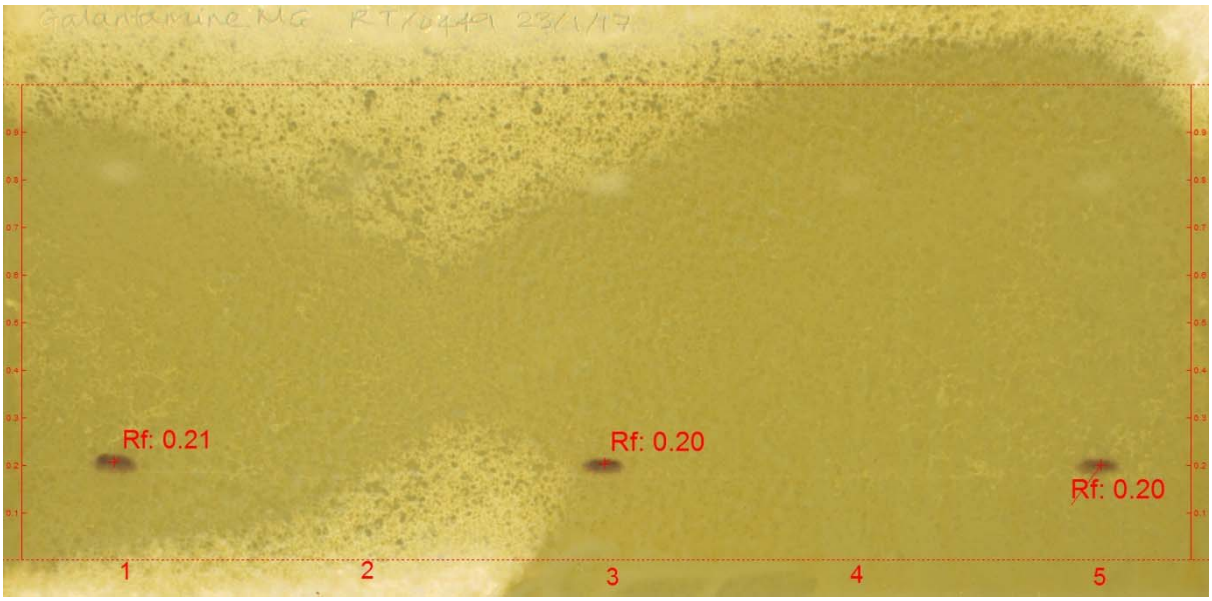
Galantamine Oral Solution – BP 2020

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.

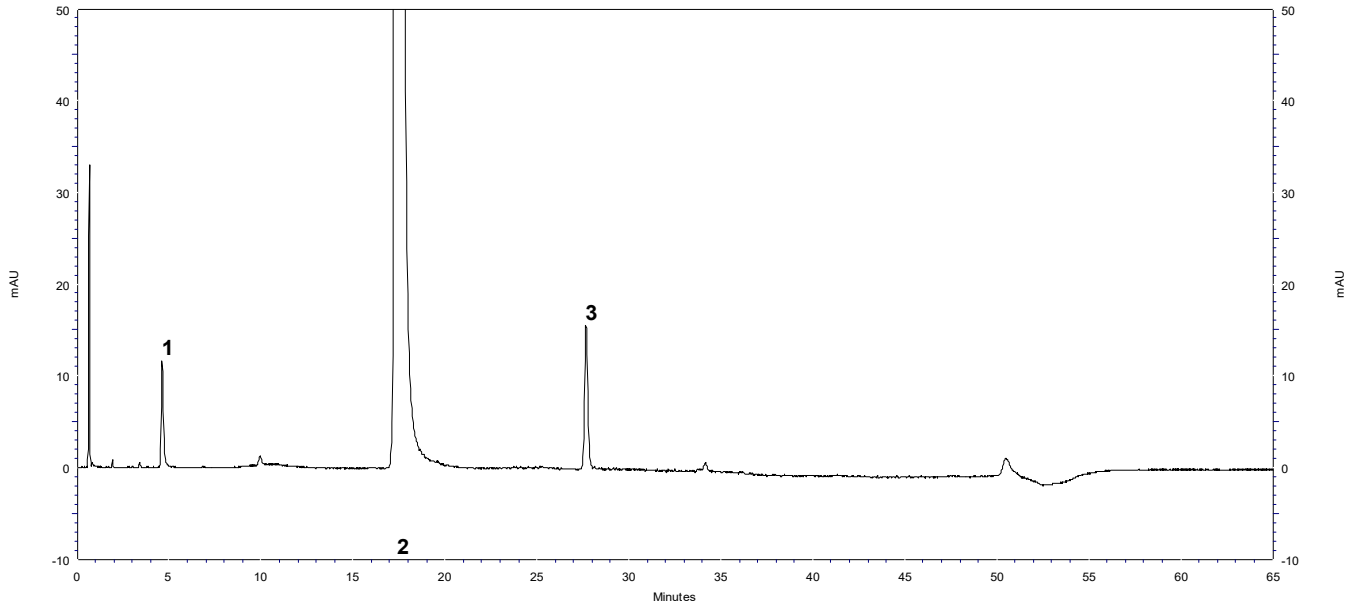
Typical chromatogram for the Identification test for Galantamine Oral Solution by Thin Layer Chromatography as published in BP 2020.



1	0.04 % w/v galantamine standard solution
2	Blank
3	0.02 % w/v oral solution sample solution
4	Blank
5	0.04 % w/v galantamine standard solution

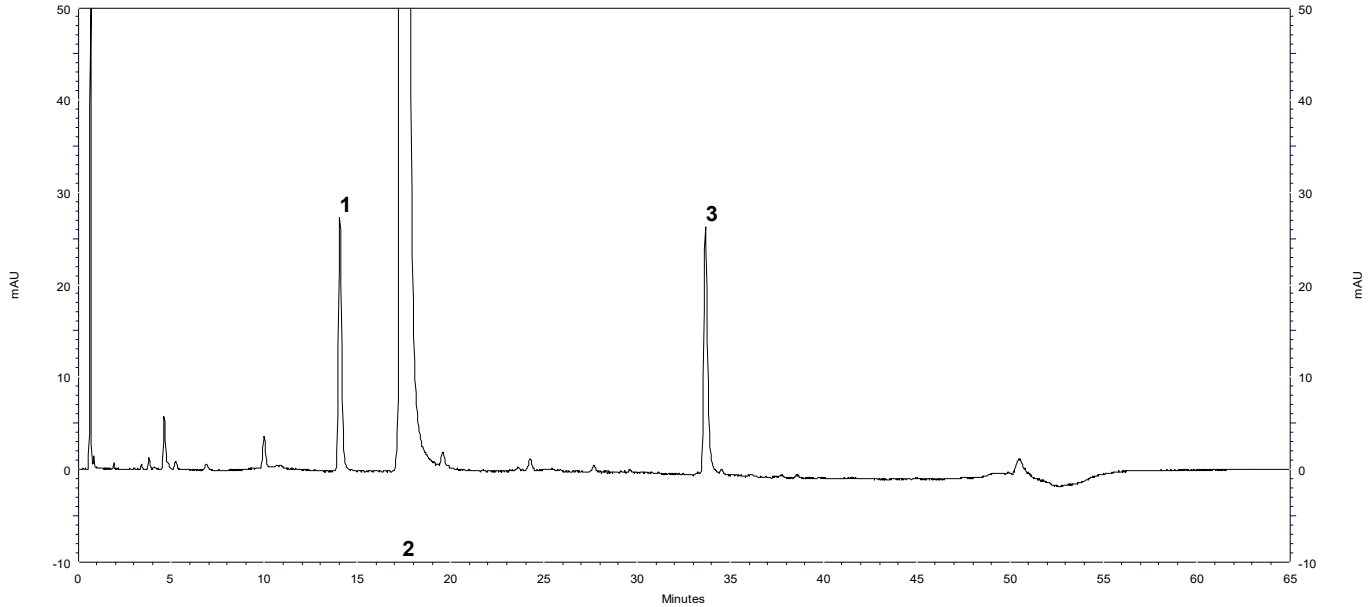
TLC plate	Merck HPTLC silica gel 60 F_{254} plate 20 cm × 10 cm
Plate preconditioning	N/A
Diluent	Acetonitrile
Mobile Phase	Glacial acetic acid: butanol: water (10:40:50, v/v/v) mixed in a separating funnel, and the top layer used as mobile phase
Mobile Phase volume	100 mL
Band application	5 mm band size with a spotting volume of 10 µL
Chamber saturation	20 minutes at room temperature
Development	80 mm
Development time	105 minutes
Drying time	5 minutes in air
Derivatisation	Sprayed with potassium iodobismuthate solution, immediately followed by hydrogen peroxide, 3 % solution
Visualisation	Derivatised plate was visualised under white light

Typical chromatogram for solution (3) in the Related Substances test for Galantamine Oral Solution as published in BP 2020.



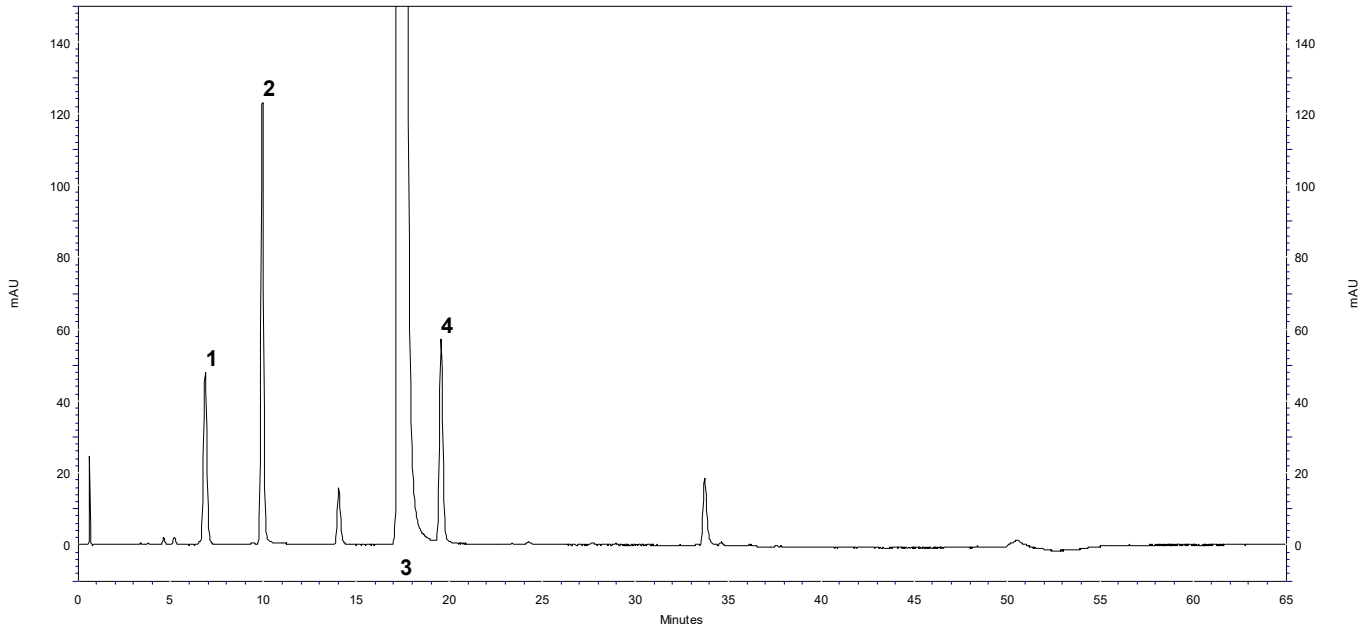
Peak ID: 1: Impurity E; 2: Galantamine; 3: Impurity A

Typical chromatogram for solution (4) in the Related Substances test for Galantamine Oral Solution as published in BP 2020.



Peak ID: 1: Impurity C; 2: Galantamine; 3: Impurity D

Typical chromatogram for solution (5) in the Related Substances test for Galantamine Oral Solution as published in BP 2020.



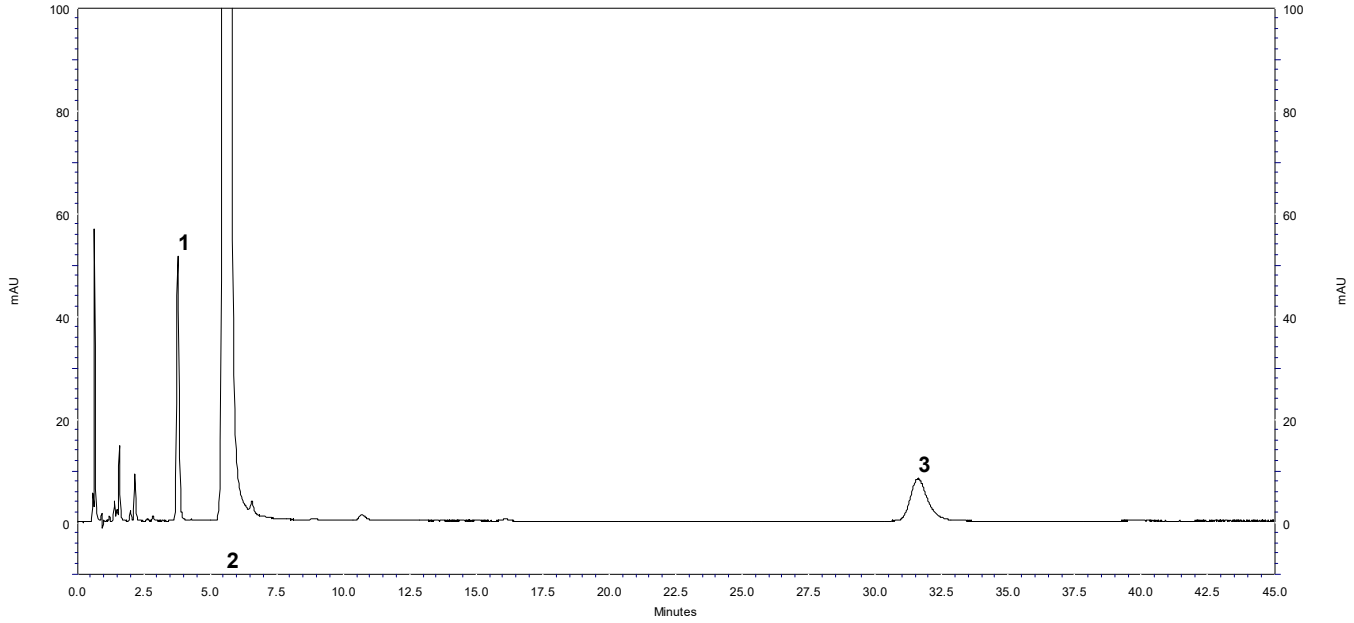
Peak ID: 1: Impurity 2; 2: Impurity 1; 3: Galantamine; 4: Impurity B

Column	:	Waters, C18 XTerra RP (100 mm x 4.6 mm, 3.5 µm)
Method Ref.	:	Related substances for the Galantamine Oral Solution monograph from BP 2020
Buffer	:	0.079 % w/v disodium hydrogen phosphate and 0.246 % w/v sodium dihydrogen phosphate
Mobile Phase A	:	Methanol: buffer (5:95, v/v)
Mobile Phase B	:	Acetonitrile
Gradient	:	

Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0 – 6	100	0
6 – 20	100 → 95	0 → 5
20 – 35	95 → 85	5 → 15
35 – 50	85 → 80	15 → 20
50 – 51	80 → 100	20 → 0
51 – 65	100	0

Diluent	:	Methanol: water (5:95, v/v)
Flow rate	:	1.5 mL/min
Column Temp	:	55 °C
Injection Volume	:	20 µL
Detection	:	UV, 230 nm

Typical chromatogram for solution (3) in the Assay test for Galantamine Oral Solution as published in BP 2020.



Peak ID: 1: Impurity C; 2: Galantamine; 3: Impurity D

Column	:	Waters, C18 XTerra RP (100 mm x 4.6 mm, 3.5 µm)
Buffer	:	0.079 % w/v disodium hydrogen phosphate and 0.246 % w/v sodium dihydrogen phosphate
Solution A	:	Methanol: buffer (5:95, v/v)
Mobile Phase	:	Acetonitrile: solution A (5:95, v/v)
Diluent	:	Methanol: water (5:95, v/v)
Flow rate	:	1.5 mL/min
Column Temp	:	55 °C
Injection Volume	:	20 µL
Detection	:	UV, 230 nm