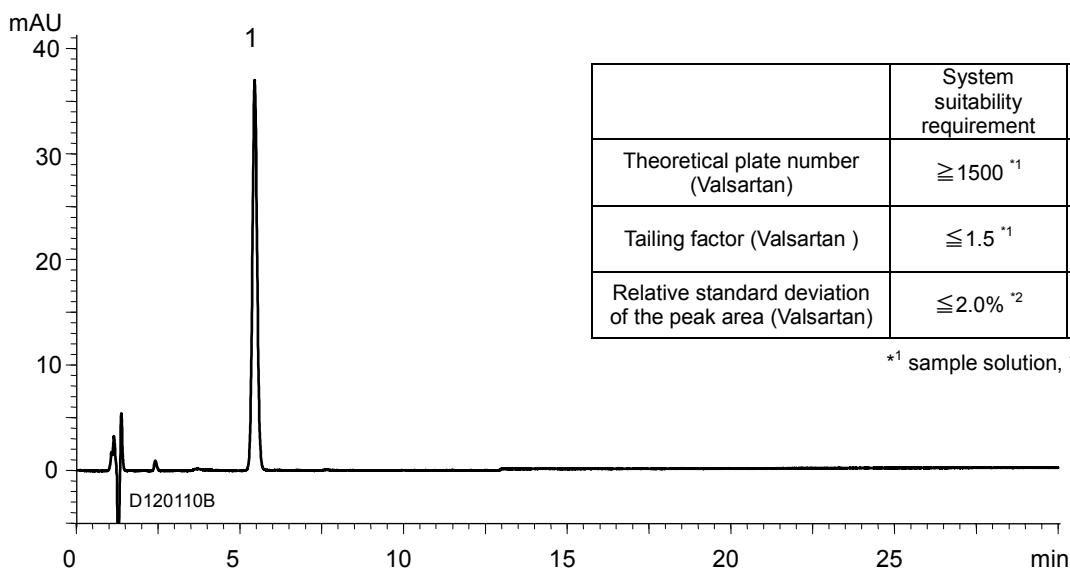


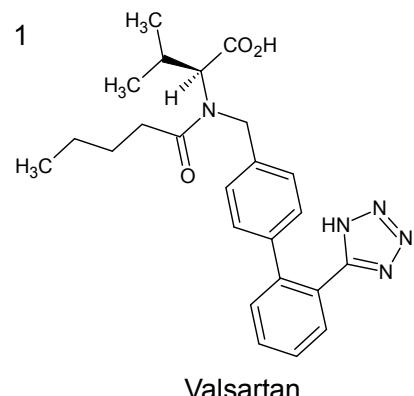
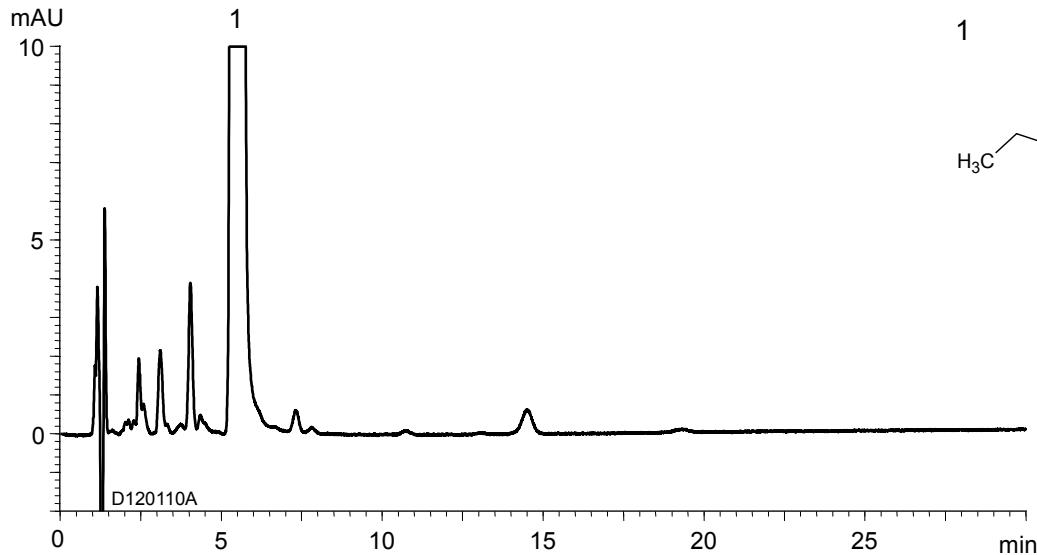
バルサルタン（日本薬局方収載原案記載条件）

Valsartan (The draft for the Japanese Pharmacopoeia)

D120110D

A) Standard solution^{*1} (0.005 mg/mL Valsartan)

	System suitability requirement	Result for standard solution	Result for sample solution
Theoretical plate number (Valsartan)	≥ 1500 ^{*1}	6700	N.C.
Tailing factor (Valsartan)	≤ 1.5 ^{*1}	1.06	N.C.
Relative standard deviation of the peak area (Valsartan)	$\leq 2.0\%$ ^{*2}	0.10%	—

^{*1} sample solution, ^{*2} standard solutionB) Sample solution^{*1} (0.5 mg/mL Valsartan)

Column	: YMC-Triart C18 (5 μ m, 12 nm) 125 X 3.0 mmI.D.
Eluent	: acetonitrile/water/acetic acid (50/50/0.1)
Flow rate	: 0.45 mL/min (<i>adjust the flow rate so that the retention time of valsartan is about 5 min</i>)
Temperature	: 25°C
Detection	: UV at 225 nm
Injection	: 10 μ L

(The draft for the Japanese Pharmacopoeia; Related substances)

^{*1} Standard and sample solutions were prepared from Valsartan supplied as a reagent for laboratory use.

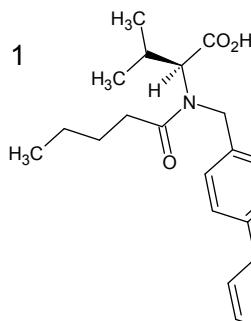
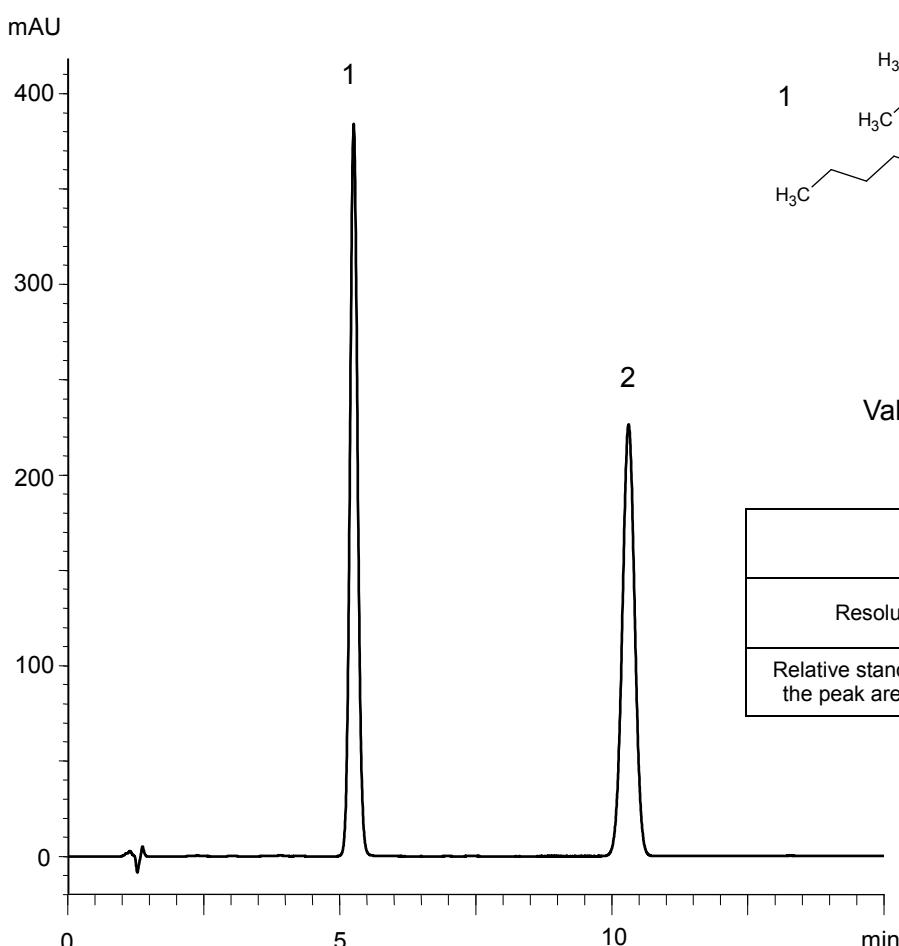
バルサルタン・バルサルタン錠（日本薬局方収載原案記載条件）

Valsartan · Valsartan tablets (The draft for the Japanese Pharmacopoeia)

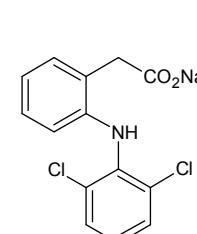
D120111A

Standard solution*

(0.05 mg/mL Valsartan, 0.06 mg/mL Diclofenac sodium)



Valsartan



Diclofenac sodium (I.S.)

	System suitability requirement	Result
Resolution (1, 2)	≥5	14.9
Relative standard deviation of the peak area ratio of 1 to 2	≤1.0%	0.05%

Column	: YMC-Triart C18 (5 µm, 12 nm) 125 X 3.0 mmI.D.
Eluent	: acetonitrile/water/acetic acid (50/50/0.1)
Flow rate	: 0.45 mL/min (<i>adjust the flow rate so that the retention time of valsartan is about 5 min</i>)
Temperature	: 25°C
Detection	: UV at 225 nm
Injection	: 10 µL
(The draft for the Japanese Pharmacopoeia; Assay)	

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