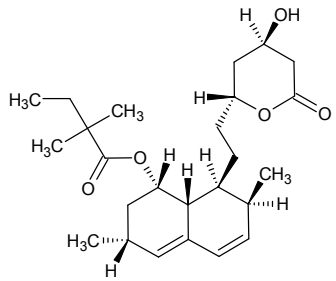
HPLC DATA SHEET

シンバスタチン（日本薬局方記載条件）
Simvastatin (The Japanese Pharmacopoeia)

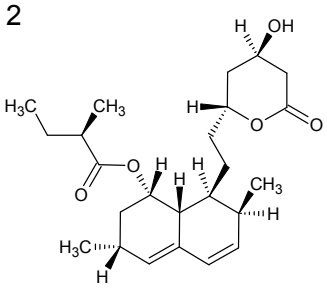
U120619B

1



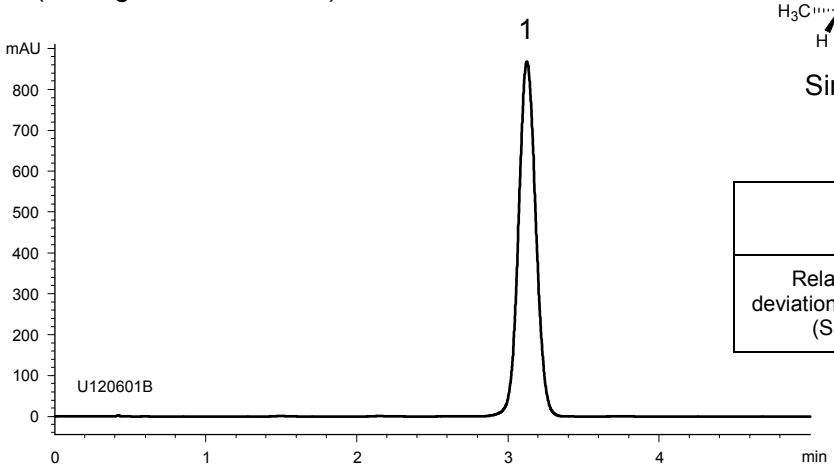
Simvastatin

2



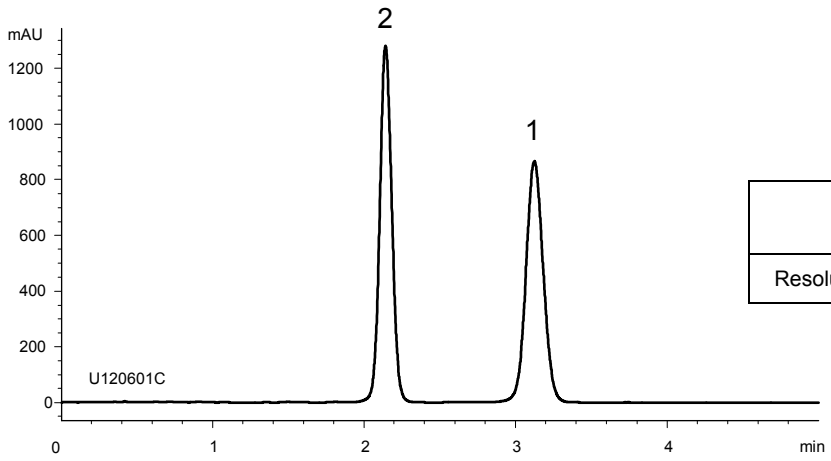
Lovastatin

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



	System suitability requirement	Result
Relative standard deviation of the peak area (Simvastatin)	≦1.0%	0.44%

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



	System suitability requirement	Result
Resolution (1, 2)	≧3	5.6

Column	: YMC-Triart C18 (3 μm, 12 nm)
	35 X 4.6 mmI.D.
Eluent	: acetonitrile/water/phosphoric acid (50/50/0.05)
Flow rate	: 3.0 mL/min *(adjust the flow rate so that the retention time of simvastatin is about 3 min)*
Temperature	: 25℃
Detection	: UV at 238 nm
Injection	: 5 μL

(The Japanese Pharmacopoeia 16th; Assay)

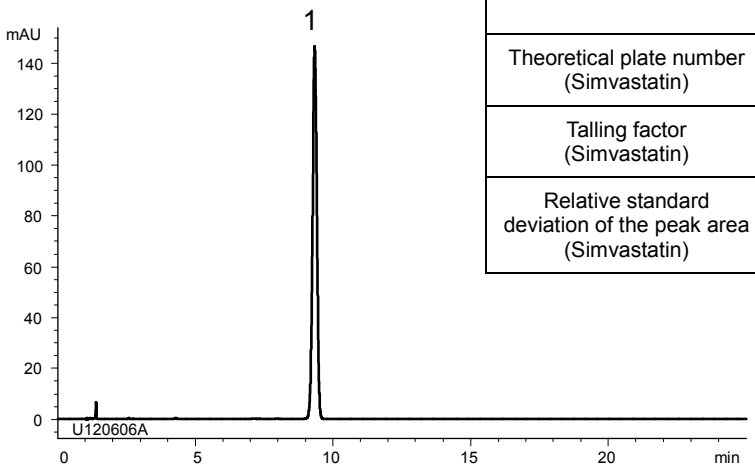
* All solutions were prepared from Simvastatin supplied as a reagent for laboratory use.

HPLC DATA SHEET

シンバスタチン錠（日本薬局方収載原案記載条件）
Simvastatin tablets (The draft for the Japanese Pharmacopoeia)

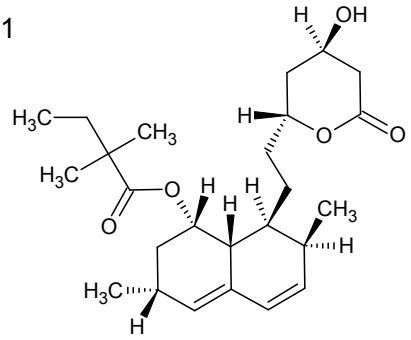
U120608C

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



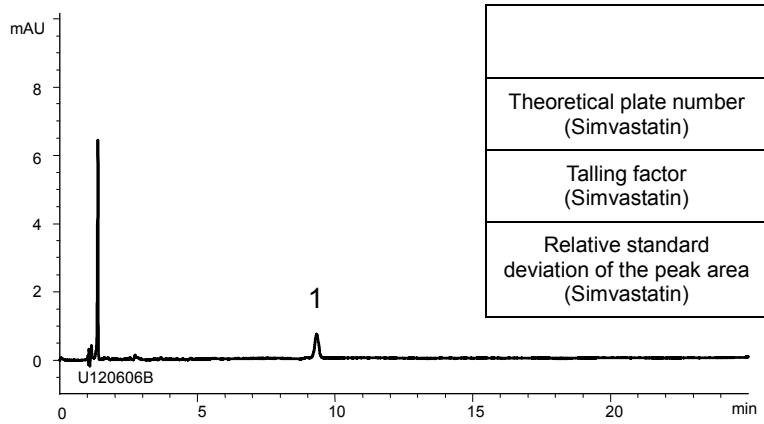
	System suitability requirement	Result
Theoretical plate number (Simvastatin)	≧6000	17600
Talling factor (Simvastatin)	0.9≦Tf≦1.1	0.98
Relative standard deviation of the peak area (Simvastatin)	≦1.0%	0.07%

1



Simvastatin

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



	System suitability requirement	Result
Theoretical plate number (Simvastatin)	≧6000	17200
Talling factor (Simvastatin)	0.9≦Tf≦1.1	1.00
Relative standard deviation of the peak area (Simvastatin)	≦2.0%	1.05%

Column	: YMC-Triart C18 (5 μm, 12 nm) 250 X 4.6 mmI.D.
Eluent	: phosphate buffer (pH 4.5)*2/acetonitrile (35/65)
	*2 *Dissolve 3.90 g of $NaH_2PO_4 \cdot 2H_2O$ 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℃
Detection	: UV at 238 nm
Injection	: 10 μL

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

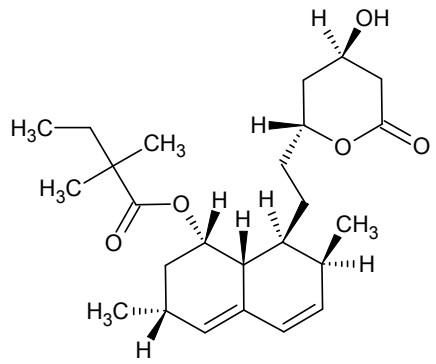
*1 All standard solutions were prepared from Simvastatin supplied as a reagent for laboratory use.

HPLC DATA SHEET

シンバスタチン錠（日本薬局方収載原案記載条件）
Simvastatin tablets (The draft for the Japanese Pharmacopoeia)

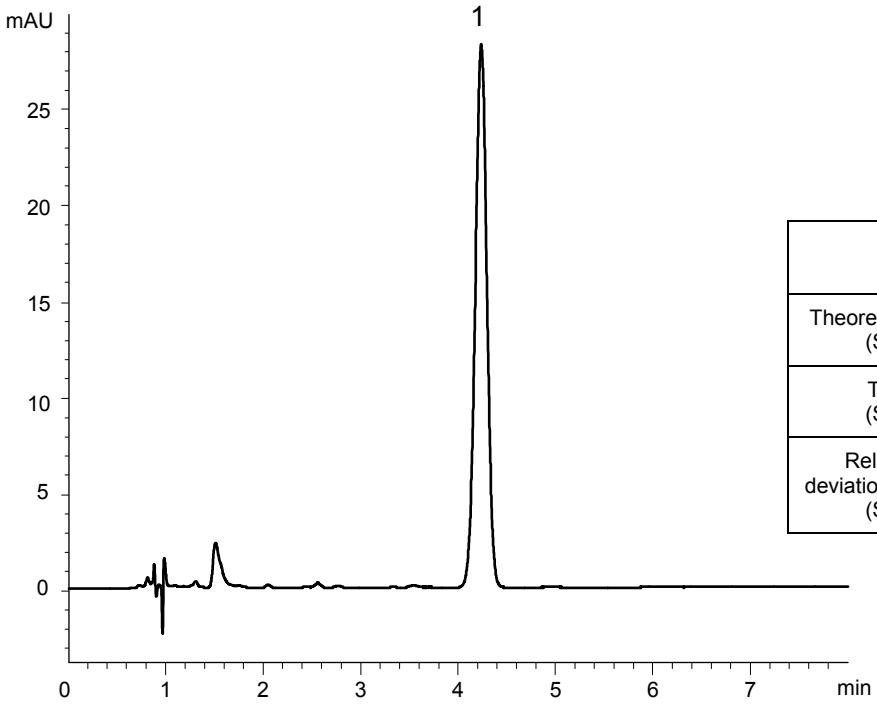
U120608B

1



Simvastatin

Standard solution*
(0.0055 mg/mL Simvastatin)



	System suitability requirement	Result
Theoretical plate number (Simvastatin)	≧3000	6000
Talling factor (Simvastatin)	≦2.0	0.99
Relative standard deviation of the peak area (Simvastatin)	≦1.0%	0.05%

Column	: YMC-Triart C18 (5 μm, 12 nm) 150 X 4.0 mmI.D.
Eluent	: methanol/0.02 M KH_2PO_4 (4/1)
Flow rate	: 1.3 mL/min *(adjust the flow rate so that the retention time of simvastatin is about 4 min)*
Temperature	: 50℃
Detection	: UV at 238 nm
Injection	: 20 μL

(The draft for the Japanese Pharmacopoeia; Dissolution)

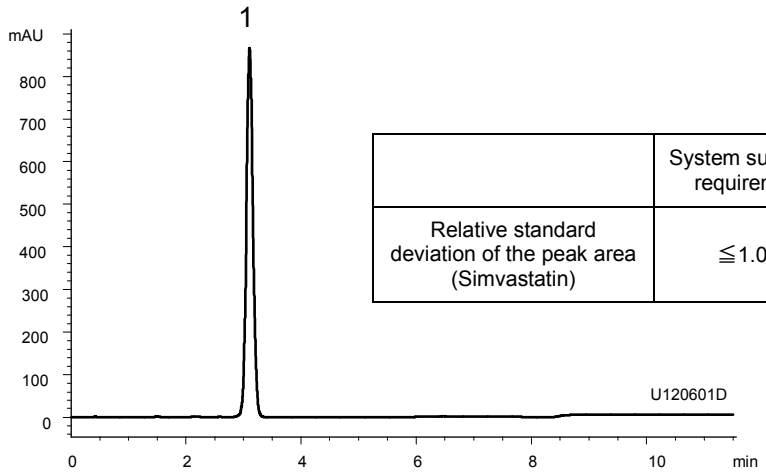
* Standard solution was prepared from Simvastatin supplied as a reagent for laboratory use.

HPLC DATA SHEET

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

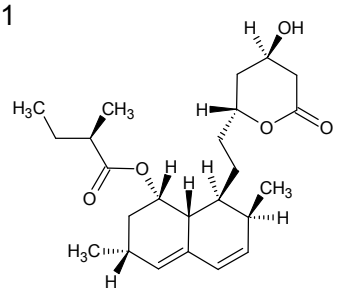
U120622A

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



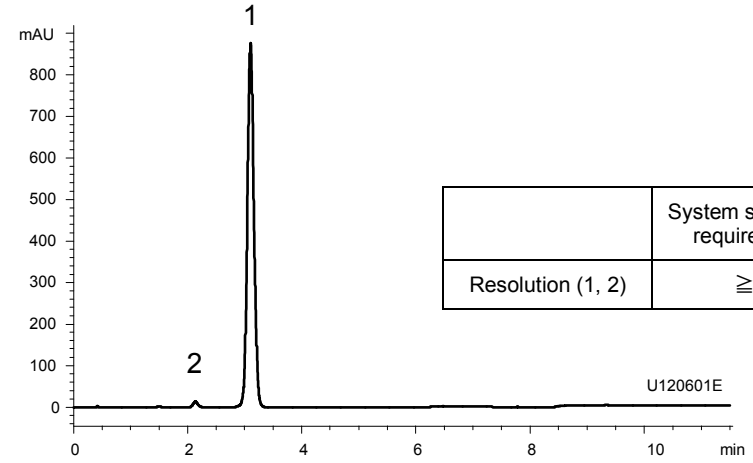
	System suitability requirement	Result
Relative standard deviation of the peak area (Simvastatin)	≦1.0%	0.19%

1



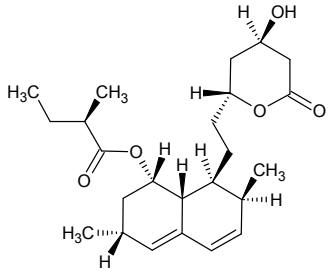
Simvastatin

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



Lovastatin

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)

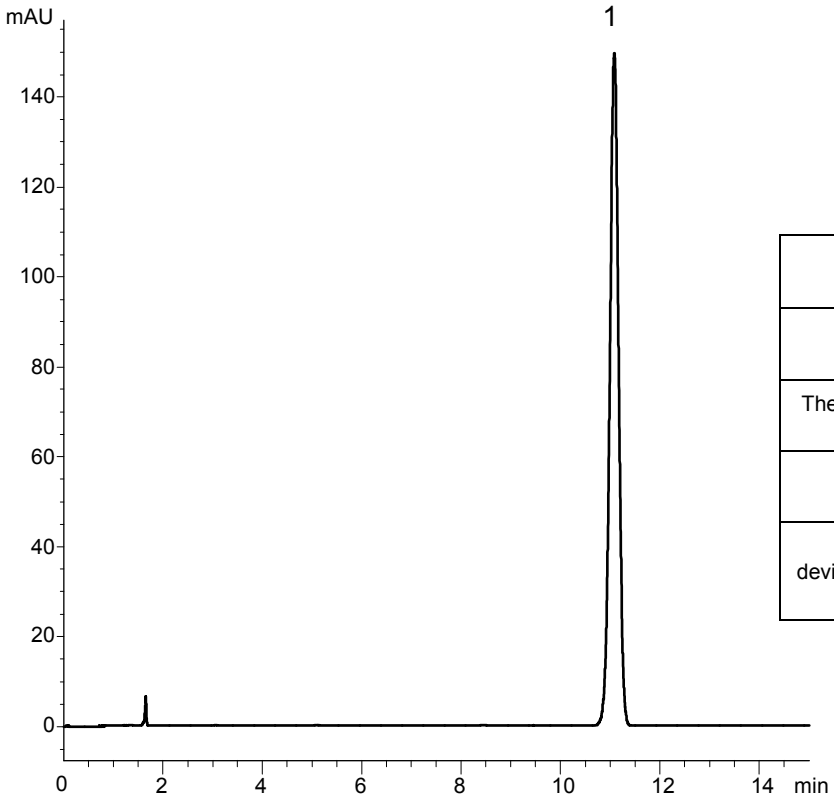
* All preparations were prepared from Simvastatin supplied as a reagent for laboratory use.

HPLC DATA SHEET

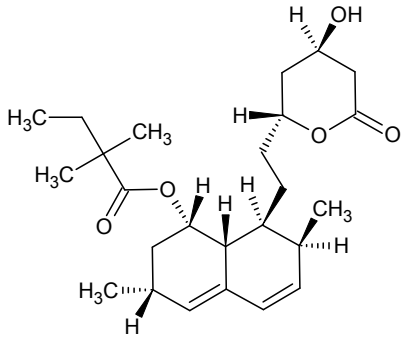
シンバスタチン錠（米国薬局方記載条件）
Simvastatin tablets (The United States Pharmacopeia)

U120605E

Standard preparation*1
(0.1 mg/mL Simvastatin)



1



Simvastatin

	System suitability requirement	Result
Capacity factor (Simvastatin)	≧3.0	5.69
Theoretical plate number (Simvastatin)	≧4500	19200
Talling 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 mmI.D.
Eluent	: phosphate buffer (pH 4.5)*2/acetonitrile (35/65)
	*2 *Dissolve 3.90 g of $NaH_2PO_4 \cdot 2H_2O$ in 900 mL water, adjust pH 4.5 with H_3PO_4, and add water to make 1000 mL*
Flow rate	: 1.5 mL/min
Temperature	: 45℃
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.