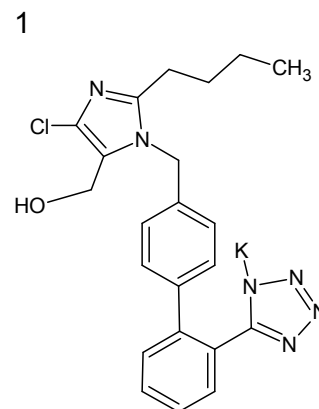
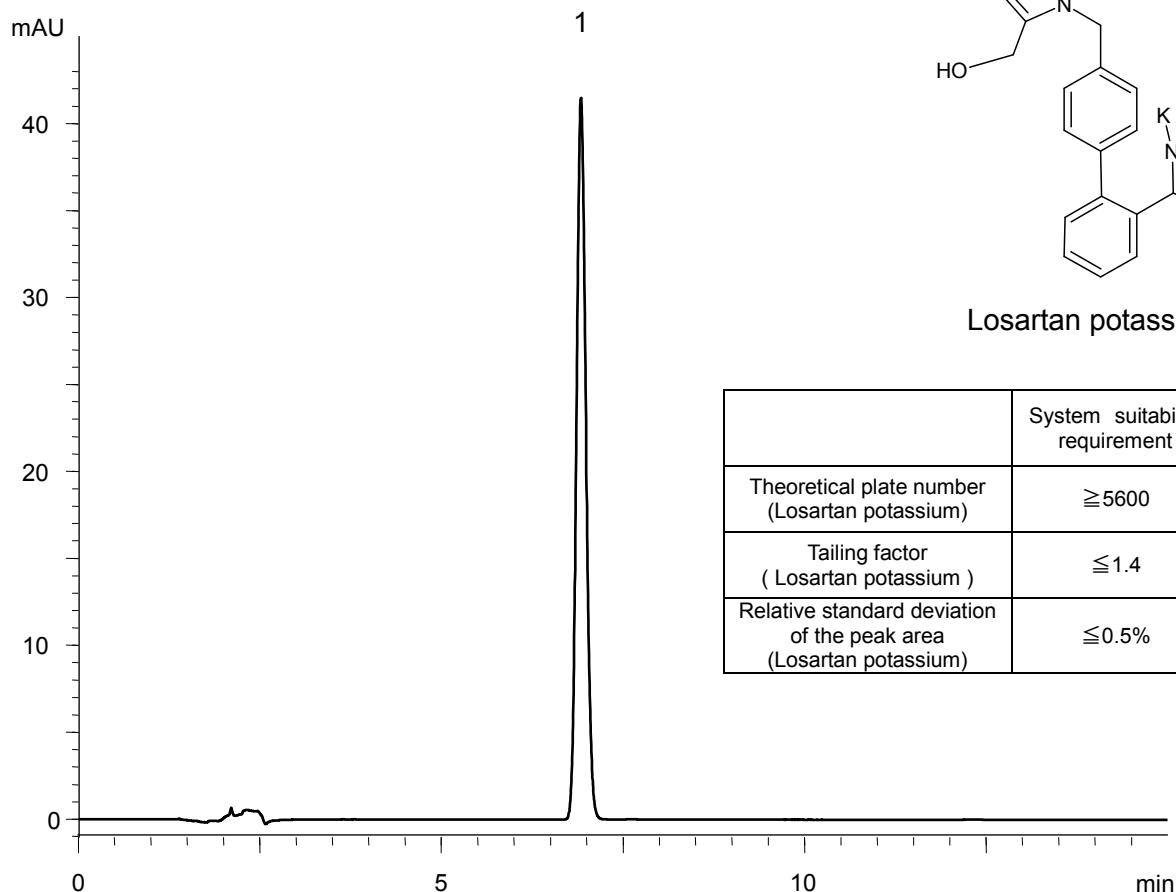


ロサルタンカリウム  
Losartan potassium

D111104A

Standard solution \*  
(0.25 mg/mL Losartan potassium)



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

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

Flow rate : 1.0 mL/min

Temperature : 35°C

Detection : UV at 254 nm

Injection : 10  $\mu$ L

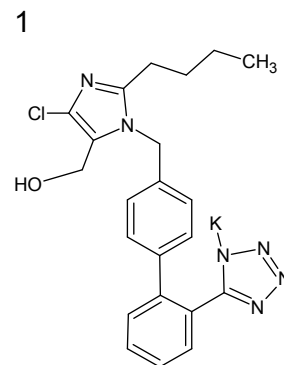
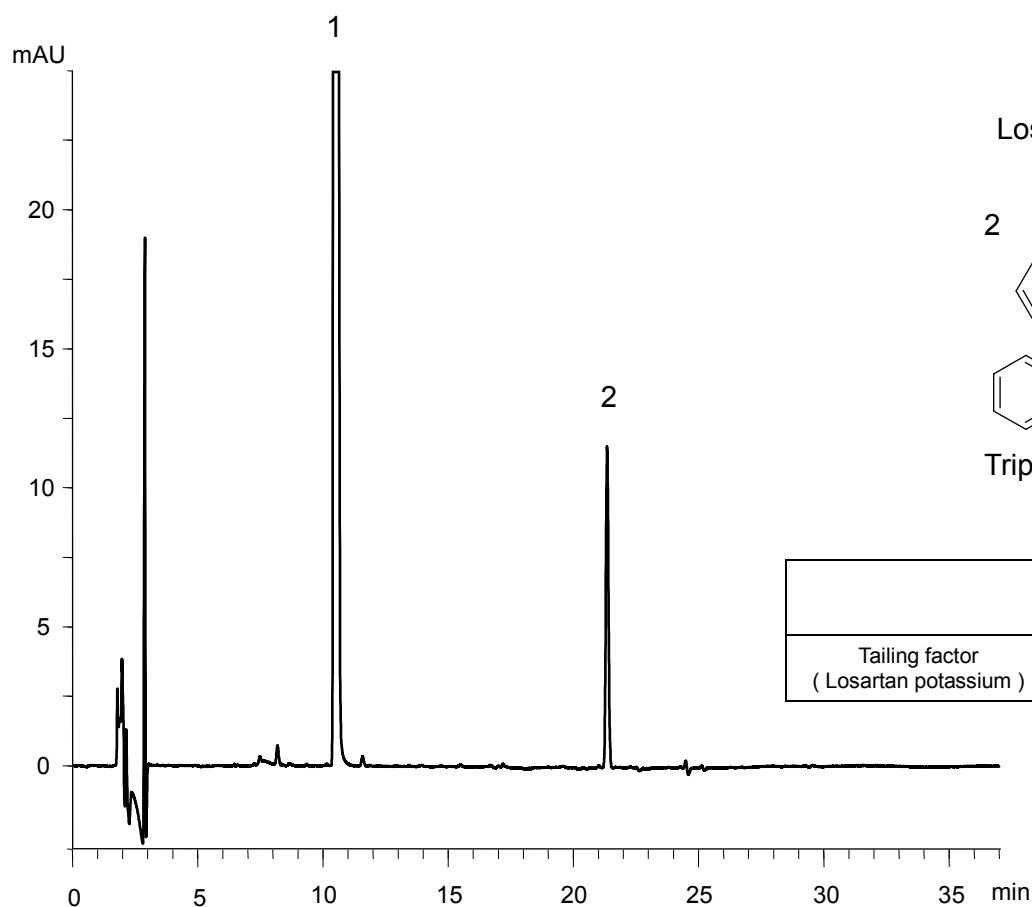
(The United States Pharmacopeia 34th; Assay)

\* Standard solution was prepared from Losartan potassium supplied as a reagent for laboratory use.

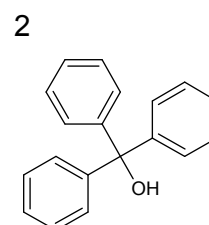
ロサルタンカリウム  
Losartan potassium

D111122A

System suitability solution \*  
(0.3 mg/mL Losartan potassium, 0.002 mg/mL Triphenylmethanol)



Losartan potassium



Triphenylmethanol

	System suitability requirement	Result
Tailing factor ( Losartan potassium )	≤ 1.6	1.16

Column : YMC-Triart C18 (5 μm, 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 μL

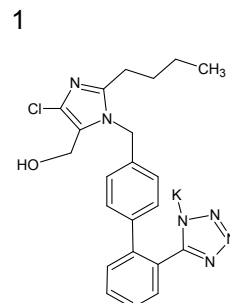
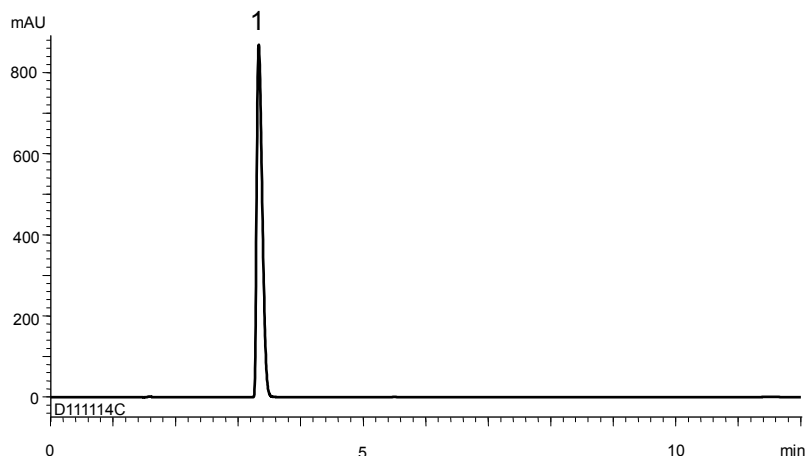
(The United States Pharmacopeia 34th; Chromatographic purity)

\* System suitability solution was prepared from Losartan potassium supplied as a reagent for laboratory use.

ロサルタンカリウム錠  
Losartan potassium tablets

D111229B

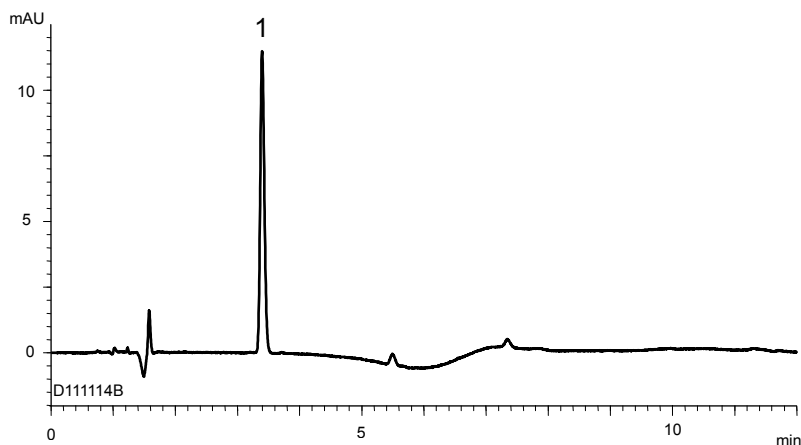
A) Assay: Standard solution\*<sup>1</sup> (0.25 mg/mL Losartan potassium)



Losartan Potassium

	System suitability requirement	Result
Theoretical plate number (Losartan potassium)	$\geq 3000$	6300
Tailing factor (Losartan potassium)	$\leq 2.0$	1.59

B) Impurities: Standard solution\*<sup>1</sup> (0.0025 mg/mL Losartan potassium)



	System suitability requirement	Result
Theoretical plate number (Losartan potassium)	$\geq 3000$	12200
Tailing factor (Losartan potassium)	$\leq 2.0$	1.18
Relative standard deviation of the peak area (Losartan potassium)	$\leq 5.0\%$	0.60%

Column : YMC-Triart C8 (5  $\mu$ m, 12 nm)  
150 X 4.0 mm I.D.

Eluent : A) phosphate buffer (pH 6.7)\*<sup>2</sup>/acetonitrile (85/15)  
B) acetonitrile  
20-60%B (0-10 min)  
*\*<sup>2</sup> Dissolve 1.25 g of  $KH_2PO_4$  and 2.01 g  $Na_2HPO_4 \cdot 12H_2O$  in 1000 mL of water*

Flow rate : 1.0 mL/min

Temperature : 25°C

Detection : UV at 250 nm

Injection : 10  $\mu$ L

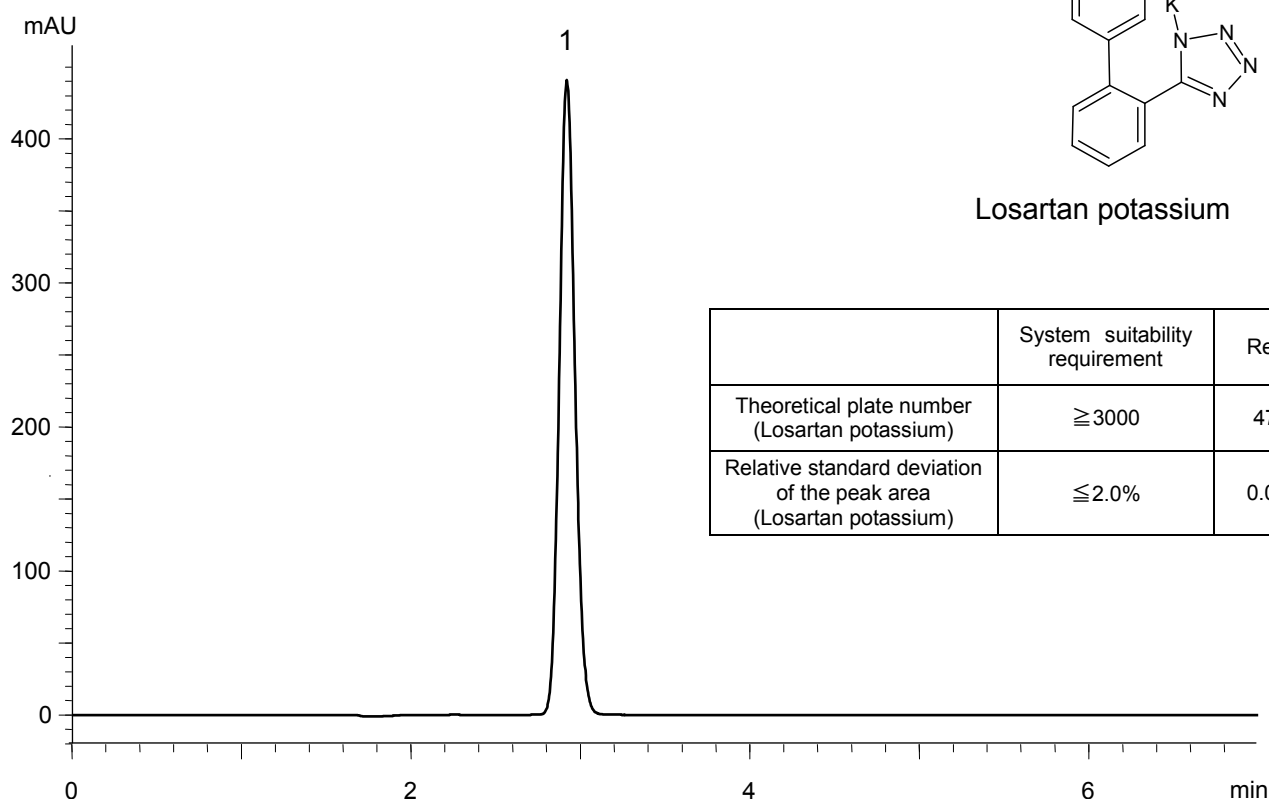
(The United States Pharmacopeia 34th)

\*<sup>1</sup> Standard solution was prepared from Losartan potassium supplied as a reagent for laboratory use.

ロサルタンカリウム錠  
Losartan potassium tablets

D111031B

Standard solution \*1  
(0.05 mg/mL Losartan potassium)



Column : YMC-Pack C<sub>8</sub> (10 μm, 12 nm)  
250 X 4.6 mm I.D.

Eluent : phosphate buffer (pH 2.5)\*<sup>2</sup>/acetonitrile (40/60)  
*\*<sup>2</sup> Dissolve 1.36 g of KH<sub>2</sub>PO<sub>4</sub> in 1000 mL of water, and adjust pH 2.5 with H<sub>3</sub>PO<sub>4</sub>*

Flow rate : 1.4 mL/min

Temperature : 25°C

Detection : UV at 230 nm

Injection : 20 μL

(The United States Pharmacopeia 34th; Uniformity of dosage units)

\*<sup>1</sup> Standard solution was prepared from Losartan potassium supplied as a reagent for laboratory use.