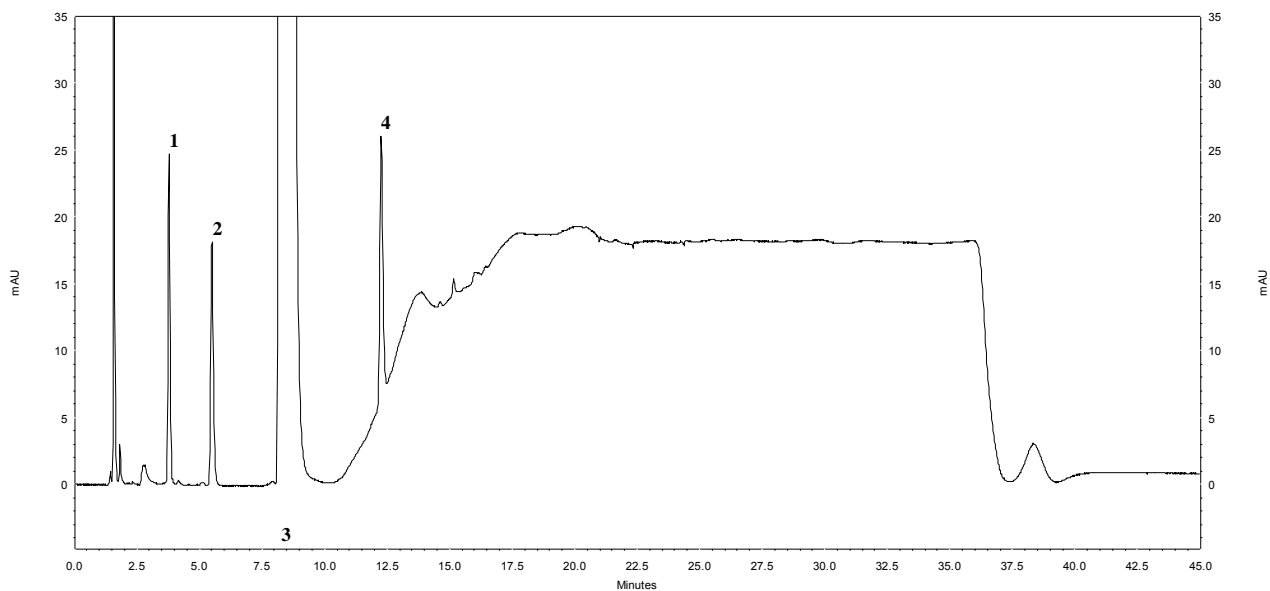




Amlodipine Oral Solution – BP 2019

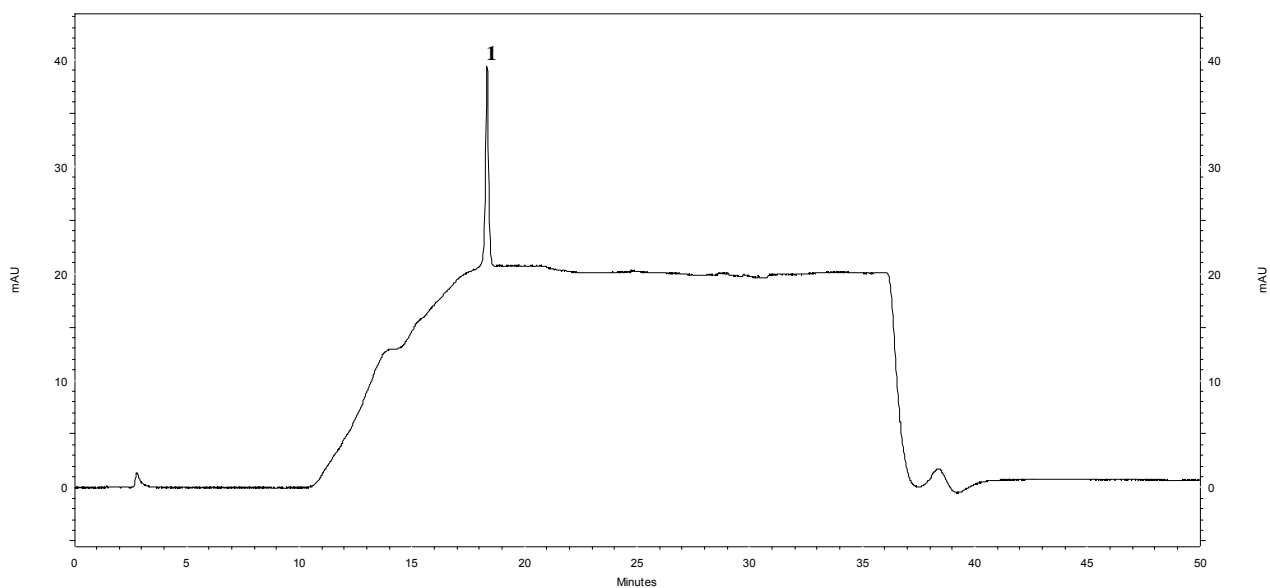
These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.

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



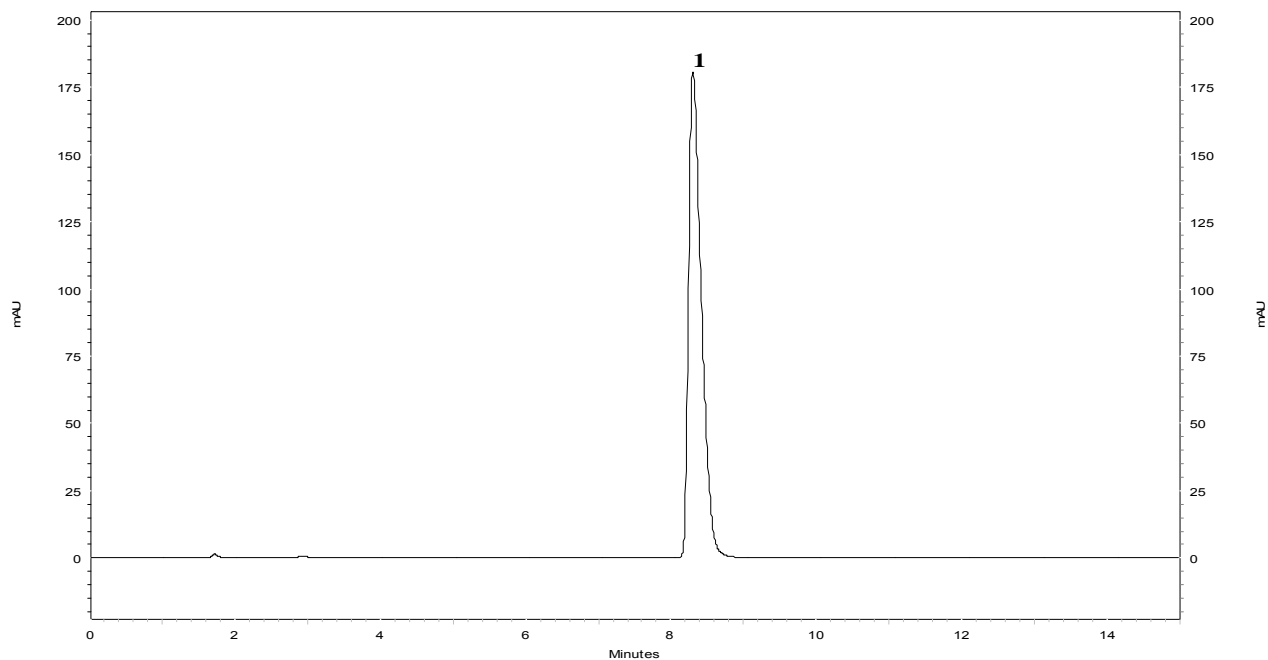
Column : Phenomenex, Kinetex C18 (100 mm × 4.6 mm, 2.6 µm)
Mobile Phase A : 45 volumes of 0.03M potassium dihydrogen orthophosphate, adjusted to pH 3.0 with orthophosphoric acid, and 55 volumes of methanol
Mobile Phase B : 30 volumes of 0.03M potassium dihydrogen orthophosphate, adjusted to pH 3.0 with 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 Oral Solution as published in BP 2019.



Peak ID: 1: Amlodipine

Column	: Phenomenex, Kinetex C18 (100 mm x 4.6 mm, 2.6 μ m)
Mobile Phase	: 45 volumes of 0.03M potassium dihydrogen orthophosphate, adjusted to pH 3.0 with orthophosphoric acid, and 55 volumes of methanol
Sample diluent	: Mobile phase
Flow Rate	: 0.6 mL/min
Column Temp	: 25°C
Injection Volume	: 10 μ L
Detection	: UV, 238 nm