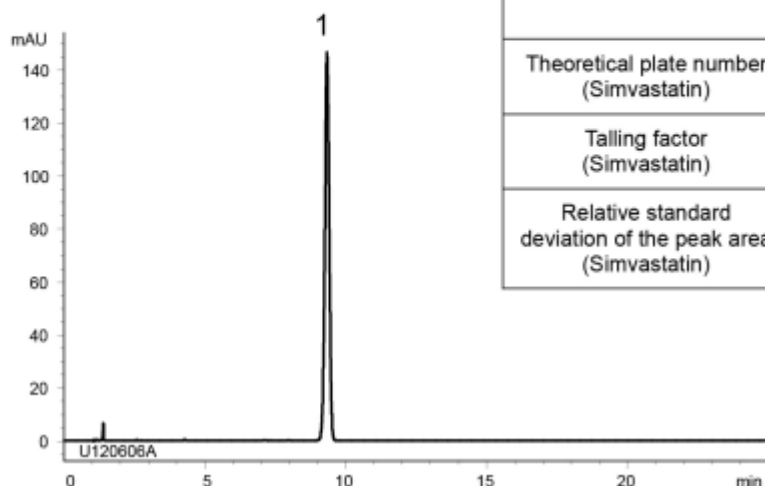
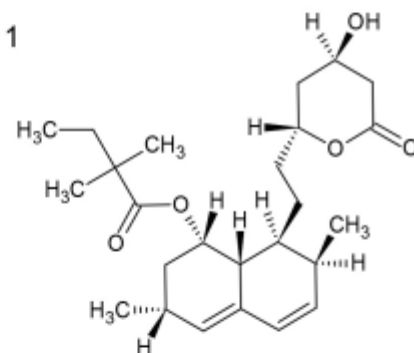


A) Assay: Standard solution*¹
(0.1 mg/mL Simvastatin)



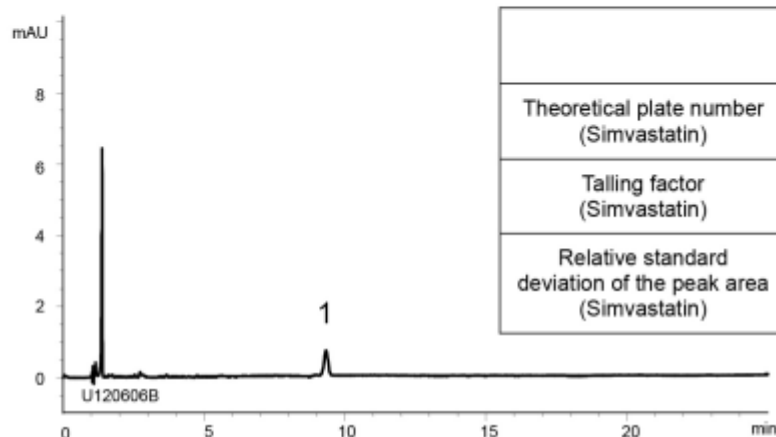
	System suitability requirement	Result
Theoretical plate number (Simvastatin)	≥ 6000	17600
Tailing factor (Simvastatin)	$0.9 \leq Tf \leq 1.1$	0.98
Relative standard deviation of the peak area (Simvastatin)	$\leq 1.0\%$	0.07%

1



Simvastatin

B) Related substances: Standard solution*¹
(0.0005 mg/mL Simvastatin)



	System suitability requirement	Result
Theoretical plate number (Simvastatin)	≥ 6000	17200
Tailing factor (Simvastatin)	$0.9 \leq Tf \leq 1.1$	1.00
Relative standard deviation of the peak area (Simvastatin)	$\leq 2.0\%$	1.05%

Column : YMC-Triart C18 (5 μ m, 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 $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$ in 900 mL water, adjust pH 4.5 with H_3PO_4 , and add water to make 1000 mL

Flow rate : 1.8 mL/min (adjust the flow rate so that the retention time of simvastatin is about 9 min)

Temperature : 45°C

Detection : UV at 238 nm

Injection : 10 μ L

(The draft for the Japanese Pharmacopoeia; Assay, Related substances)

*¹ All standard solutions were prepared from Simvastatin supplied as a reagent for laboratory use.