

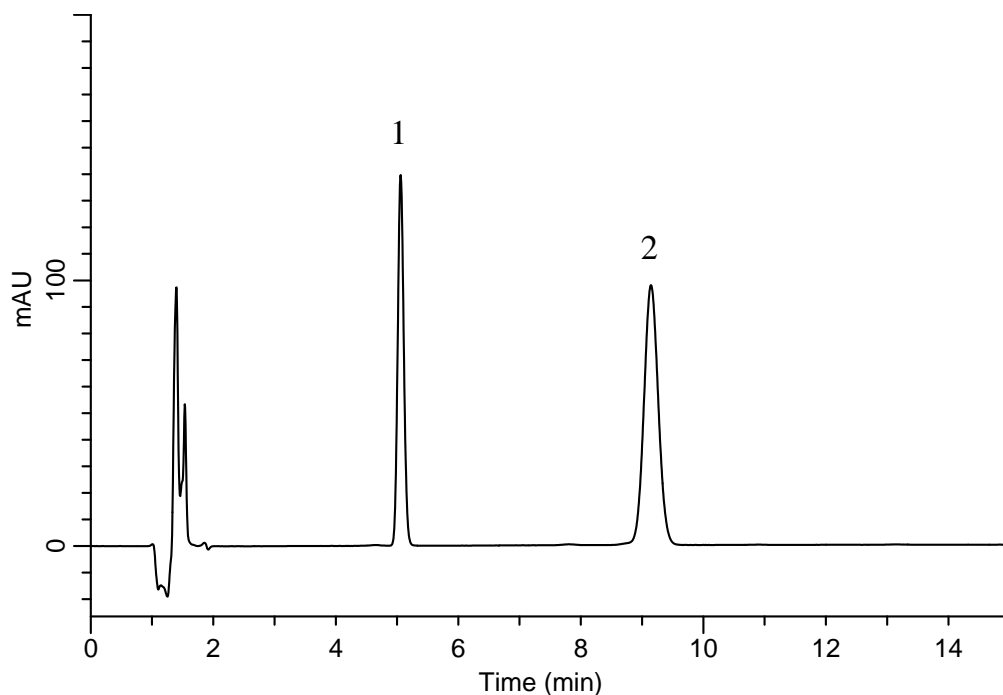
InertSearch™ for LC

Inertsil® Applications

Analysis of Atorvastatin Calcium

(Under the Condition of Japanese Pharmacopoeia, Atorvastatin Calcium Tablets)

Data No. LB023-0894



Conditions

System : GL-7400 HPLC system
Column : InertSustain C18 (5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-07346
Eluent : A) THF
 B) CH₃CN
 C) Citric acid buffer*
 A/B/C = 20/27/53, v/v/v (Premix)
Flow rate : 1.8 mL/min
Col. Temp. : 30 °C
Detection : UV 244 nm (GL-7452A PDA Detector)
Injection Vol. : 10 μ L
Sample : Standard

Analyte:

1. 1,3-Dinitrobenzene 0.04 mg/mL
2. Atorvastatin calcium 0.11 mg/mL

Uniformity of dosage units and Assay (Standard Solution)

| | System suitability requirement | Result |
|-------------------|--------------------------------|--------|
| Resolution (1, 2) | ≥ 10 | 13.4 |

* Dissolve 10.5 g of citric acid monohydrate in 900 mL of water.
Adjust pH 4.0 by 28 % ammonia solution.
Add water to make 1000 mL.