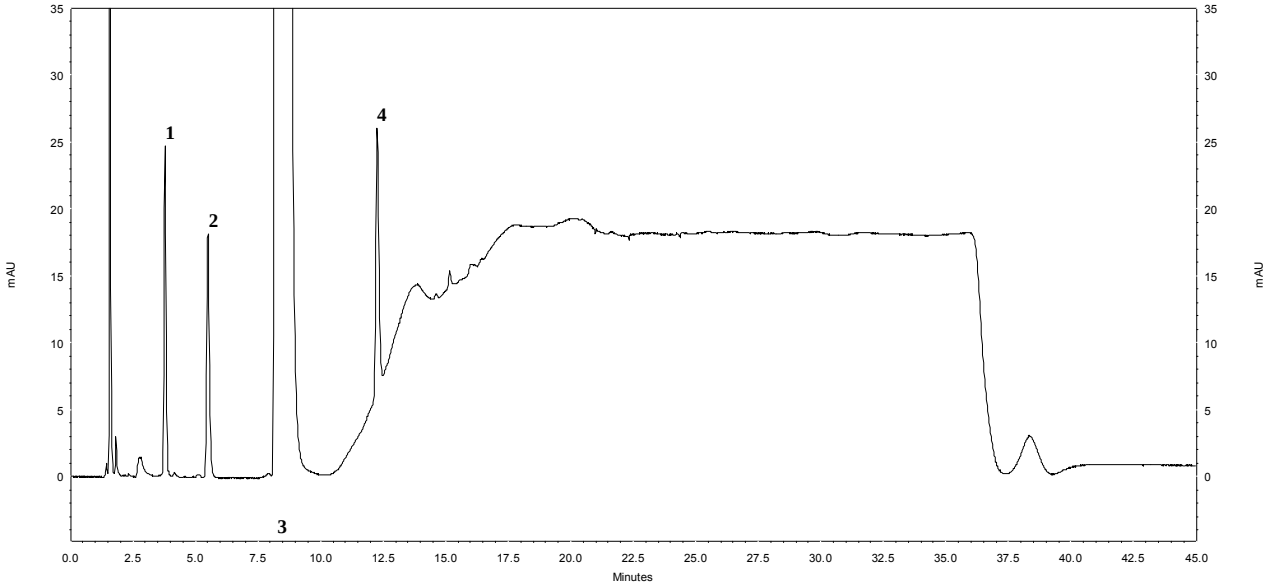
Amlodipine Besilate Tablets – BP 2019

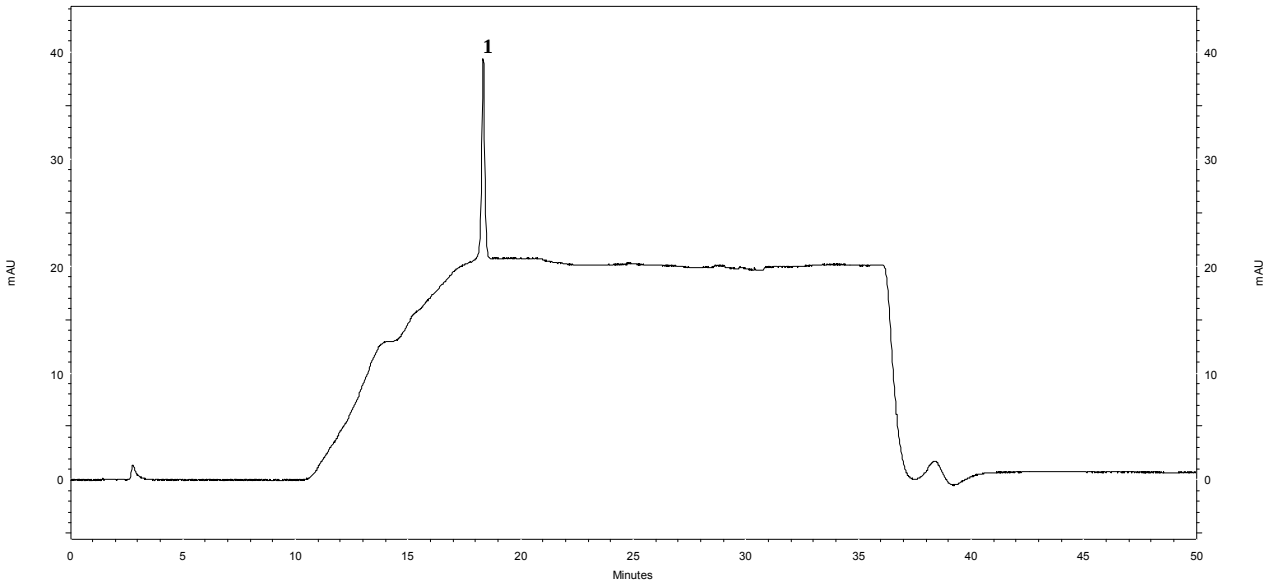
These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for solution (3) in the Related Substances test for Amlodipine Besilate Tablets as published in BP 2019.



Peak ID: 1: Impurity D; 2: Impurity F; 3: Amlodipine, 4: Impurity E

Typical chromatogram for solution (4) in the Related Substances test for Amlodipine Besilate Tablets as published in BP 2019.



Peak ID: 1: Impurity 1

Column : Phenomenex, Kinetex C18 (100 mm × 4.6 mm, 2.6 µm)

Mobile Phase A : 45 volumes of 0.03M potassium dihydrogen orthophosphate, adjusted to pH 3.0 with orthophosphoric acid, and 55 volumes of methanol

Mobile Phase B : 30 volumes of 0.03M potassium dihydrogen orthophosphate, adjusted to pH 3.0 with orthophosphoric acid, and 70 volumes of methanol

Gradient :

Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0 - 8	100	0
8 - 13	100 - 0	0 - 100
13 - 34	0	100
34 - 35	0 - 100	100 - 0
35 - 45	100	0

Sample diluent : a mixture of 45 volumes of 0.03M potassium dihydrogen orthophosphate and 55 volumes of methanol (solution A)

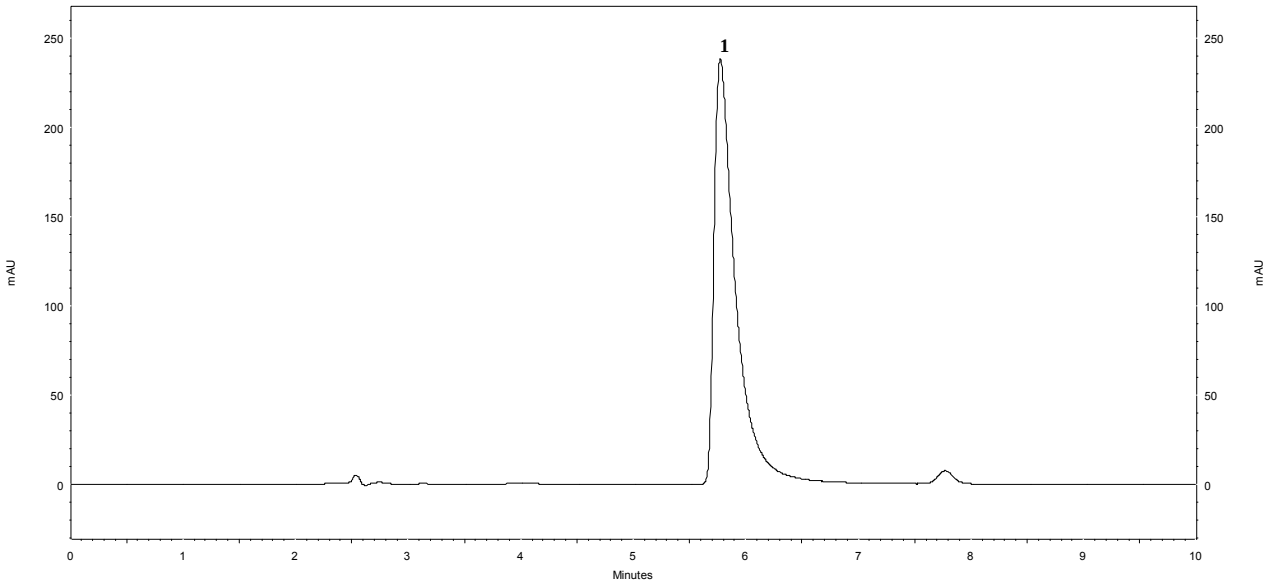
Flow Rate : 0.6 mL/min

Column Temp : 25°C

Injection Volume : 10 µL

Detection : UV, 238 nm

Typical chromatogram for solution (2) in the Assay test for Amlodipine Besilate Tablets as published in BP 2019.



Peak ID: 1: Amlodipine

Column	: Thermo, Hypersil C18 (250 mm x 4.6 mm, 5 µm)
Mobile Phase	: 30 volumes of 0.007% v/v of triethylamine in water, adjusted to pH 3.0 with orthophosphoric acid, 35 volumes of acetonitrile and 35 volumes of methanol
Sample diluent	: 15 volumes of acetonitrile, 35 volumes of methanol and 50 volumes of 0.007% v/v of trimethylamine in water, adjusted to pH 3.0 with orthophosphoric acid (solution B)
Flow Rate	: 1.0 mL/min
Column Temp	: 25°C
Injection Volume	: 20 µL
Detection	: UV, 240 nm