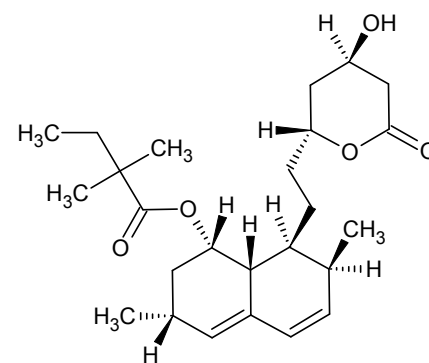


シンバスタチン錠（日本薬局方収載原案記載条件）

Simvastatin tablets (The draft for the Japanese Pharmacopoeia)

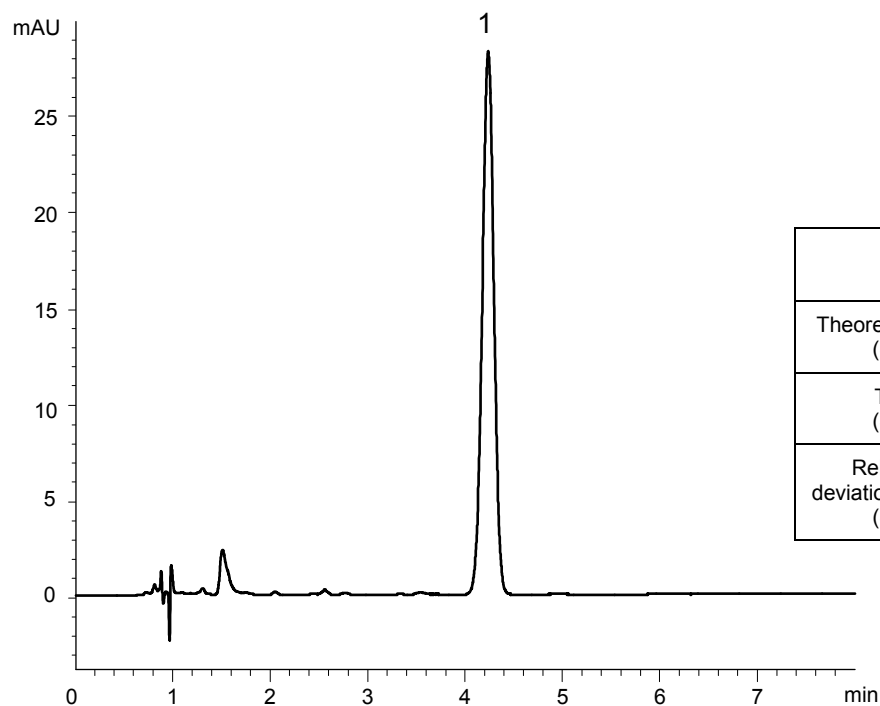
U120608B

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Simvastatin

Standard solution*
(0.0055 mg/mL Simvastatin)



	System suitability requirement	Result
Theoretical plate number (Simvastatin)	≥ 3000	6000
Tailing factor (Simvastatin)	≤ 2.0	0.99
Relative standard deviation of the peak area (Simvastatin)	$\leq 1.0\%$	0.05%

Column : YMC-Triart C18 (5 μ m, 12 nm)
150 X 4.0 mmI.D.
Eluent : methanol/0.02 M KH₂PO₄ (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°C
Detection : UV at 238 nm
Injection : 20 μ L
(The draft for the Japanese Pharmacopoeia; Dissolution)

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