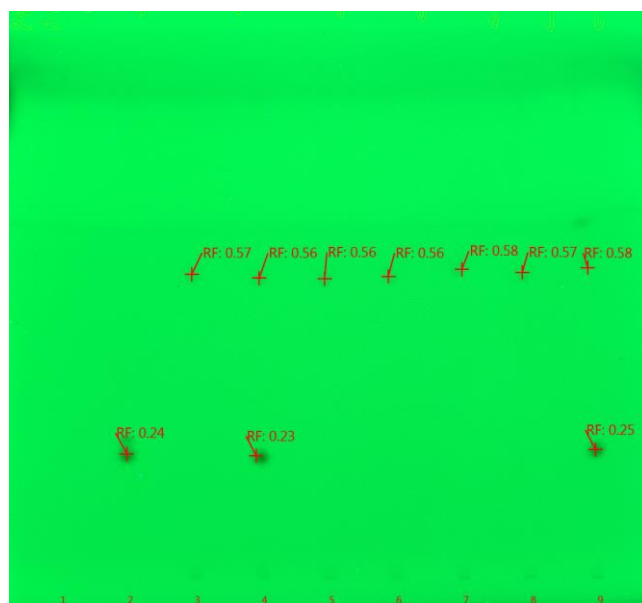




Rivastigmine Capsules – BP 2022

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 Rivastigmine Capsules by Thin Layer Chromatography as published in BP 2022.

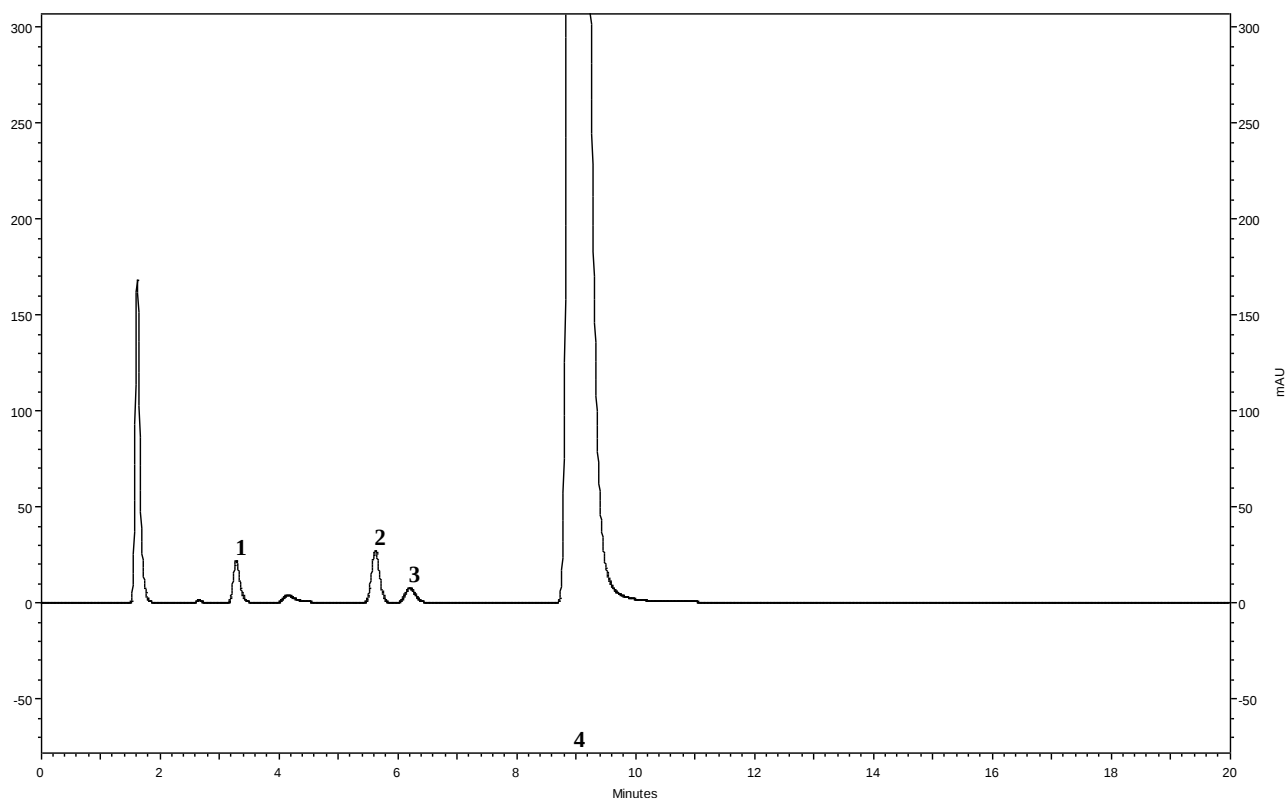


- | | |
|-------|--|
| 1 | Blank |
| 2 | 0.036 % w/v pyridostigmine bromide |
| 3 | 0.0576 % w/v rivastigmine hydrogen tartrate |
| 4 & 9 | System suitability solution (0.0576 % w/v rivastigmine hydrogen tartrate & 0.036 % w/v pyridostigmine bromide) |
| 5-8 | 0.036 % w/v rivastigmine (solution (1)) |

TLC plate	Merck TLC silica gel 60 F ₂₅₄ Plate, 20 cm × 20 cm
Plate preconditioning	N/A
Diluent	Methanol
Mobile Phase	Formic acid: water: methanol: dichloromethane (2: 5: 30: 70, v/v/v/v)
Mobile Phase volume	107 mL
Band application	3 mm band size with a spotting volume of 10 µL
Development	160 mm
Development time	60 minutes
Drying time	10 minutes in air
Derivatisation	N/A
Visualisation	Developed plate examined under UV light (254 nm)



Typical chromatogram for solution (3) in the Related Substances test for Rivastigmine Capsules as published in BP 2022.

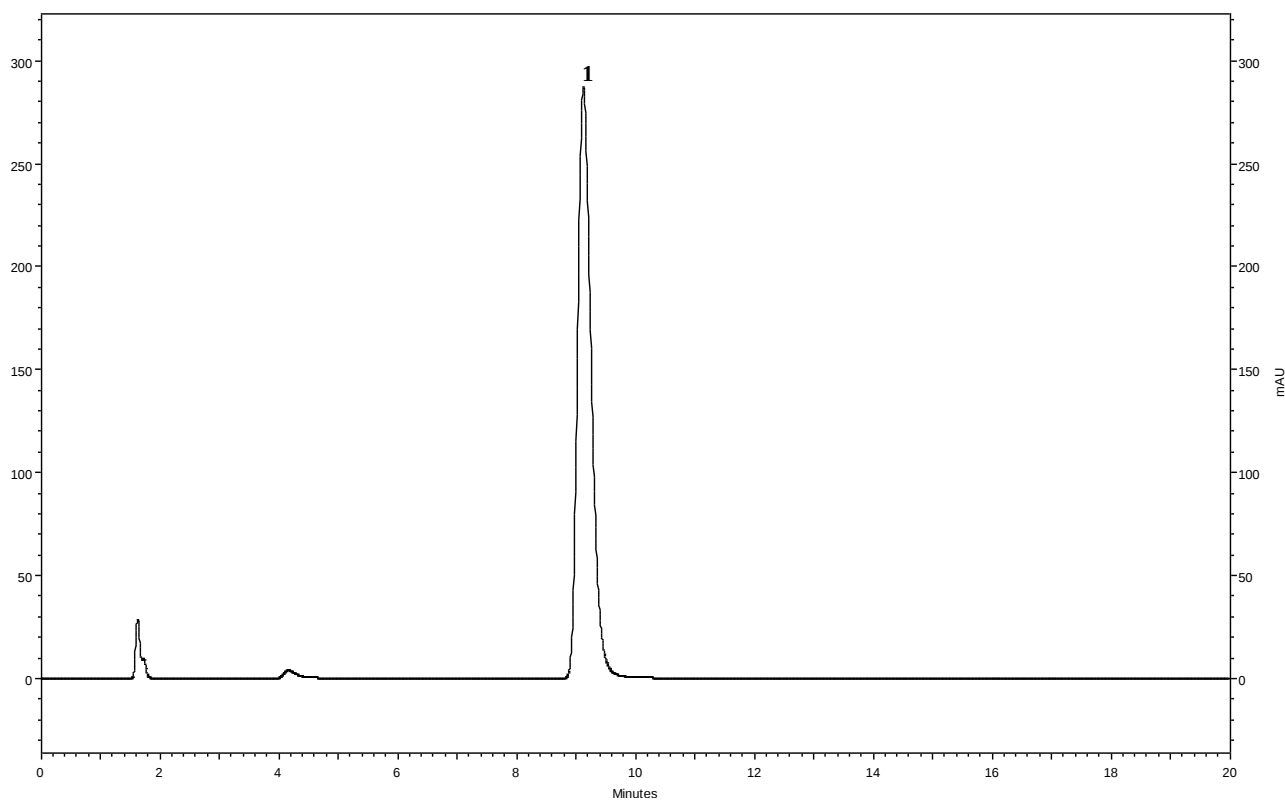


Peak ID: 1: Impurity A; 2: Impurity C; 3: Impurity B; 4: Rivastigmine

Column	: Nucleodur C18 (250 mm x 4.0 mm, 5 µm)
Method Ref.	: Related substances for the Rivastigmine Capsules monograph from BP 2022
Mobile Phase	: Buffer : methanol R1 (42:58, v/v)
Buffer	: 0.89 % w/v disodium hydrogen phosphate dihydrate, adjusted to pH 7.0 with orthophosphoric acid
Diluent	: Mobile phase
Flow rate	: 1.0 mL/min
Column Temp	: 40 °C
Injection Volume	: 20 µL
Detection	: 214 nm



Typical chromatogram for solution (2) in the Assay test for Rivastigmine Capsules as published in BP 2022.



Peak ID: 1: Rivastigmine

Column	: Nucleodur C18 (250 mm x 4.0 mm, 5 µm)
Method Ref.	: Assay for the Rivastigmine Capsules monograph from BP 2022
Mobile Phase	: Buffer : methanol R1 (42:58, v/v)
Buffer	: 0.89 % w/v disodium hydrogen phosphate dihydrate, adjusted to pH 7.0 with orthophosphoric acid
Diluent	: Mobile phase
Flow rate	: 1.0 mL/min
Column Temp	: 45 °C
Injection Volume	: 20 µL
Detection	: 214 nm