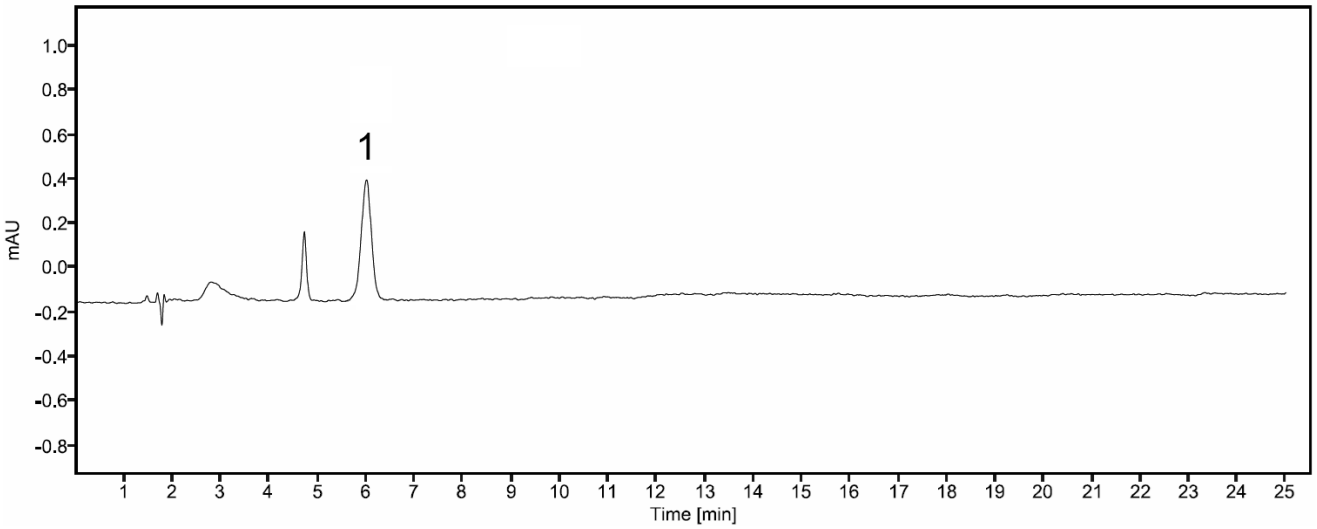
Clopidogrel Besilate Tablets – BP 2025

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 Impurity C test for Clopidogrel Besilate Tablets as published in BP 2025.

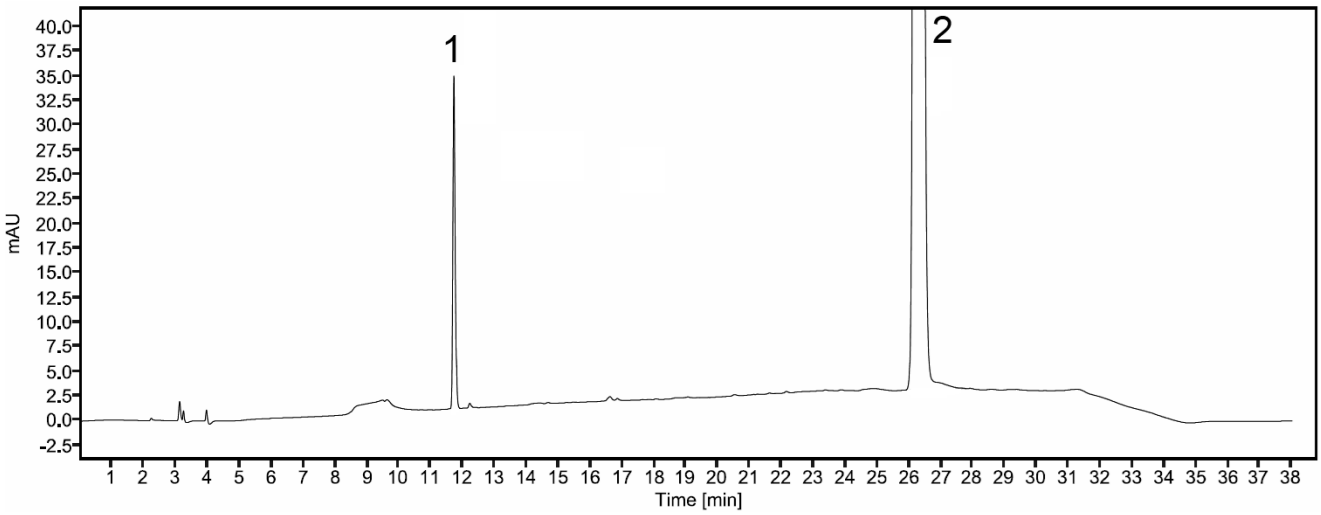


Peak ID: 1: Clopidogrel.

Column	Agilent Ultron ES-OVM (150 mm x 4.6 mm, 5 µm)
Method Ref.	Impurity C for the Clopidogrel Besilate Tablets monograph from BP 2025
Buffer	1.36 g/L Potassium dihydrogen orthophosphate adjusted to pH 4.7 with orthophosphoric acid
Mobile Phase	Acetonitrile: Buffer (25:75, v/v)
Diluent	Mobile phase
Flow rate	1.0 mL/min
Column Temp	25°C
Injection Volume	10 µL

Detection	220 nm

Typical chromatogram for solution (3) from the Related Substances test for Clopidogrel Besilate Tablets as published in BP 2025.



Peak ID: 1: Impurity A. 2: Clopidogrel.

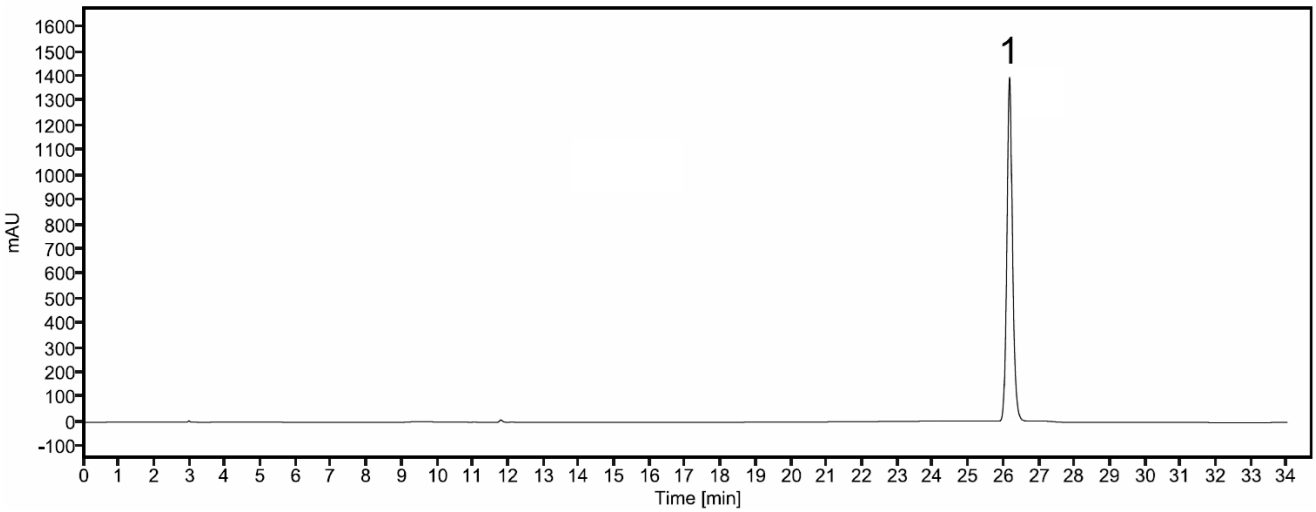
Column	Phenomenex Luna C8 (2) (250 mm x 4.6 mm, 5 µm)
Method Ref.	Related Substances for the Clopidogrel Besilate Tablets monograph from BP 2025
Buffer	1.36 g/L Potassium dihydrogen phosphate solution adjusted to pH 3.10 with orthophosphoric acid
Mobile Phase A	Buffer
Mobile Phase B	Buffer: Acetonitrile (30:70, v/v)
Diluent	Buffer: Acetonitrile (85:15, v/v)
Flow rate	Refer to gradient table below
Column Temp	25°C
Injection Volume	20 µL
Detection	220 nm

Gradient

Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Flow rate (mL/min)	Comment
0 – 20	90 → 0	10 → 100	1.0	linear gradient

20 – 28	0	100	1.0	isocratic
28 – 30	0 → 90	100 → 10	1.0	linear gradient
30 – 38	90	10	1.0	re-equilibration

Typical chromatogram for solution (2) from the Assay test for Clopidogrel Besilate Tablets as published in BP 2025.



Peak ID: 1: Clopidogrel.

Column	Phenomenex Luna C8 (2) (250 mm x 4.6 mm, 5 µm)
Method Ref.	Assay for the Clopidogrel Besilate Tablets monograph from BP 2025
Buffer	1.36 g/L Potassium dihydrogen phosphate solution adjusted to pH 3.10 with orthophosphoric acid
Mobile Phase A	Buffer
Mobile Phase B	Buffer: Acetonitrile (30:70, v/v)
Diluent	Buffer: Acetonitrile (85:15, v/v)
Flow rate	Refer to gradient table below
Column Temp	25°C
Injection Volume	20 µL
Detection	220 nm

Gradient

Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Flow rate (mL/min)	Comment
0 – 20	90 → 0	10 → 100	1.0	linear gradient

20 – 28	0	100	1.0	isocratic
28 – 30	0 → 90	100 → 10	1.0	linear gradient
30 – 34	90	10	1.0	re-equilibration