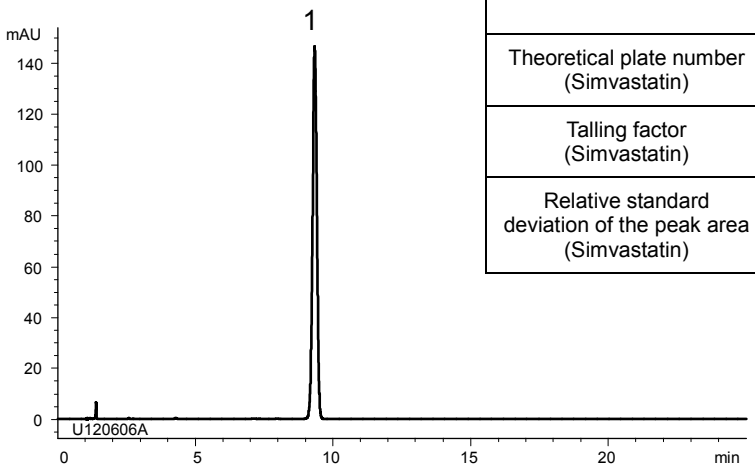
HPLC DATA SHEET

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)

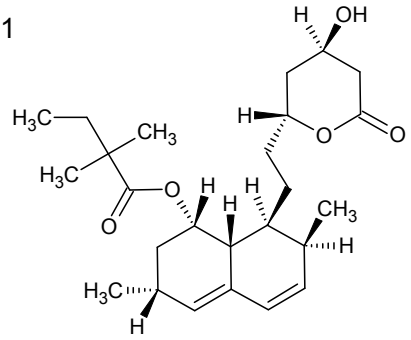
U120608C

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



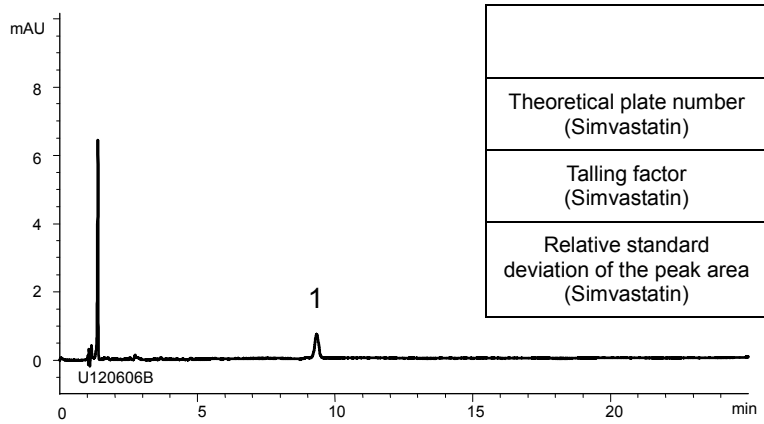
	System suitability requirement	Result
Theoretical plate number (Simvastatin)	≧6000	17600
Talling factor (Simvastatin)	0.9≦Tf≦1.1	0.98
Relative standard deviation of the peak area (Simvastatin)	≦1.0%	0.07%

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.