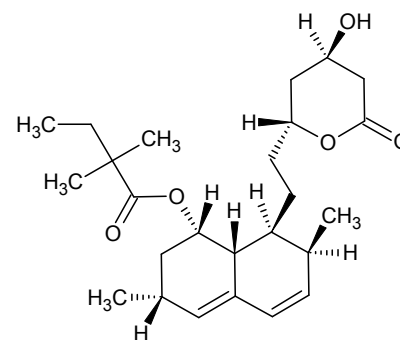


シンバスタチン錠 (米国薬局方記載条件)
Simvastatin tablets (The United States Pharmacopeia)

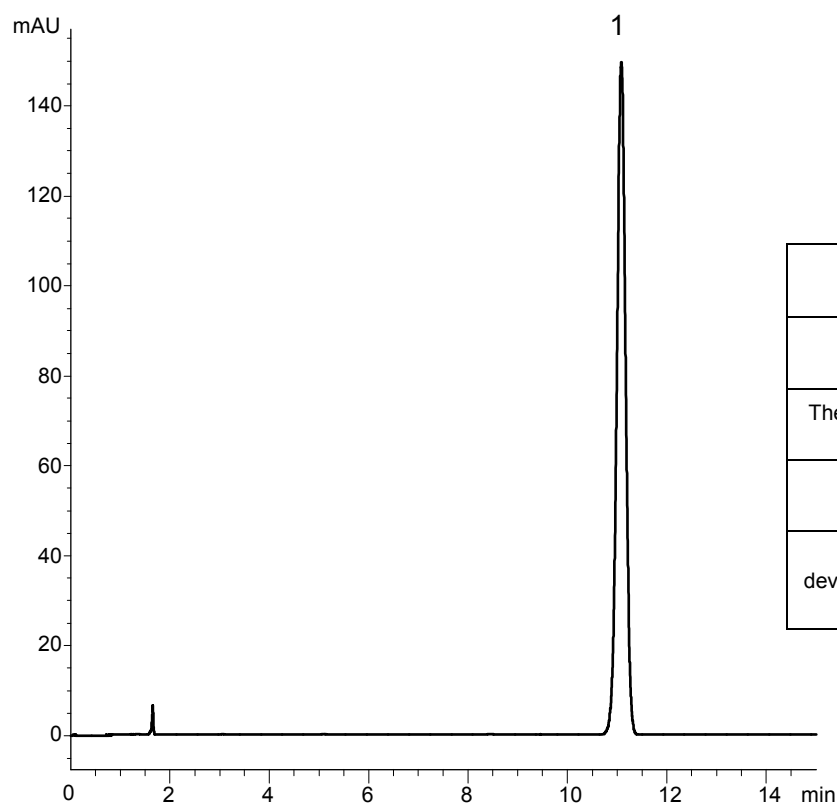
U120605E

1



Simvastatin

Standard preparation*¹
(0.1 mg/mL Simvastatin)



	System suitability requirement	Result
Capacity factor (Simvastatin)	≥ 3.0	5.69
Theoretical plate number (Simvastatin)	≥ 4500	19200
Tailing factor (Simvastatin)	≤ 2.0	0.98
Relative standard deviation of the peak area (Simvastatin)	≤ 2.0%	0.12%

Column : YMC-Triart C18 (5 μm, 12 nm)
250 X 4.6 mm I.D.

Eluent : phosphate buffer (pH 4.5)*²/acetonitrile (35/65)
*² Dissolve 3.90 g of NaH₂PO₄ · 2H₂O in 900 mL water, adjust pH 4.5 with H₃PO₄, and add water to make 1000 mL

Flow rate : 1.5 mL/min

Temperature : 45°C

Detection : UV at 238 nm

Injection : 10 μL

(The United States Pharmacopeia 34th; Assay)

*¹ Standard preparation was prepared from Simvastatin supplied as a reagent for laboratory use.