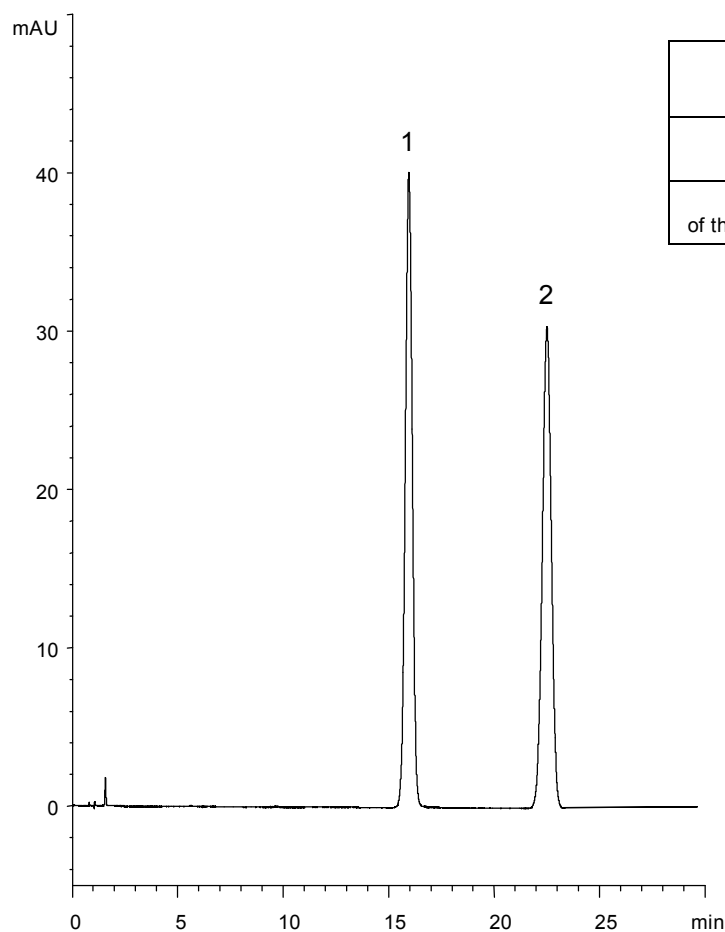


オルメサルタン メドキシミル (日本薬局方記載条件)
Olmesartan Medoxomil (The Japanese Pharmacopoeia)

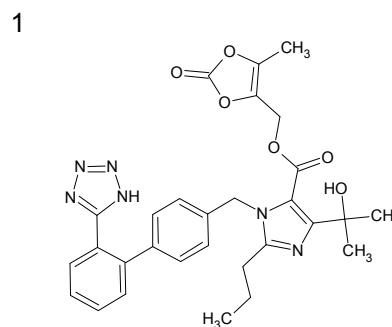
F150113K

Standard solution*1

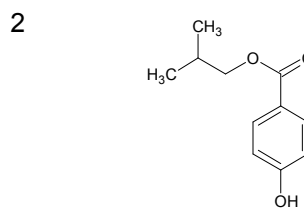
(0.05 mg/mL Olmesartan medoxomil, 0.025 mg/mL *p*-Hydroxybenzoic acid isobutyl ester)



	System suitability requirement	Result
Resolution (1, 2)	≥ 4	9.4
Relative standard deviation of the peak area ratio of 1 to 2 (n=6)	≤ 0.5%	0.30%



Olmesartan medoxomil



p-Hydroxybenzoic acid isobutyl ester (I.S.)

Column : YMC-Triart C18 ExRS (5 μm, 8 nm)
150 X 4.6 mmI.D.

Eluent : phosphate buffer (pH 3.4)*2/acetonitrile (33/17)
*2 Dissolve 2.04 g of KH₂PO₄ in 1000 mL water, adjust pH to 3.4 with a solution of 1.73 g of phosphoric acid in 1000 mL water

Flow rate : 1.2 mL/min
(adjust the flow rate so that the retention time of olmesartan medoxomil is about 16 min)

Temperature : 40°C

Detection : UV at 250 nm

Injection : 10 μL

(The Japanese Pharmacopoeia 16th 2nd supplement; Assay)

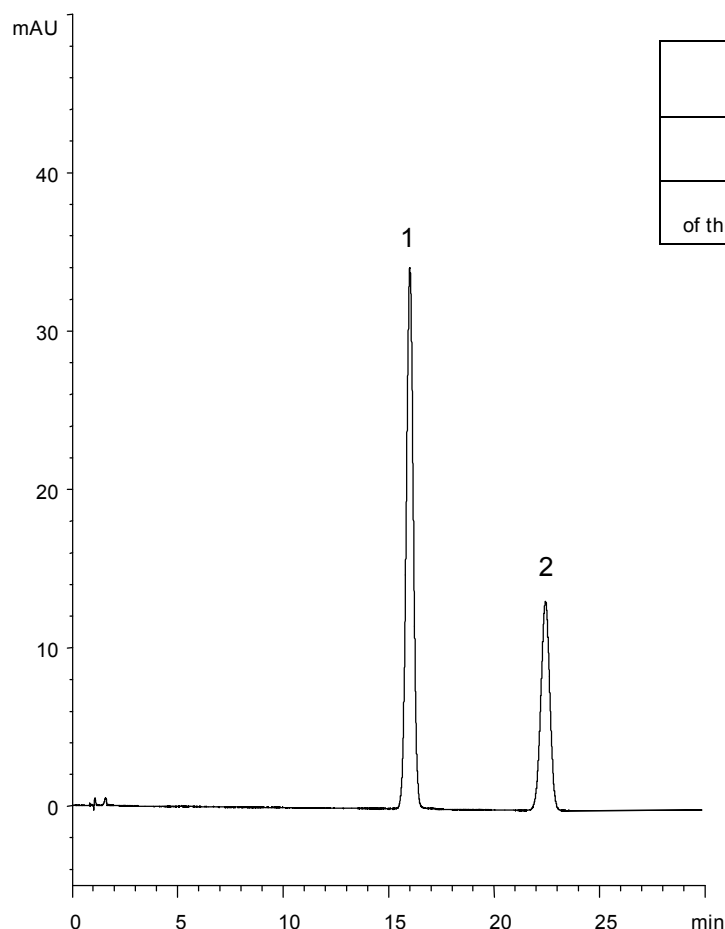
*1 Standard solution was prepared from Olmesartan medoxomil supplied as a reagent for laboratory use.

オルメサルタン メドキシミル錠 (日本薬局方記載条件)
Olmesartan Medoxomil Tablets (The Japanese Pharmacopoeia)

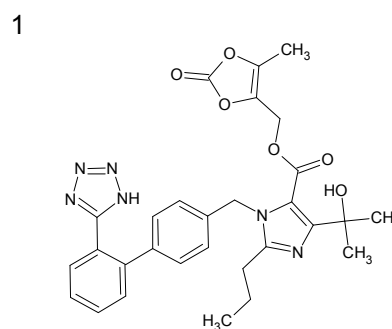
F150113J

Standard solution*¹

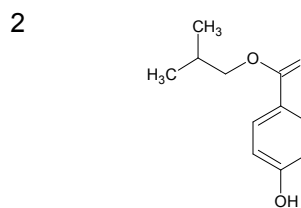
(0.04 mg/mL Olmesartan medoxomil, 0.01 mg/mL *p*-Hydroxybenzoic acid isobutyl ester)



	System suitability requirement	Result
Resolution (1, 2)	≥ 4	9.3
Relative standard deviation of the peak area ratio of 1 to 2 (n=6)	≤ 1.0%	0.85%



Olmesartan medoxomil



p-Hydroxybenzoic acid isobutyl ester (I.S.)

Column : YMC-Triart C18 ExRS (5 μm, 8 nm)
150 X 4.6 mmI.D.

Eluent : phosphate buffer (pH 3.4)*²/acetonitrile (33/17)
*² Dissolve 2.04 g of KH₂PO₄ in 1000 mL water, adjust pH to 3.4 with a solution of 1.73 g of phosphoric acid in 1000 mL water

Flow rate : 1.2 mL/min
(adjust the flow rate so that the retention time of olmesartan medoxomil is about 16 min)

Temperature : 40°C

Detection : UV at 250 nm

Injection : 10 μL

(The Japanese Pharmacopoeia 16th 2nd supplement; Assay)

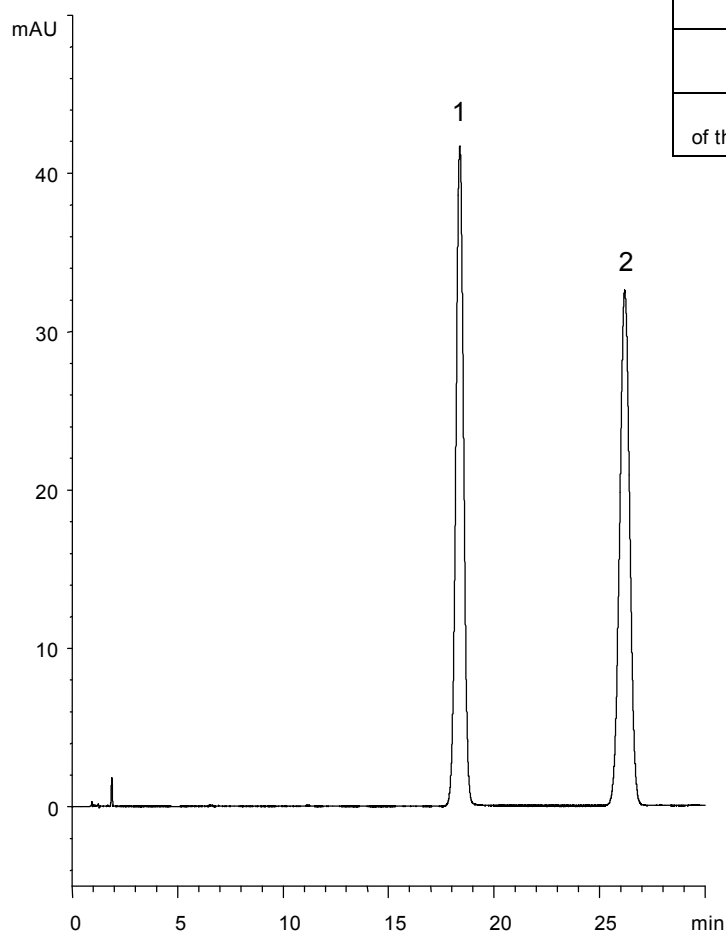
*¹ Standard solution was prepared from Olmesartan medoxomil supplied as a reagent for laboratory use.

オルメサルタン メドキシミル (米国薬局方記載条件)
Olmesartan Medoxomil (The United States Pharmacopeia)

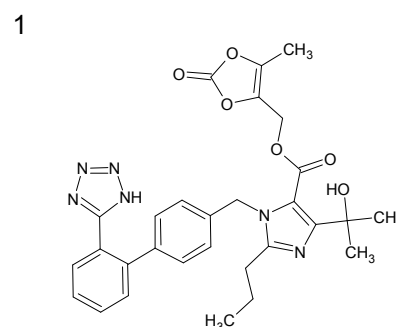
F150119A

Standard solution*¹

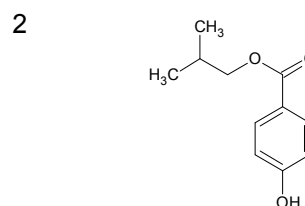
(0.05 mg/mL Olmesartan medoxomil, 0.025 mg/mL *p*-Hydroxybenzoic acid isobutyl ester)



	System suitability requirement	Result
Resolution (1, 2)	≥ 4	10.1
Relative standard deviation of the peak area ratio of 1 to 2 (n=5)	≤ 0.5%	0.09%



Olmesartan medoxomil



p-Hydroxybenzoic acid isobutyl ester (I.S.)

Column : YMC-Triart C18 ExRS (5 μm, 8 nm)
150 X 4.6 mm I.D.
Eluent : 15 mM KH₂PO₄ buffer (pH 3.4)*²/acetonitrile (33/17)
**² Adjust pH to 3.4 with 0.2% (w/v) phosphoric acid*
Flow rate : 1.0 mL/min
Temperature : 40°C
Detection : UV at 250 nm
Injection : 10 μL
(The United States Pharmacopeia 37th; Assay)

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