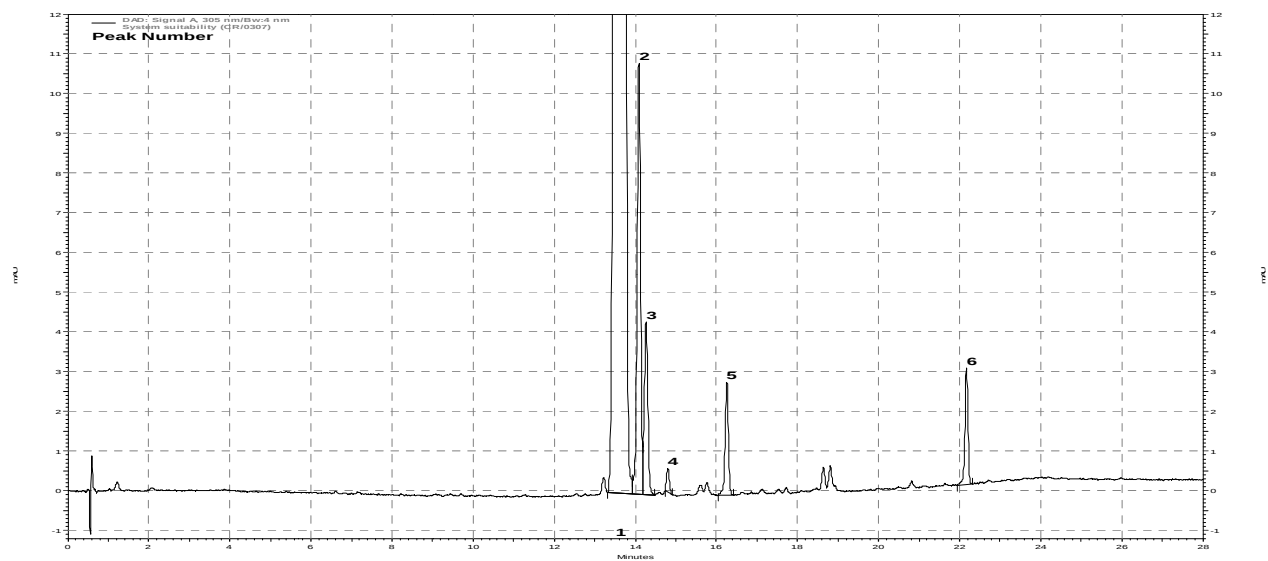


## Fluvastatin Prolonged-release Tablets – BP 2017

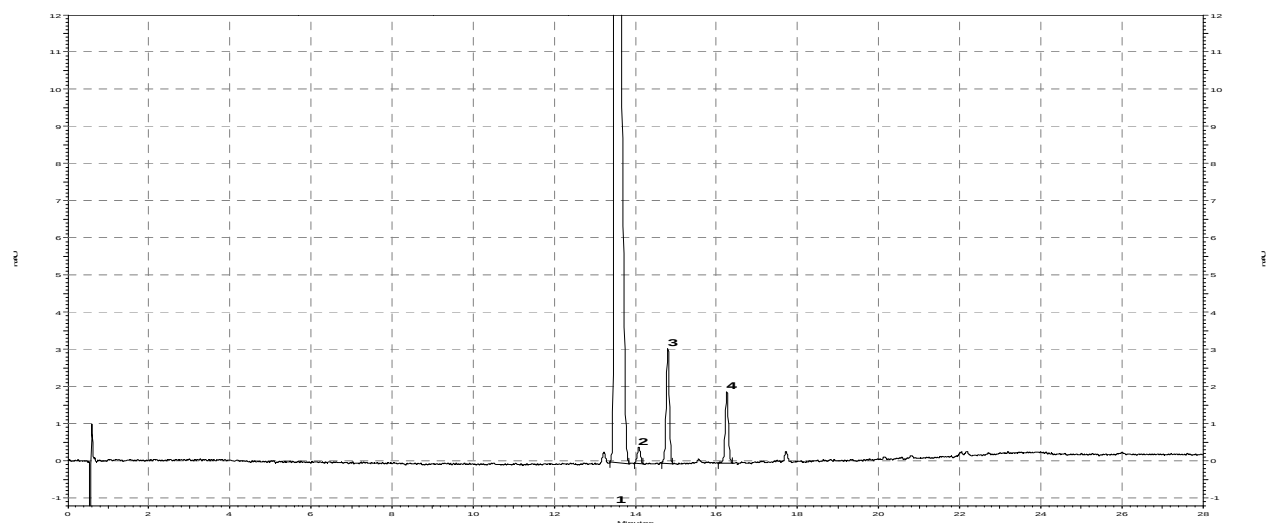
These chromatograms are provided for information only as an aid to analysts and intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for solution (4) at 305 nm in the Related Substances test for Fluvastatin Prolonged-release Tablets as published in BP 2017.



Peak ID at 305nm : 1: Fluvastatin; 2: Impurity A; 3: Unknown 1; 4: Impurity D; 5: Unknown 2; 6: Impurity B

Typical chromatogram for solution (4) at 365 nm in the Related Substances test for Fluvastatin Prolonged-release Tablets as published in BP 2017.



Peak ID at 365nm : 1: Fluvastatin; 2: Impurity A; 3: Impurity D; 4: Unknown 2



Column : YMC-Pack Pro S, C18 (100 mm x 4.6 mm, 3  $\mu$ m)  
Mobile Phase A : Buffer (20 volumes of 1.38 M tetramethylammonium hydroxide added to 880 volumes of water and adjusted to pH 7.2 with orthophosphoric acid): acetonitrile: methanol (900:40:60, v/v/v)  
Mobile Phase B : Buffer (20 volumes of 1.38 M tetramethylammonium hydroxide added to 80 volumes of water and adjusted to pH 7.2 with orthophosphoric acid): acetonitrile: methanol (100:360:540, v/v/v)

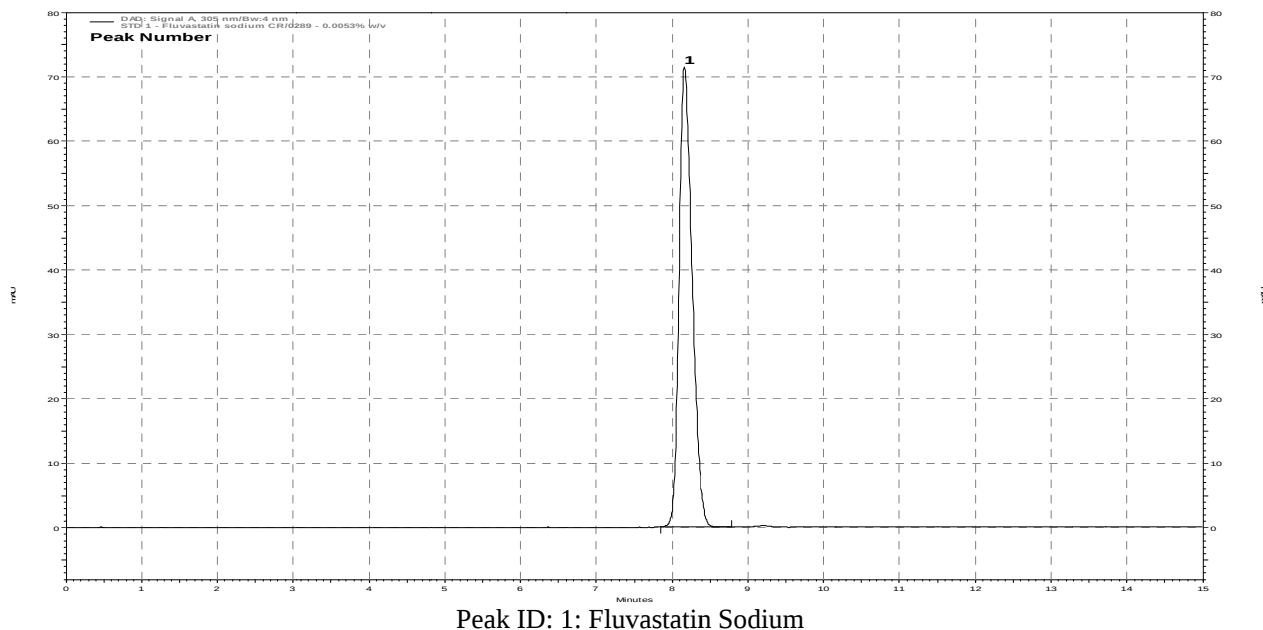
#### Gradient

| Time<br>(min) | Mobile Phase A<br>(% v/v) | Mobile Phase B<br>(% v/v) |
|---------------|---------------------------|---------------------------|
| 0-3           | 70                        | 30                        |
| 3-23          | 10                        | 90                        |
| 23-28         | 10                        | 90                        |
| 28-30         | 70                        | 30                        |
| 30-35         | 70                        | 30                        |

Flow Rate : 2.0 mL/min  
Column Temp : 40 °C  
Injection Volume : 20  $\mu$ L  
Detection : 305 nm and 365 nm



Typical chromatogram for solution (2) in the Assay test for Fluvastatin Prolonged-release Tablets as published in BP 2017.



Column : YMC-Pack Pro S, C18 (100 mm x 4.6 mm, 3  $\mu$ m)  
Method Ref. : Related substances for Fluvastatin Sodium Ph. Eur. monograph from BP 2016  
Mobile Phase : Buffer (0.069 M tetramethylammonium hydroxide adjusted to pH 7.2 with orthophosphoric acid): acetonitrile: methanol (500:240:360, v/v/v)  
Diluent : Mobile phase  
Flow Rate : 2.0 mL/min  
Column Temp : 40  $^{\circ}$ C  
Injection Volume : 20  $\mu$ L  
Detection : 305 nm