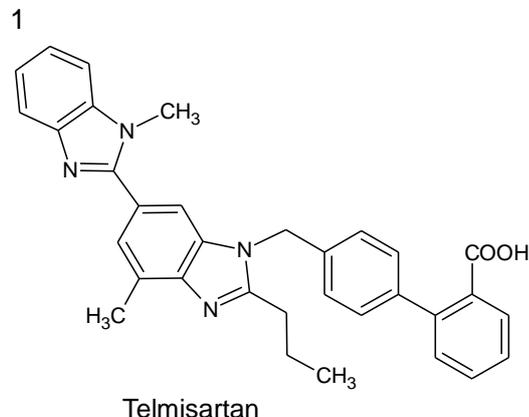
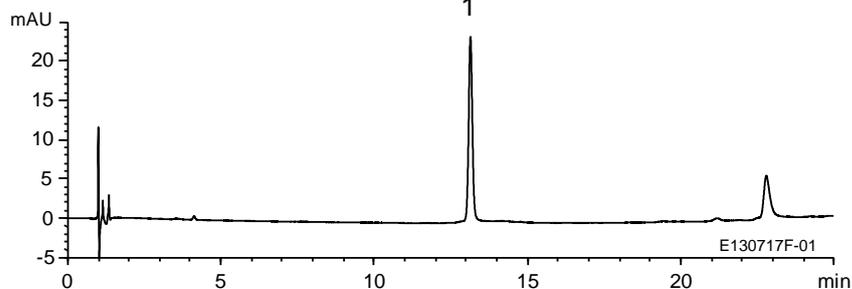


テルミサルタン（日本薬局方原案記載条件）

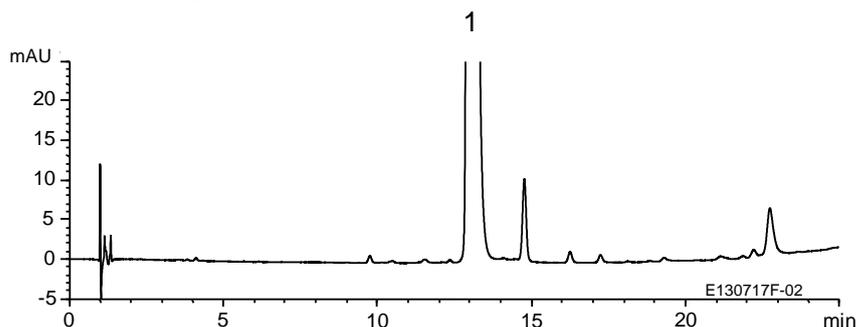
Telmisartan (The draft for the Japanese Pharmacopoeia)

E130717G

A) Standard solution*¹
(0.025 mg/mL Telmisartan)



B) Test solution*¹
(2.5 mg/mL Telmisartan)



	System suitability requirement	Result
Theoretical plate number (Telmisartan)	≥ 45000	56100
Tailing factor (Telmisartan)	≤ 1.2	1.06
Relative standard deviation of the peak area (Telmisartan)	$\leq 5.0\%$	0.62%

Column : YMC-Triart C18 (5 μ m, 12 nm)
125 X 4.0 mmI.D.

Eluent : A) buffer (pH 3.0)*²
B) acetonitrile/methanol (4 / 1)
30-80%B (0-25 min)

*² Dissolve 2.0 g of KH_2PO_4 and 3.4 g of sodium 1-pentanesulfonate in 1000 mL water, adjust pH 3.0 with H_3PO_4 (1 \rightarrow 10)

Flow rate : 1.0 mL/min

Temperature : 40°C

Detection : UV at 230 nm

Injection : 2 μ L

(The draft for the Japanese Pharmacopoeia 16th; Related compounds)

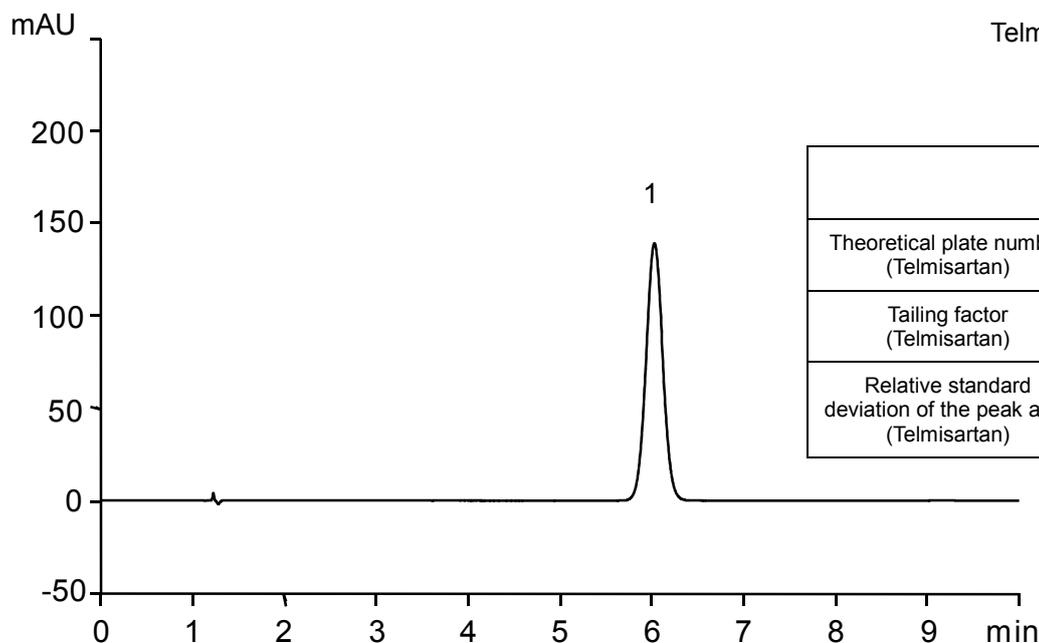
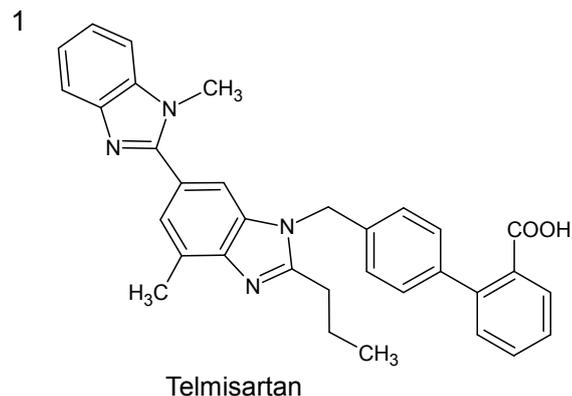
*¹ Standard and Test solutions were prepared from Telmisartan supplied as a reagent for laboratory use.

テルミサルタン錠（日本薬局方原案記載条件）

Telmisartan tablets (The draft for the Japanese Pharmacopoeia)

E130823A

Standard solution*¹
(0.08 mg/mL Telmisartan)



	System suitability requirement	Result
Theoretical plate number (Telmisartan)	≥ 3000	5200
Tailing factor (Telmisartan)	≤ 2.0	1.14
Relative standard deviation of the peak area (Telmisartan)	$\leq 1.0\%$	0.06%

Column : YMC-Triart C18 (5 μ m, 12 nm)
150 X 4.6 mm I.D.

Eluent : phosphate buffer (pH 3.0)^{*2}/ methanol (300/700)
^{*2} Dissolve 2.0 g of (NH₄)₂HPO₄ in 1000 mL water, adjust pH 3.0 with H₃PO₄ (1→10)

Flow rate : 1.25 mL/min (adjust the flow rate so that the retention time of telmisartan is about 6 min)

Temperature : 40°C

Detection : UV at 295 nm

Injection : 10 μ L

(The draft for the Japanese Pharmacopoeia 16th; Assay)

*¹ Standard solution was prepared from Telmisartan supplied as a reagent for laboratory use.