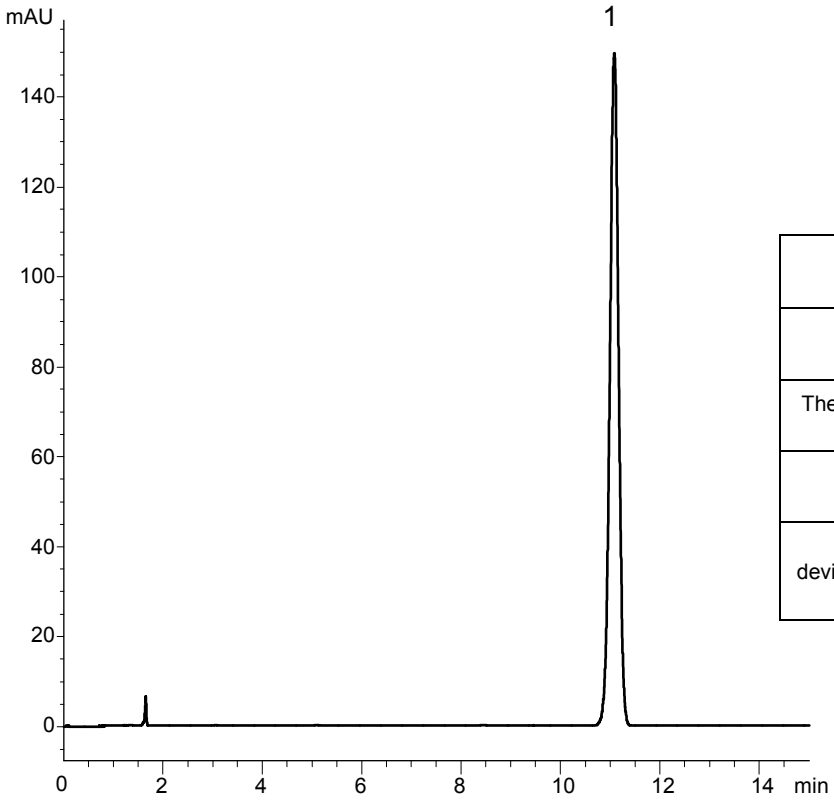
HPLC DATA SHEET

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)



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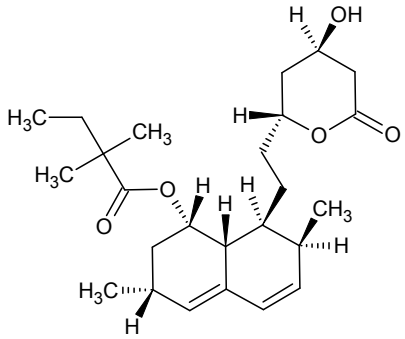

Simvastatin

	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.