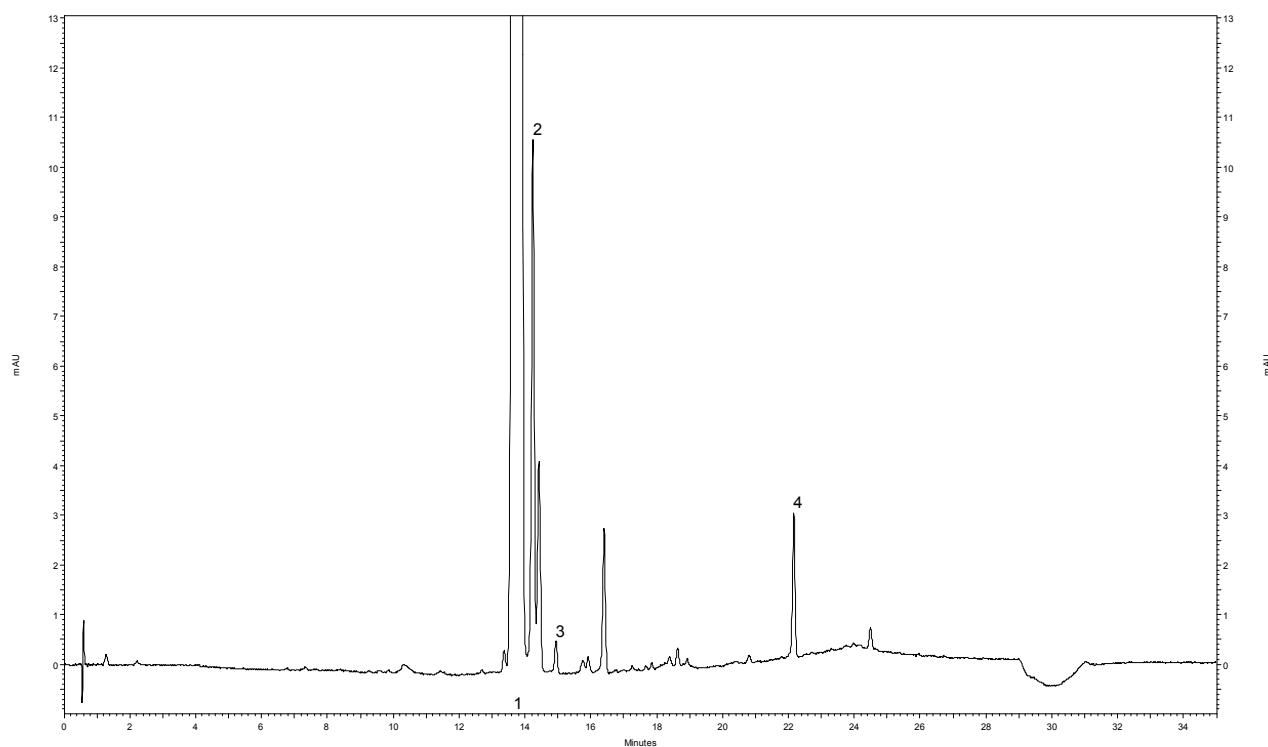




Fluvastatin prolonged-release Tablets – BP 2018

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.

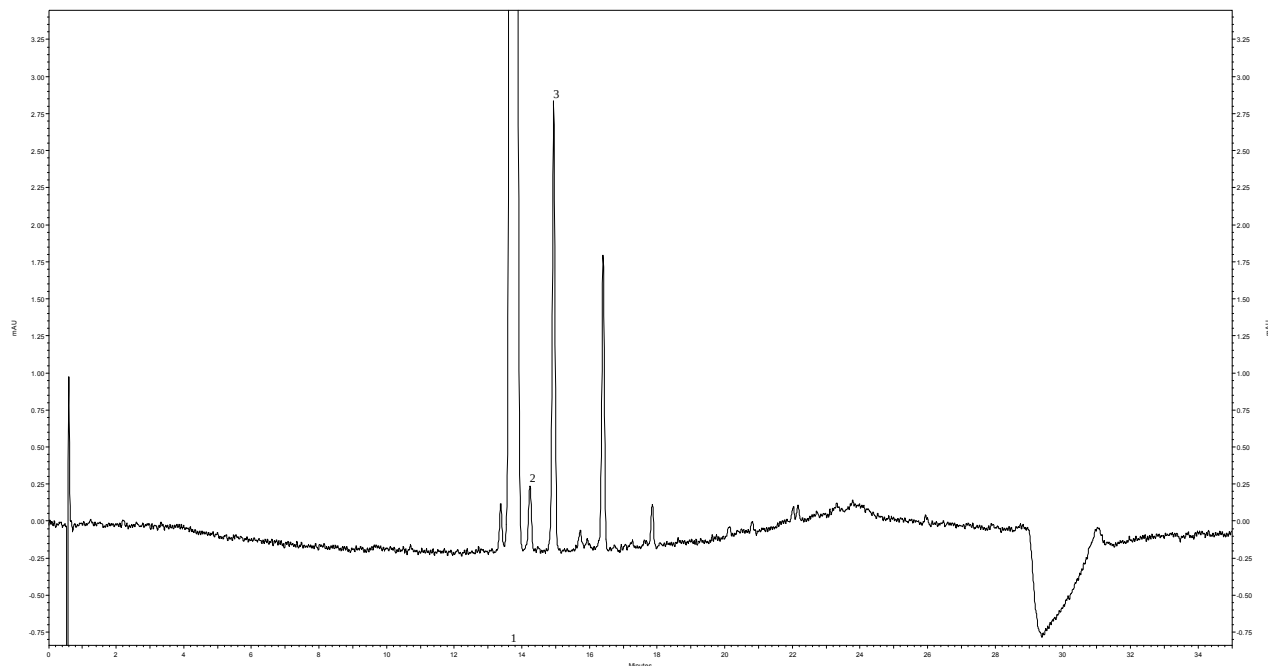
Typical chromatogram for solution (4) in the Related Substances test for Fluvastatin prolonged-release Tablets as published in BP 2018, at 305 nm.



Peak ID: 1: Fluvastatin; 2: Impurity A; 3: Impurity D; 4: Impurity B



Typical chromatogram for solution (3) in the Related Substances test for Fluvastatin prolonged-release Tablets as published in BP 2018, at 365 nm.

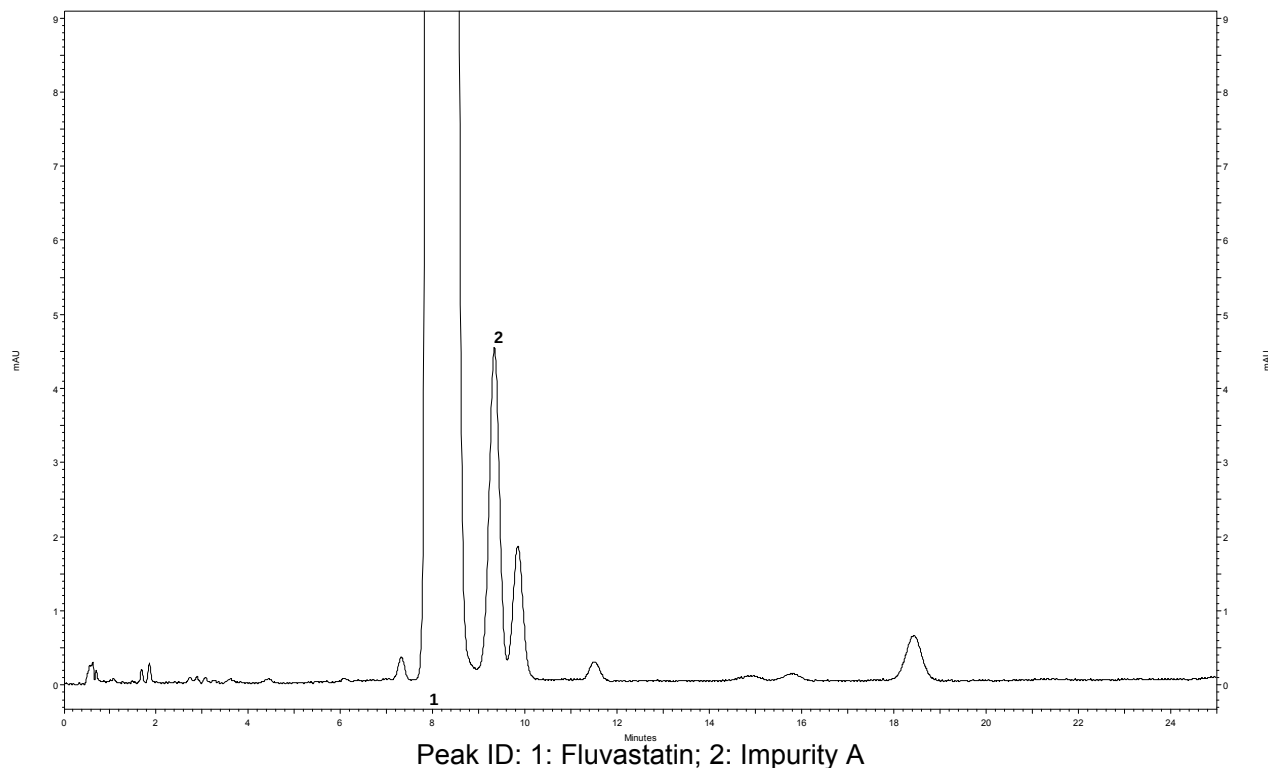


Peak ID: 1: Fluvastatin; 2: Impurity A; 3: Impurity D

Column	: YMC-Pack Pro S, C18 (100 mm x 4.6 mm, 3 µm)
Method Ref.	: Related Substances from the Fluvastatin prolonged-release Tablets draft monograph
Mobile phase A	: Buffer : acetonitrile : methanol (900:40:60, v/v/v)
Mobile phase B	: Buffer : acetonitrile : methanol (100:360:540, v/v/v)
Buffer	: 20 volumes of 1.38 M tetramethylammonium hydroxide added to 880 volumes of water, adjusted to pH 7.2 with orthophosphoric acid
Diluent	: Mobile phase A : mobile phase B (20:30, v/v)
Flow Rate	: 2.0 mL/min
Column Temp	: 40°C
Injection Volume	: 20 µL
Detection	: 305 nm and 365 nm



Typical chromatogram for solution (3) in the Assay test for Fluvastatin prolonged-release Tablets as published in BP 2018.



Column	: YMC-Pack Pro S, C18 (100 mm x 4.6 mm, 3 µm)
Method Ref.	: Assay method from Fluvastatin prolonged-release Tablets draft monograph
Mobile Phase	: Buffer : acetonitrile : methanol (500:240:360, v/v/v)
Buffer	: 0.069 M buffer tetramethylammonium hydroxide adjusted to pH 7.2 with orthophosphoric acid
Diluent	: Mobile phase
Flow Rate	: 2.0 mL/min
Column Temp	: 40°C
Injection Volume	: 20 µL
Detection	: UV, 305 nm