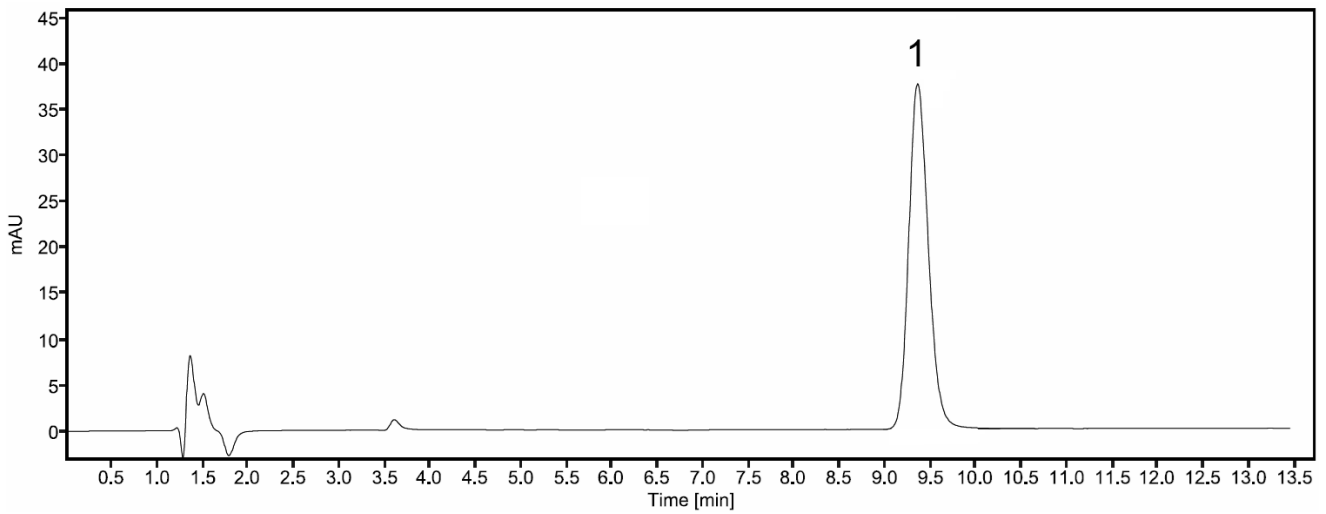
Typical chromatogram for solution (2) from the Assay test for Solifenacin Oral Suspension as published in BP 2025.



Peak ID: 1: Solifenacin.

Column	Waters XTerra MS C18 (150 mm x 4.6 mm, 3.5 µm)
Method Ref.	Assay for the Solifenacin Oral Suspension monograph from BP 2025
Buffer	0.05M Ammonium dihydrogen orthophosphate adjusted to pH 2.4 with orthophosphoric acid
Mobile Phase	Acetonitrile: Buffer (3:7 v/v)
Diluent (Solution A)	Acetonitrile: 0.1M Hydrochloric acid (20:30, v/v)
Flow rate	1.0 mL/min
Column Temp	40°C
Autosampler Temp	5°C
Injection Volume	25 µL
Detection	210 nm

Typical chromatogram for solution (2) from the Assay test for Solifenacin Oral Suspension as published in BP 2025 using scaled chromatographic conditions.



Peak ID: 1: Solifenacin.

Column	Waters XTerra MS C18 (150 mm x 2.1 mm, 3.5 µm)
Method Ref.	Assay for the Solifenacin Oral Suspension monograph from BP 2025
Buffer	0.05M Ammonium dihydrogen orthophosphate adjusted to pH 2.4 with orthophosphoric acid
Mobile Phase	Acetonitrile: Buffer (3:7 v/v)
Diluent (Solution A)	Acetonitrile: 0.1M Hydrochloric acid (20:30, v/v)
Flow rate	0.31 mL/min
Column Temp	40°C
Autosampler Temp	5°C
Injection Volume	5.2 µL
Detection	210 nm