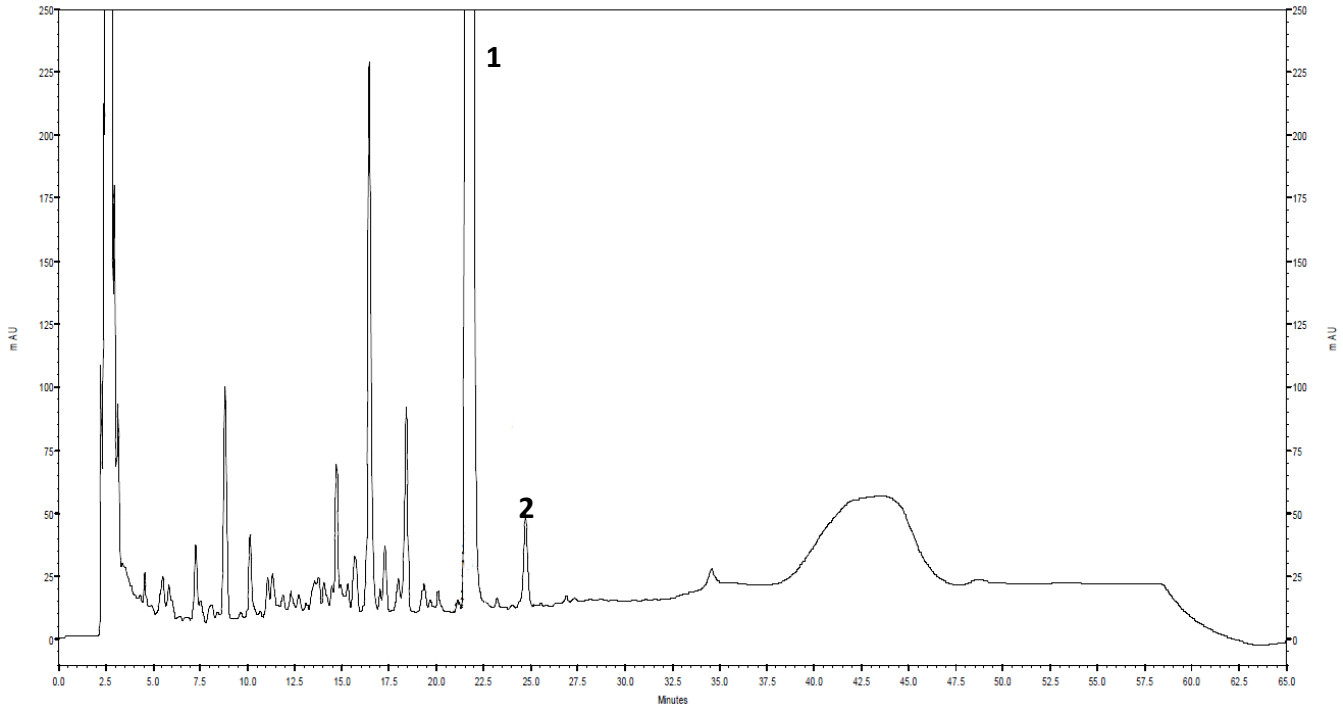
Solifenacin Tablets – BP 2023

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.

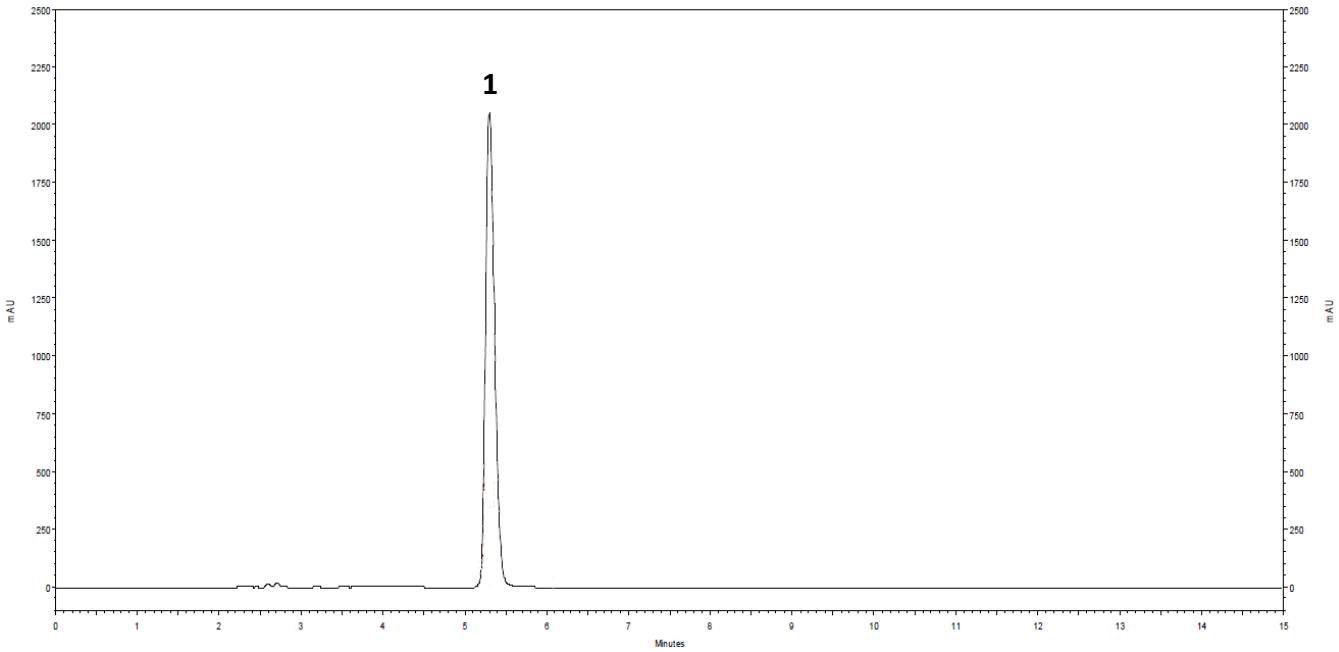
Typical chromatogram for solution (3) in the Related substances test for Solifenacin Tablets as published in BP 2023.



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

Column	Waters Symmetry C8 (250 mm x 4.6 mm, 5 µm)
Method Ref.	Related substances for the Solifenacin Tablets monograph from BP 2023
Mobile Phase A	Acetonitrile : methanol : buffer (15:15:70, v/v/v)
Mobile Phase B	Buffer : acetonitrile : methanol (30:35:35, v/v/v)
Buffer	4.11 g/L potassium dihydrogen orthophosphate solution with 1 mL triethylamine, adjusted to pH 3.3 with 85% orthophosphoric acid
Diluent	Buffer : acetonitrile (50:50, v/v)
Flow rate	1.0 mL/min
Column Temp	30 °C
Injection Volume	10 µL
Detection	220 nm

Typical chromatogram for solution (2) in the Assay test for Solifenacin Tablets as published in BP 2023.



Peak ID: 1: Solifenacin

Column	Agilent Zorbax SB-CN (250 mm x 4.6 mm, 5.0 µm)
Method Ref.	Assay for the Solifenacin Tablets monograph from BP 2023
Mobile Phase	Buffer : a solution containing 20 volumes of water, 40 volumes of acetonitrile and 40 volumes of methanol (40;60, v/v)
Buffer	3.4 g/L potassium dihydrogen orthophosphate solution adjusted to pH 3.5 with 85% orthophosphoric acid
Diluent	Mobile phase
Flow rate	1.0 mL/min
Column Temp	35 °C
Injection Volume	20 µL
Detection	220 nm