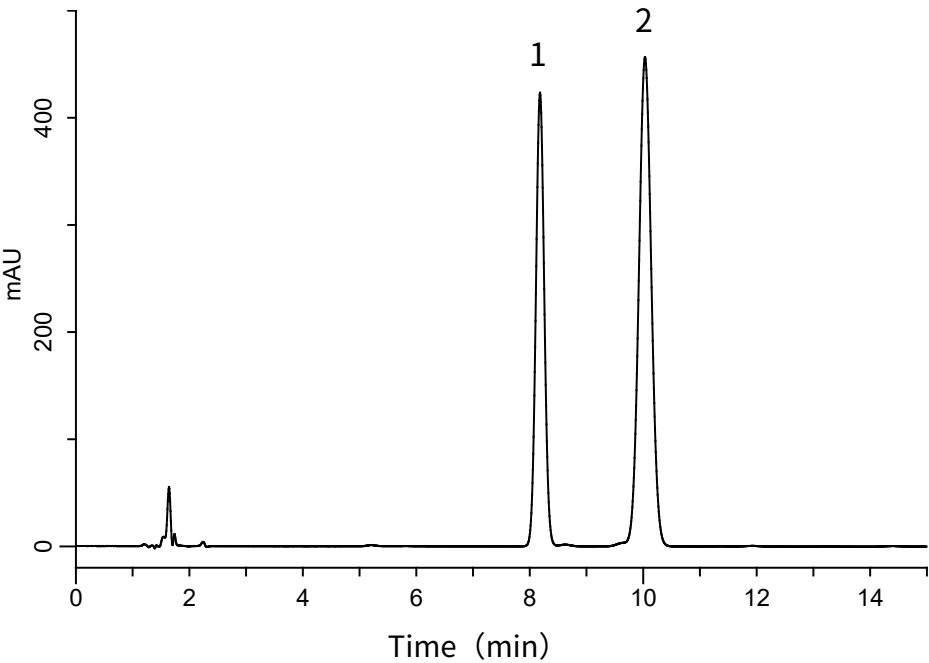


Analysis of Atorvastatin Calcium

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

Data No. LB025-0894



Conditions

System : GL-7400 HPLC system
Column : InertSustain C18 (5μm, 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 : 1.5 mL/min
Col. Temp. : 40 °C
Detection : UV 254 nm (GL-7452A PDA Detector)
Injection Vol. : 10 μL
Sample : Standard

Analyte:

1. *p*-Hydroxy benzoic acid butyl 0.13 mg/mL
2. Atorvastatin calcium 0.4 mg/mL

Assay (Standard Solution)

	System suitability requirement	Result
Resolution (1, 2)	≥5	5.5

* 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.