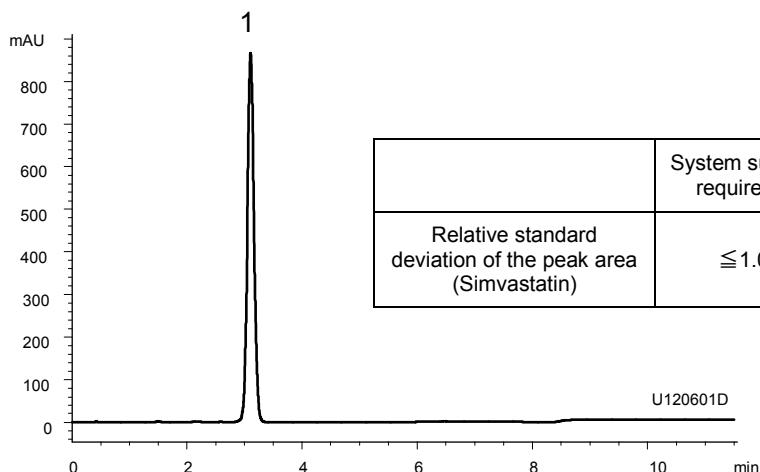


シンバスタチン（米国薬局方記載条件）

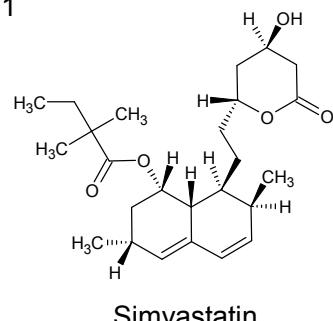
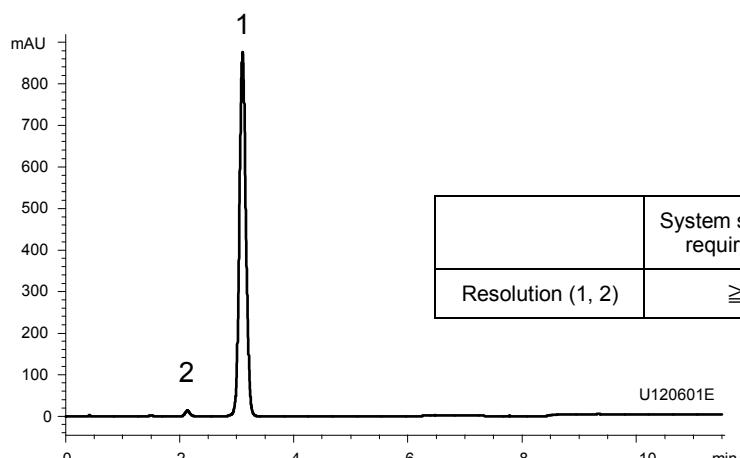
Simvastatin (The United States pharmacopeia)

U120622A

(A) Standard preparation*
(1.5 mg/mL Simvastatin)

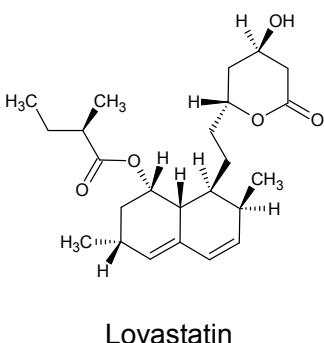
	System suitability requirement	Result
Relative standard deviation of the peak area (Simvastatin)	≤1.0%	0.19%

1

(B) System suitability preparation*
(0.015 mg/mL Lovastatin, 1.5 mg/mL Simvastatin)

	System suitability requirement	Result
Resolution (1, 2)	≥3	5.5

2



Column	: YMC-Triart C18 (3 µm, 12 nm) 35 X 4.6 mmI.D.
Eluent	: A) acetonitrile/water/phosphoric acid (50/50/0.05) B) acetonitrile/phosphoric acid (100/0.1) 0% B(0-4.5 min), 0-5% B(4.5-4.6 min), 5-75% B(4.6-8.0 min), 75% B(8.0-11.5 min)
Flow rate	: 3.0 mL/min
Temperature	: 25°C
Detection	: UV at 238 nm
Injection	: 5 µL
(The United States Pharmacopeia 34th; Assay)	

* All preparations were prepared from Simvastatin supplied as a reagent for laboratory use.