

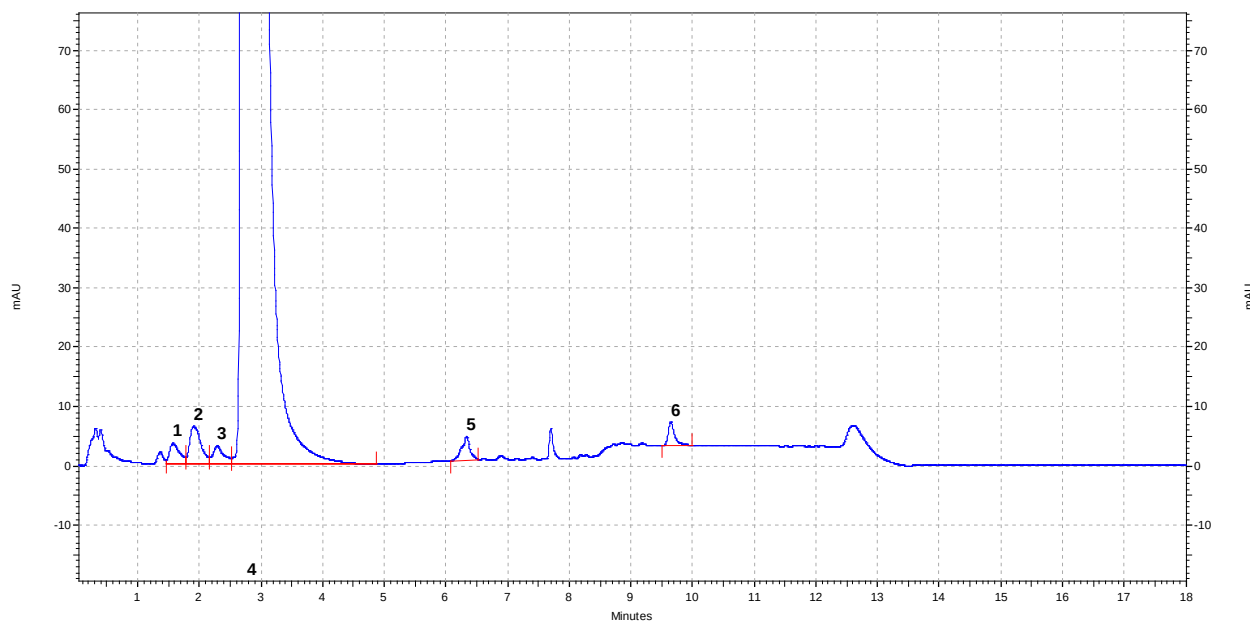


Simvastatin Oral Suspension – BP 2015

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

Column	: Phenomenex Gemini C18 Cartridge (30 mm x 4.6 mm, 5µm)																					
Method Ref.	: Related substances method for the Simvastatin Oral Suspension monograph from BP 2015																					
Mobile Phase A	: A mixture of 50 volumes of acetonitrile and 50 volumes of a 0.1% v/v solution of orthophosphoric acid.																					
Mobile Phase B	: 0.1% v/v solution of orthophosphoric acid in acetonitrile.																					
Gradient	: <table><tr><th>Time (min)</th><th>Mobile Phase A (% v/v)</th><th>Mobile Phase B (% v/v)</th></tr><tr><td>0-4.5</td><td>100</td><td>0</td></tr><tr><td>4.5-4.6</td><td>100-95</td><td>0-5</td></tr><tr><td>4.6-8.0</td><td>95-25</td><td>5-75</td></tr><tr><td>8.0-11.5</td><td>25</td><td>75</td></tr><tr><td>11.5-12.5</td><td>25-100</td><td>75-0</td></tr><tr><td>12.5-17.5</td><td>100</td><td>0</td></tr></table>	Time (min)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)	0-4.5	100	0	4.5-4.6	100-95	0-5	4.6-8.0	95-25	5-75	8.0-11.5	25	75	11.5-12.5	25-100	75-0	12.5-17.5	100	0
Time (min)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)																				
0-4.5	100	0																				
4.5-4.6	100-95	0-5																				
4.6-8.0	95-25	5-75																				
8.0-11.5	25	75																				
11.5-12.5	25-100	75-0																				
12.5-17.5	100	0																				
Diluent	: A mixture of 45 volumes of a 0.14% w/v solution of potassium dihydrogen phosphate, adjusted to pH 4.0 with orthophosphoric acid, and 55 volumes of acetonitrile.																					
Flow Rate	: 3.0 mL/min																					
Column Temp	: 30°C																					
Injection Volume	: 75 µL																					
Detection	: 238 nm																					

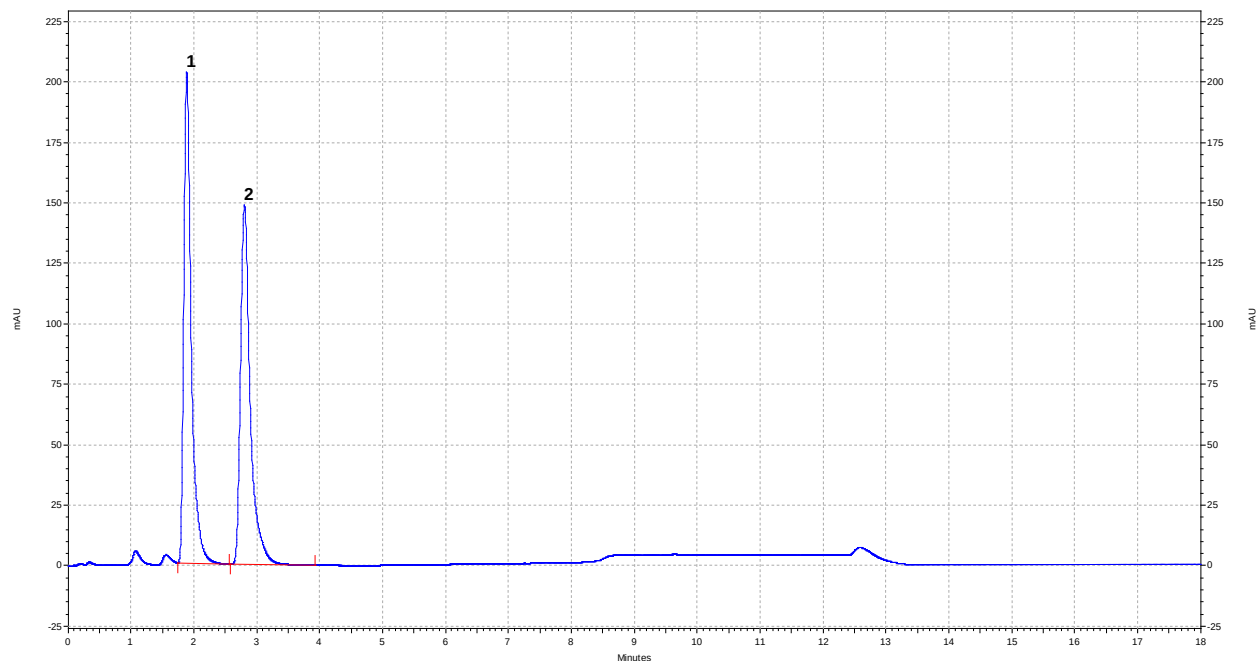
Typical chromatogram for solution (5) in the Related substances test for Simvastatin Oral Suspension as published in BP 2015.



Peak ID: 1: Impurity A; 2: Impurity E+F; 3: Impurity G; 4: Simvastatin; 5: Impurity B+C; 6: Impurity D



Typical chromatogram for solution (4) in the Related substances test and solution (3) in the Assay for Simvastatin Oral Suspension as published in BP 2015.



Peak ID: 1: Impurity E; 2: Simvastatin