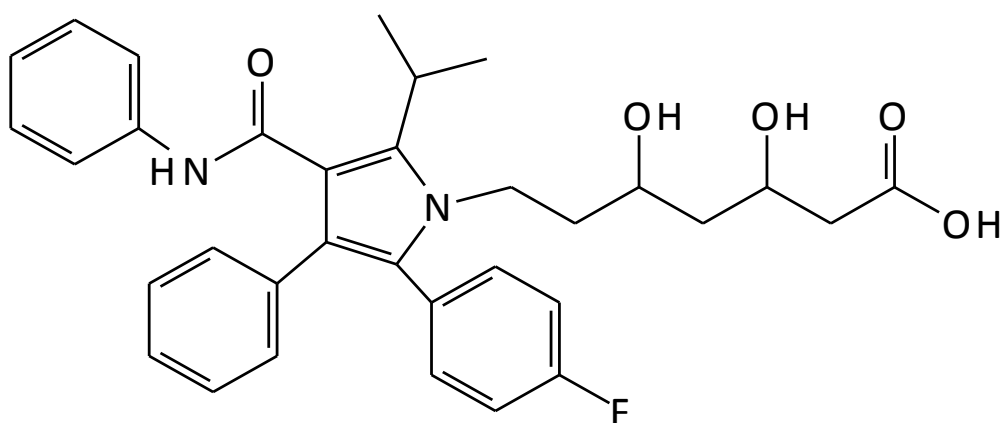


Atorvastatin – Calcium Tablet



Atorvastatin is marketed as a calcium salt under the trade name Lipitor. It belongs to a drug class known as statins and used for lowering blood cholesterol.

Atorvastatin calcium tablets are marketed by Pfizer under the trade name Lipitor for oral administration. Pfizer also packages the drug in combination with other drugs, such as with Caduet. In some countries, atorvastatin calcium is made in tablet form by generic drug makers under various brand names including Stator, Atoris, Atorlip, Lipvas, Sortis, Torvast, Torvacard, Totalip, and Tulip.

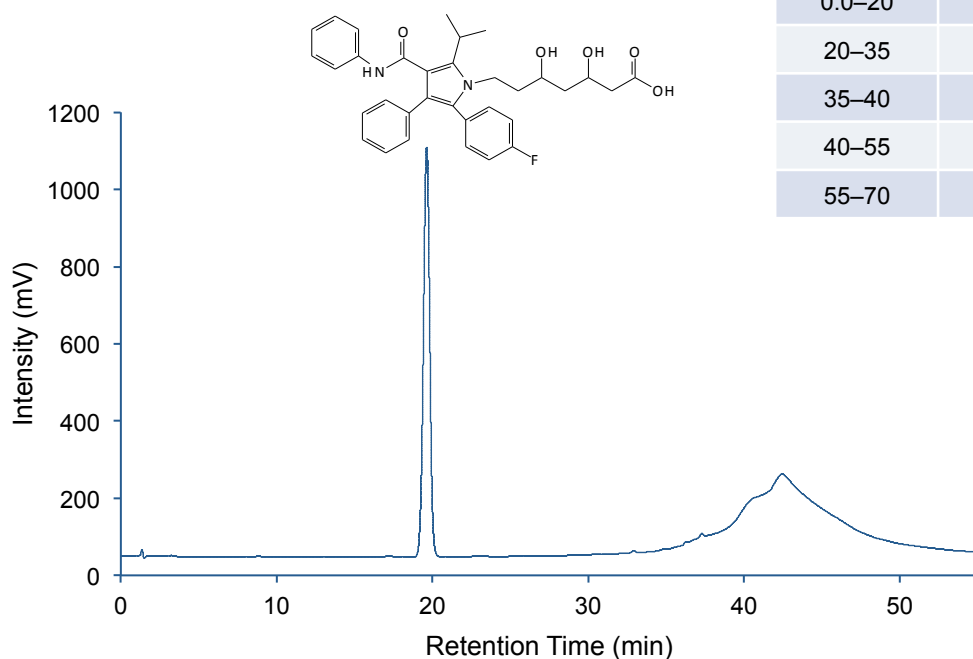
Atorvastatin – Calcium Tablet

Particulate C18 HPLC column

Chromatographic Conditions

Column: Particulate C18 HPLC column, 250 x 4.6 mm, 5.0 µm
Injection: 20 µL
Detection: Shimadzu 2010 CHT, UV 245 nm
Cell: 10 µL
Flow Rate: 1.5 mL/min
Mobile Phase (v/v): A: Acetonitrile: Tetrahydrofuran (92.5:7.5).
 B: 5.75 g ammonium dihydrogenphosphate
 C: Mix Buffer B, mobile phase A and methanol 20:20:60 (v/v)
Gradient: See Table.
Temperature: 25 °C
Diluent (v/v): Acetonitrile and water (40:60)
Sample: Crush 20 tablets and homogenise. Weigh an equivalent weight of 50 mg tablet. Disperse in 10 mL methanol. Add 20 mL diluent. Sonicate for 30 minutes. Dilute finally to 100 mL and filter solution (0.45 µm filter) prior analysis.
Pressure Drop: 220–200 Bar (3190–2900 psi)

Time (min)	Solution B (%)	Solution C (%)	Flow rate (mL/min)
0.0–20	100	0	1.8
20–35	100→25	0→75	1.5
35–40	25	75	1.5
40–55	100	0	1.5
55–70	100	0	1.8



Chromatographic Data

No.	Compound	Time (min)	T _{USP}	Theoretical Plate
1	Atorvastatin	19.6	1.0	11000

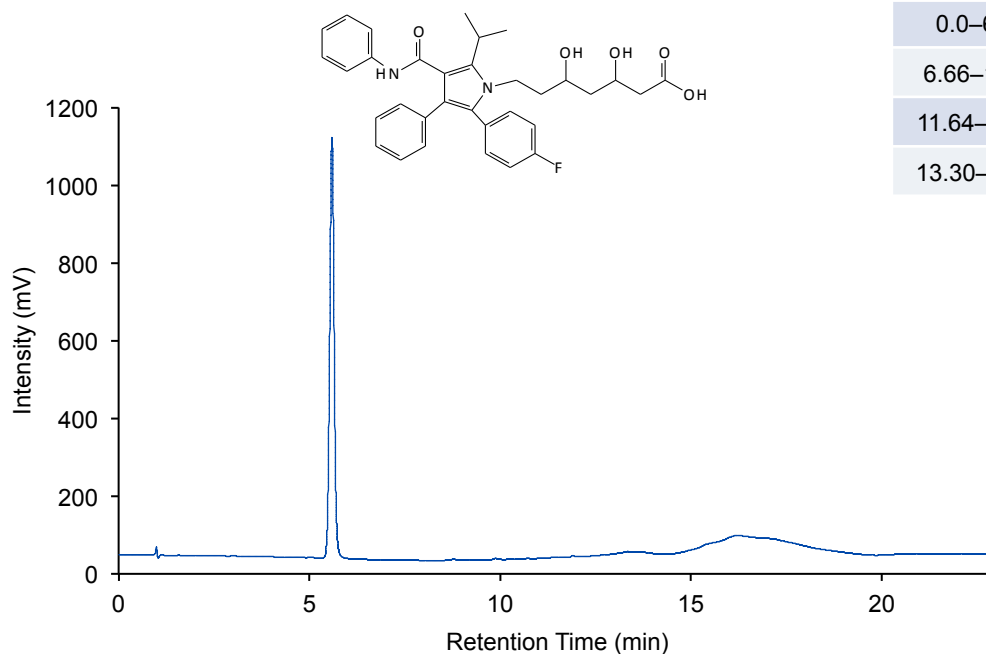
Atorvastatin – Calcium Tablet

Chromolith® HighResolution RP-18 endcapped

Chromatographic Conditions

Column:	Chromolith® HighResolution RP-18endcapped, 100 x 4.6 mm (1.52022.0001)
Injection:	5 µL
Detection:	Shimadzu 2010 CHT, UV 245 nm
Cell:	10 µL
Flow Rate:	1.5 mL/min
Mobile Phase (v/v):	A: Acetonitrile : Tetrahydrofuran (92.5:7.5). B: 5.75 g ammonium dihydrogenphosphate (NH ₄ H ₂ PO ₄) diluted in 1 L water. Mix B and A 58:42 (v/v) C: Mix Buffer B, mobile phase A and methanol 20:20:60 (v/v)
Gradient:	See Table.
Temperature:	25 °C
Diluent (v/v):	Acetonitrile and water (40:60)
Sample	Crush 20 tablets and homogenise. Weigh an equivalent weight of 50 mg tablet. Disperse in 10 mL methanol. Add 20 mL diluent. Sonicate for 30 minutes. Dilute finally to 100 mL and filter solution (0.45 µm filter) prior analysis.
Pressure Drop:	87–83 Bar (1260–1203 psi)

Time (min)	Solution B (%)	Solution C (%)
0.0–6.65	100	0
6.66–11.63	100→25	0→75
11.64–13.29	25	75
13.30–23.30	100	0



Chromatographic Data

No.	Compound	Time (min)	T _{USP}	Theoretical Plate
1	Atorvastatin	5.6	1.0	11400

Atorvastatin – Method Comparison

Particulate C18 HPLC column

Chromolith® HighResolution RP-18endcapped

