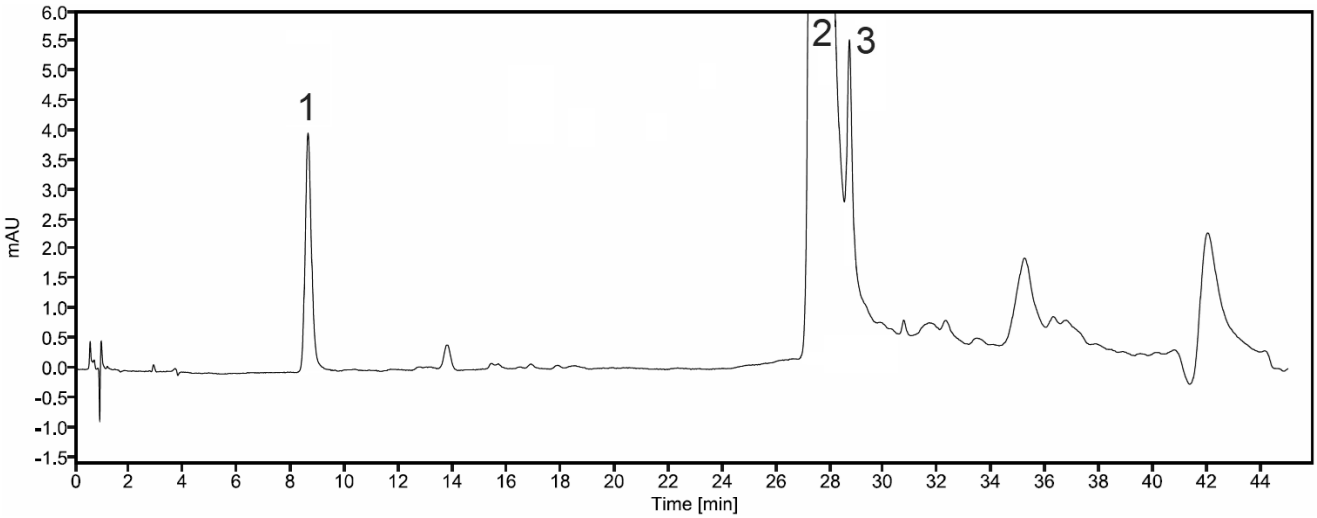
Imatinib Capsules – BP 2025

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 Imatinib Capsules as published in BP 2025.

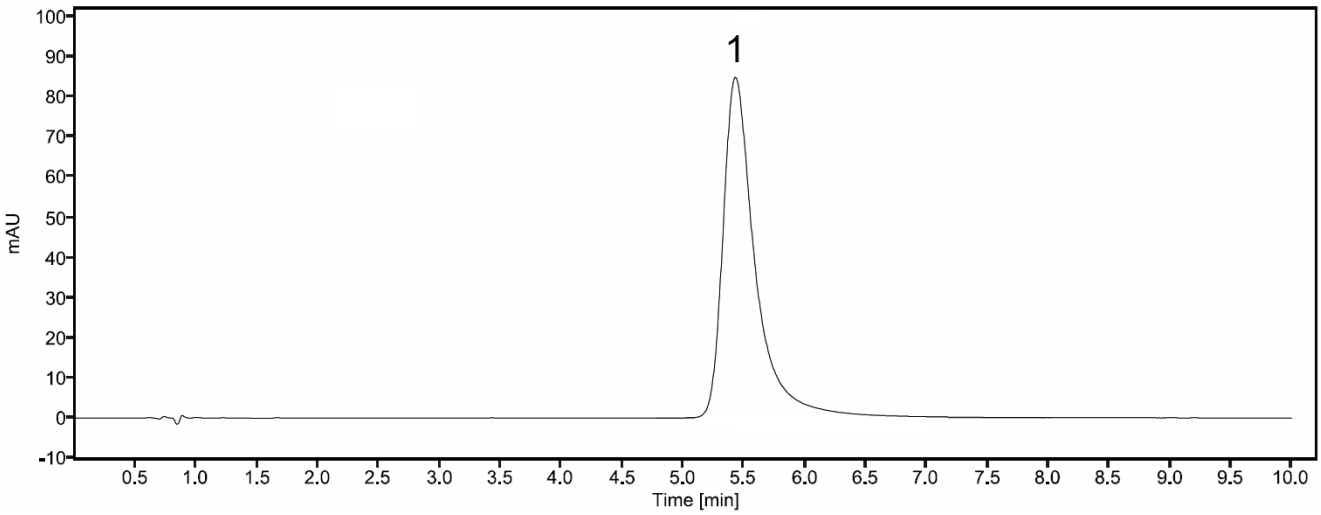


Peak ID: 1: Impurity Z3. 2: Imatinib. 3: Impurity C.

Column	Waters Symmetry C18 (150 mm x 3.9 mm, 5 µm)
Method Ref.	Related Substances for the Imatinib Capsules monograph from BP 2025
Buffer	0.75% w/v of sodium octanesulfonate monohydrate in 1 volume of triethylamine and 500 volumes of water, adjusted to pH 6.2 with orthophosphoric acid
Mobile Phase A	Methanol: Buffer (2:98, v/v)
Mobile Phase B	Methanol
Diluent	50% Methanol
Flow rate	Refer to gradient table below

Column Temp	30°C			
Injection Volume	10 µL			
Detection	269 nm			
Gradient				
Time (minutes)	**Mobile phase A (% v/v)**	**Mobile phase B (% v/v)**	**Flow rate (mL/min)**	**Comment**
0 – 2	67	33	1.2	isocratic
2 – 15	67 → 52	33 → 48	1.2	linear gradient
15 – 22	52	48	1.2	isocratic
22 – 30	52 → 37	48 → 63	1.2	linear gradient
30 – 39	37	63	1.2	isocratic
39 – 40	37 → 67	63 → 33	1.2	linear gradient
40 – 45	67	33	1.2	re-equilibration

Typical chromatogram for solution (2) from the Assay test for Imatinib Capsules as published in BP 2025.



Peak ID: 1: Imatinib.

Column	Waters Symmetry C18 (150 mm x 3.9 mm, 5 µm)
Method Ref.	Assay for the Imatinib Capsules monograph from BP 2025
Buffer	0.75% w/v of sodium octanesulfonate monohydrate in 1 volume of triethylamine and 500 volumes of water, adjusted to pH 6.2 with orthophosphoric acid
Mobile Phase	Buffer: Methanol (42:58, v/v)
Diluent	Phosphate buffer solution pH 4.5, 0.05M
Flow rate	1.2 mL/min
Column Temp	30°C
Injection Volume	5 µL
Detection	269 nm