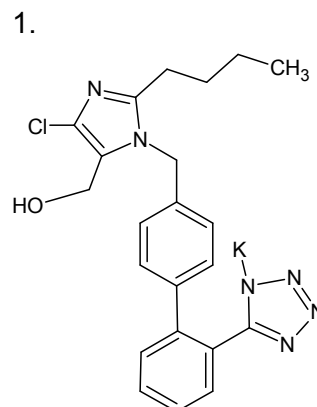
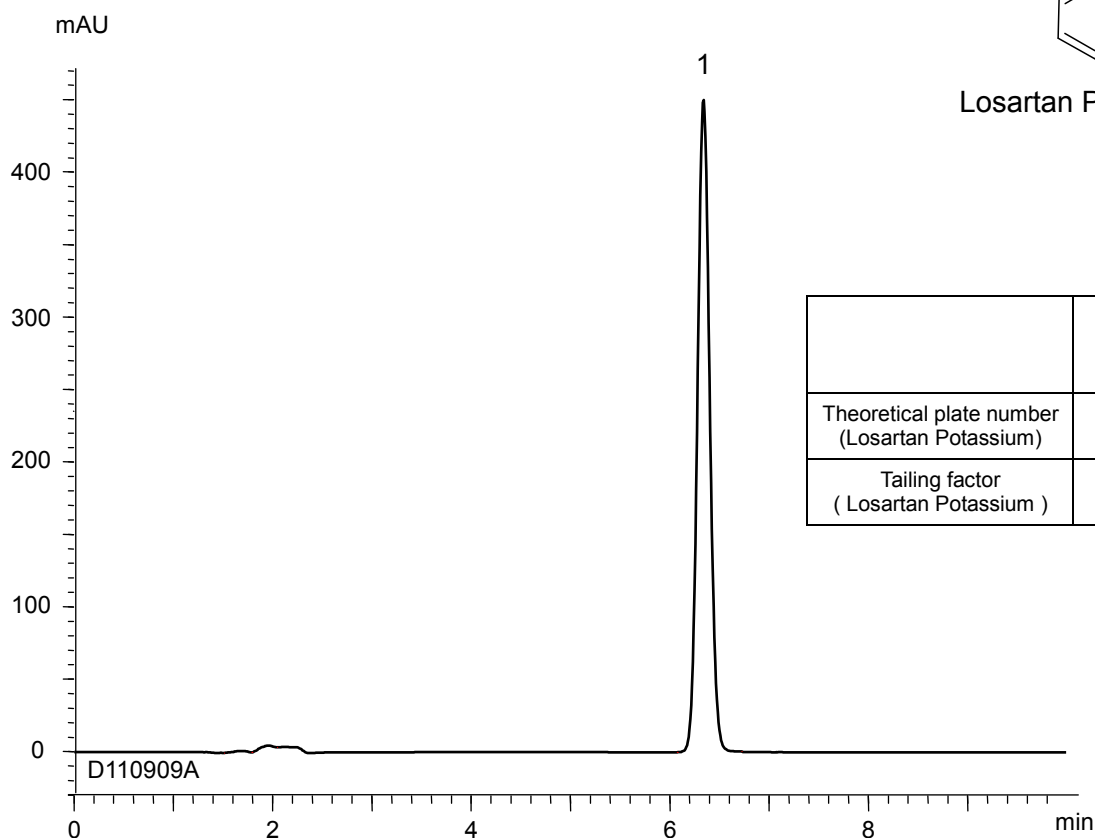


ロサルタンカリウム
Losartan Potassium

D110909A



Losartan Potassium



	System suitability requirement	result
Theoretical plate number (Losartan Potassium)	≥ 5500	12800
Tailing factor (Losartan Potassium)	≤ 1.4	1.11

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

Eluent : 0.1% phosphoric acid/acetonitrile (60/40)

Flow rate : 1.1 mL/min
(adjust the flow rate so that the retention time of losartan is about 6 min)

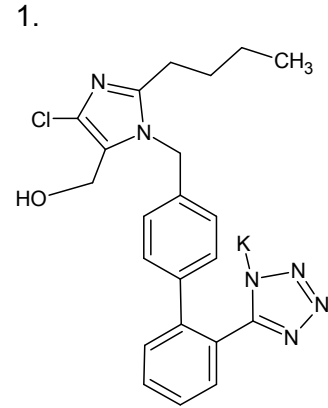
Temperature : 35°C

Detection : UV at 254 nm

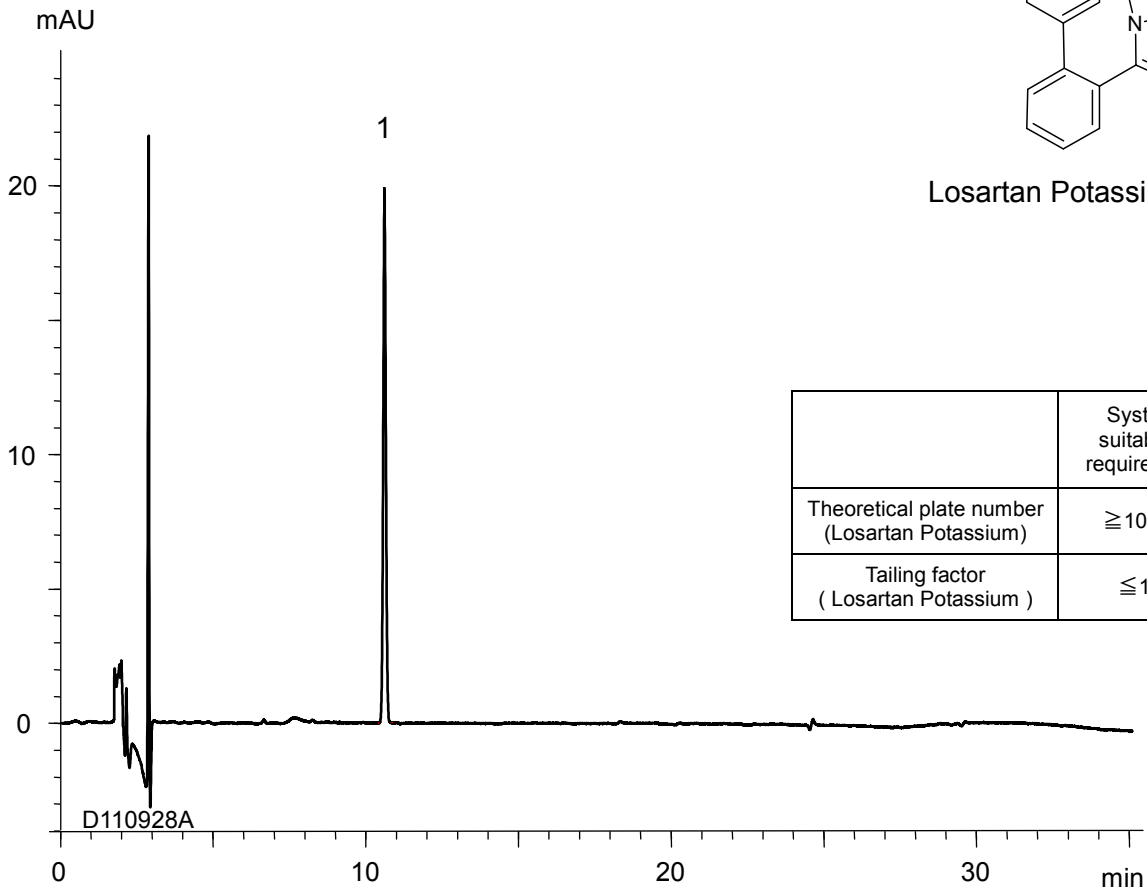
Injection : 10 μ L (0.25 mg/mL)
(The Japanese Pharmacopoeia 16th; Assay)

ロサルタンカリウム
Losartan Potassium

D110928A



Losartan Potassium



	System suitability requirement	result
Theoretical plate number (Losartan Potassium)	≥ 10000	66800
Tailing factor (Losartan Potassium)	≤ 1.3	1.07

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

Eluent : A) 0.1% phosphoric acid
B) acetonitrile
25-90%B (0-25 min), 90%B (25-35 min)

Flow rate : 1.0 mL/min

Temperature : 25°C

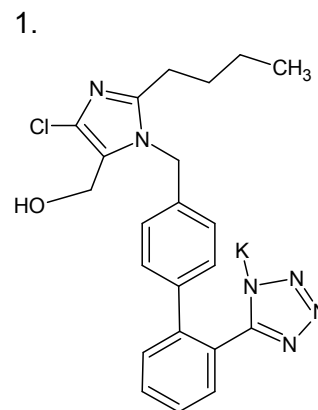
Detection : UV at 220 nm

Injection : 10 μ L (0.003 mg/mL)

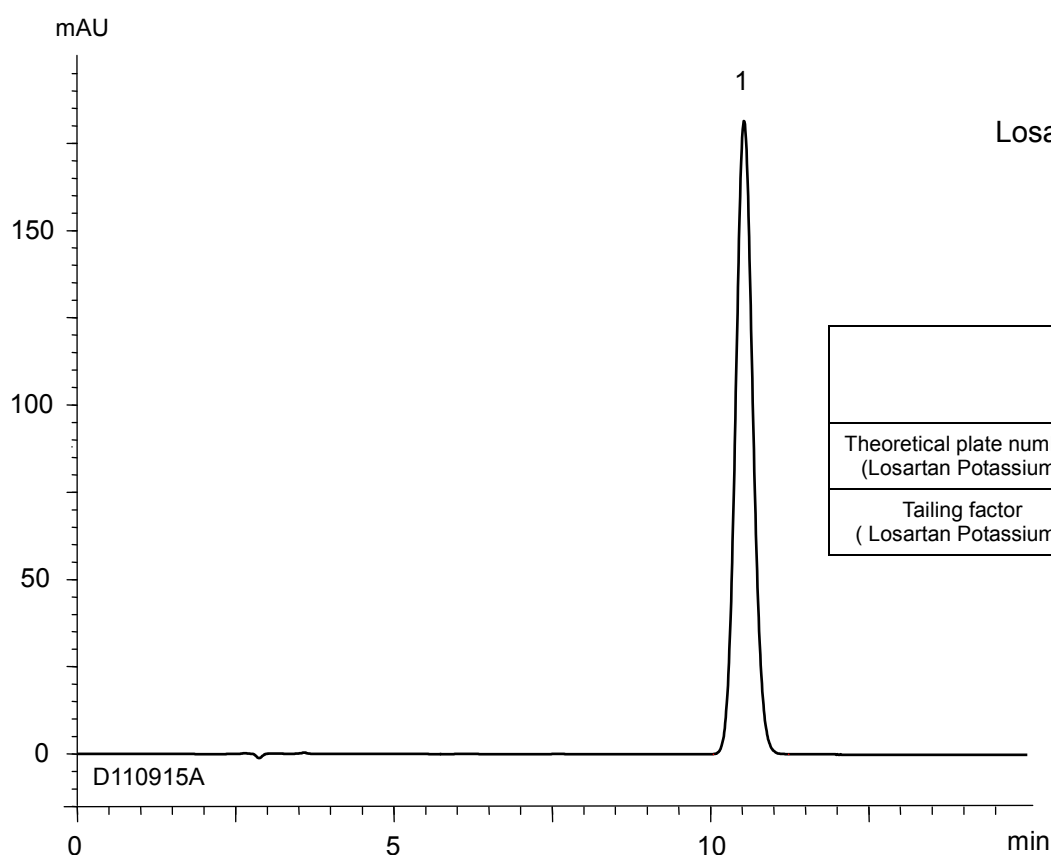
(The Japanese Pharmacopoeia 16th; Related substances)

ロサルタンカリウム錠
Losartan Potassium Tablets

D110915A



Losartan Potassium



	System suitability requirement	result
Theoretical plate number (Losartan Potassium)	≥ 3000	7100
Tailing factor (Losartan Potassium)	≤ 1.5	1.08

Column : YMC-Pack C₈ (10 μ m, 12 nm)
250 X 4.6 mm I.D.

Eluent : phosphate buffer (pH 2.5)* / acetonitrile (60/40)
*Dissolve 1.36 g of NaH₂PO₄ in 900 mL of water, adjust pH 2.5 with H₃PO₄, and add water to make 1000 mL

Flow rate : 0.9 mL/min
(adjust the flow rate so that the retention time of losartan is about 10 min)

Temperature : 35°C

Detection : UV at 230 nm

Injection : 20 μ L (0.05 mg/mL)

(The draft for the Japanese Pharmacopoeia; Assay)