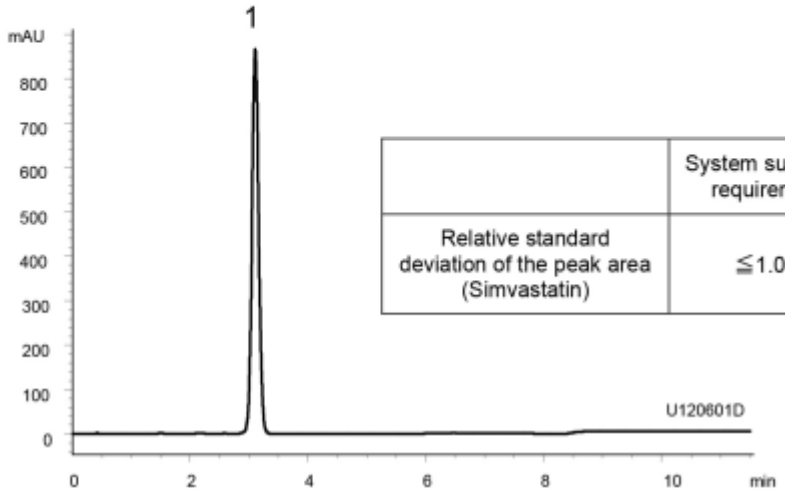
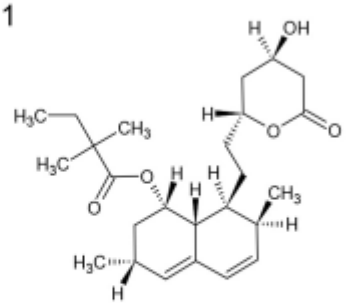
(A) Standard preparation*
(1.5 mg/mL Simvastatin)



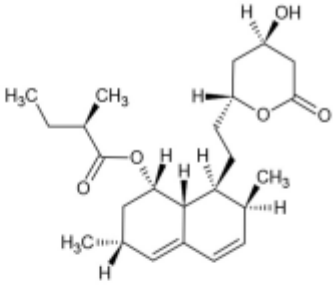
	System suitability requirement	Result
Relative standard deviation of the peak area (Simvastatin)	≦1.0%	0.19%

1



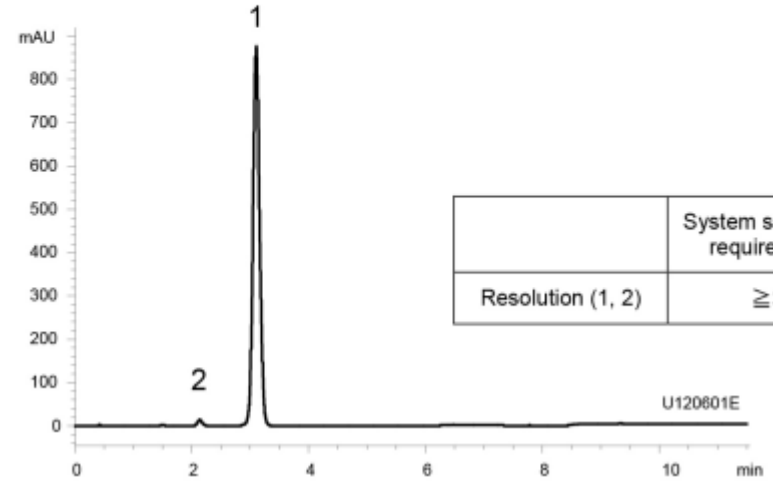
Simvastatin

2



Lovastatin

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



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

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℃
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.