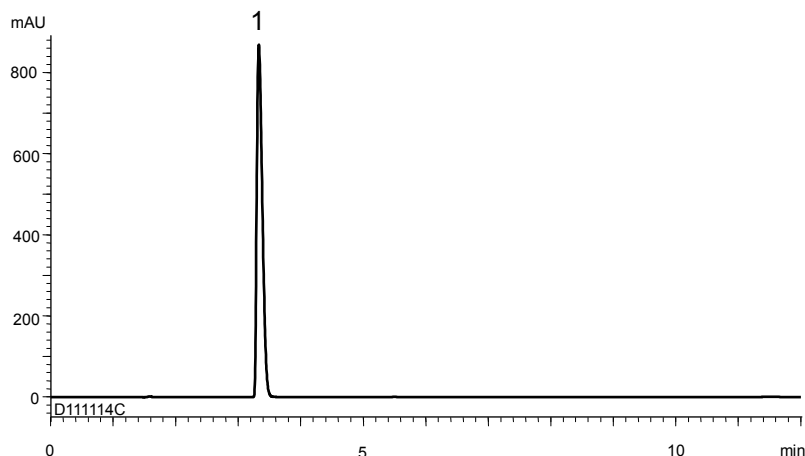


ロサルタンカリウム錠 (米国薬局方記載条件)

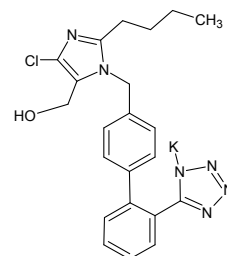
Losartan potassium tablets (The United States Pharmacopeia)

D111229B

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



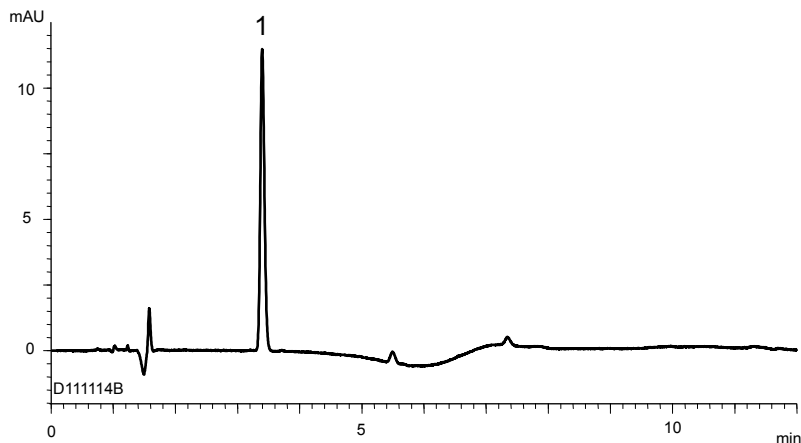
1



Losartan Potassium

	System suitability requirement	Result
Theoretical plate number (Losartan potassium)	≥ 3000	6300
Tailing factor (Losartan potassium)	≤ 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)	≥ 3000	12200
Tailing factor (Losartan potassium)	≤ 2.0	1.18
Relative standard deviation of the peak area (Losartan potassium)	≤ 5.0%	0.60%

Column : YMC-Triart C8 (5 μm, 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<sub>2</sub>PO<sub>4</sub> and 2.01 g Na<sub>2</sub>HPO<sub>4</sub> · 12H<sub>2</sub>O in 1000 mL of water

Flow rate : 1.0 mL/min

Temperature : 25°C

Detection : UV at 250 nm

Injection : 10 μL

(The United States Pharmacopeia 34th)

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