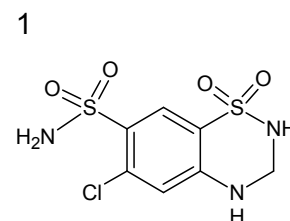


ロサルタンカリウム・ヒドロクロロチアジド錠（米国薬局方記載条件）

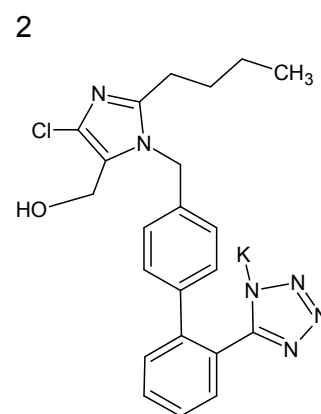
Losartan potassium and Hydrochlorothiazide tablets (The United States Pharmacopeia)

D111117A

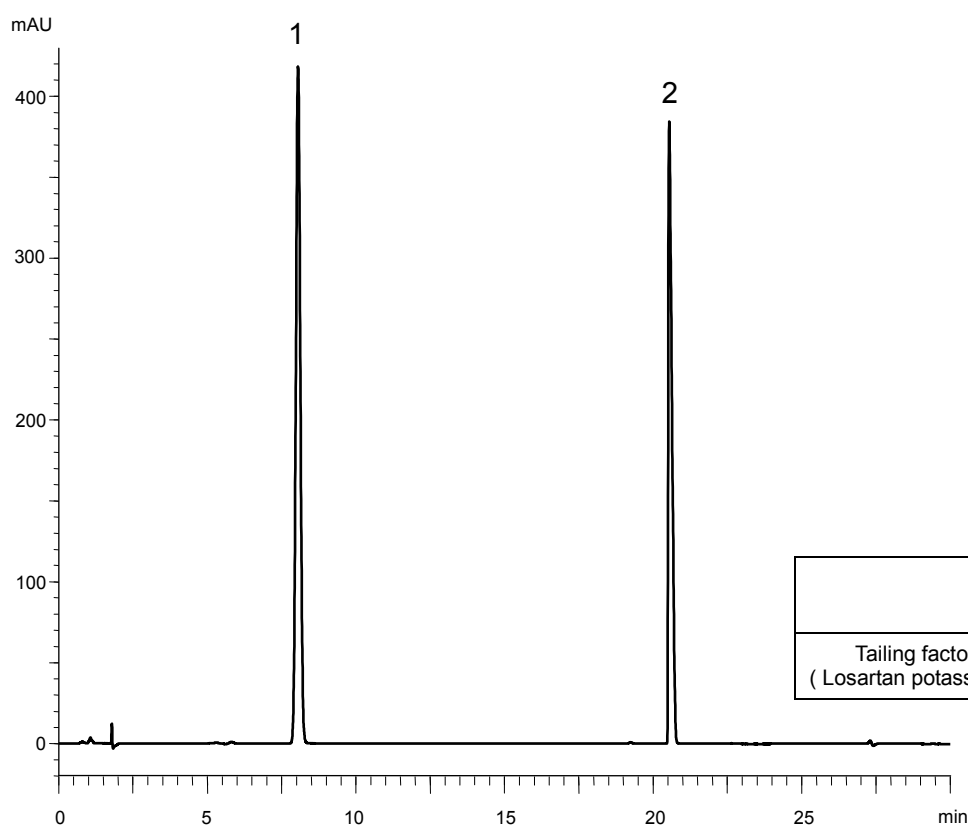
Standard solution *1
(0.1 mg/mL Hydrochlorothiazide, 0.4 mg/mL Losartan potassium)



Hydrochlorothiazide



Losartan potassium



	System suitability requirement	Result
Tailing factor (Losartan potassium)	≤ 2.5	2.28

Column : YMC-Triart C8 (5 μm, 12 nm)
150 X 4.0 mmI.D.

Eluent : A) phosphate buffer (pH 6.7)*2/acetonitrile (93/7)
B) acetonitrile
0-8%B (0-12 min), 8-62%B (12-28 min)

*2 Dissolve 1.25 g of KH_2PO_4 and 2.01 g of $Na_2HPO_4 \cdot 12H_2O$ in 1000 mL of water

Flow rate : 1.0 mL/min

Temperature : 35°C

Detection : UV at 280 nm

Injection : 20 μL

(The United States Pharmacopeia 34th; Assay)

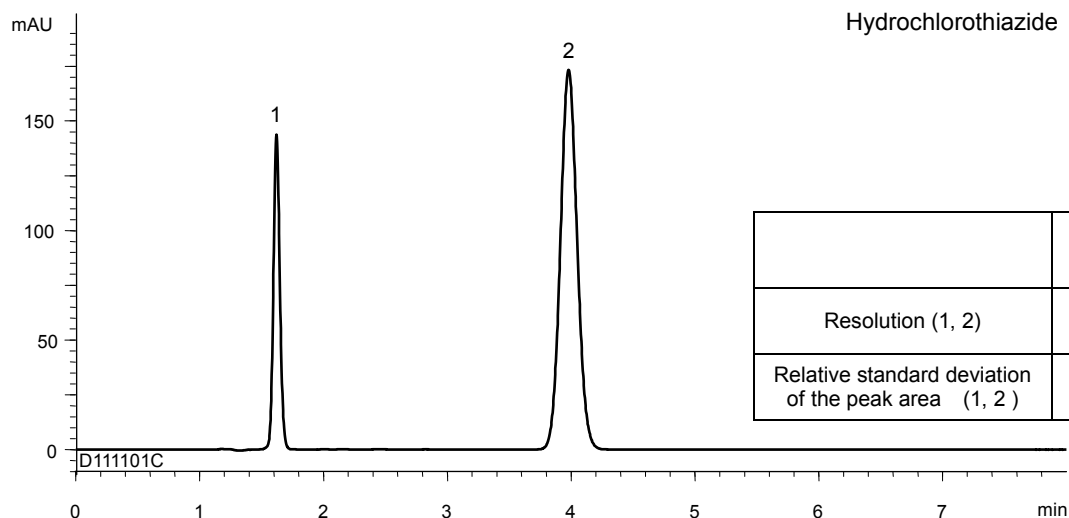
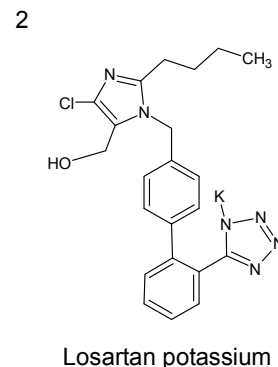
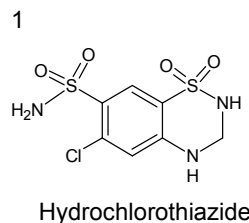
*1 Standard solution was prepared from Hydrochlorothiazide and Losartan potassium supplied as a reagent for laboratory use.

ロサルタンカリウム・ヒドロクロロチアジド錠 (米国薬局方記載条件)

Losartan potassium and Hydrochlorothiazide tablets (The United States Pharmacopeia)

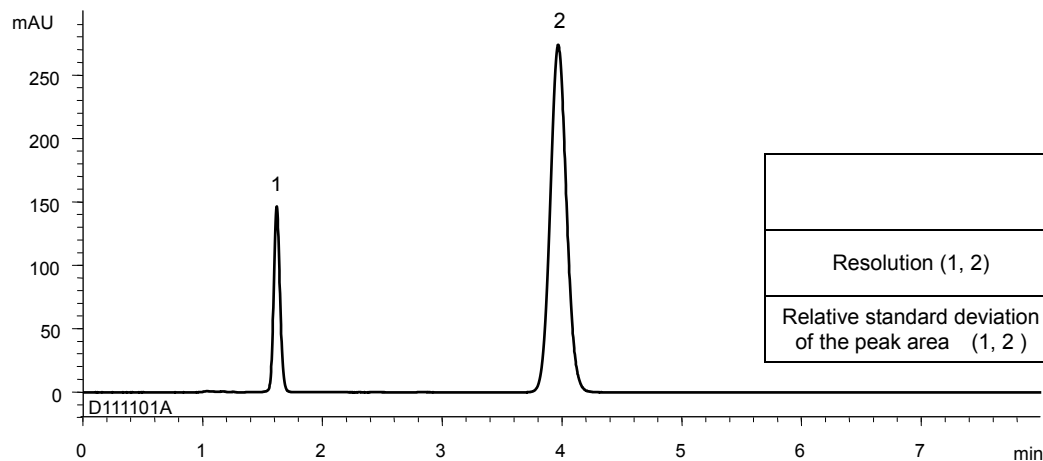
D111229A

A) Dissolution: Standard solution*1
(0.014 mg/mL Hydrochlorothiazide, 0.055 mg/mL Losartan potassium)



	System suitability requirement	Result
Resolution (1, 2)	≥ 2	13.8
Relative standard deviation of the peak area (1, 2)	$\leq 2.0\%$	0.02%

B) Uniformity of dosage units: Standard solution*1
(0.014 mg/mL Hydrochlorothiazide, 0.06 mg/mL Losartan potassium)



	System suitability requirement	Result
Resolution (1, 2)	≥ 2	13.7
Relative standard deviation of the peak area (1, 2)	$\leq 2.0\%$	0.02%

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

Eluent : phosphate buffer (pH 2.5)*2 / acetonitrile (60/40)

*2 Dissolve 1.36 g of KH₂PO₄ in 1000 mL of water, and adjust pH 2.5 with H₃PO₄

Flow rate : 2.3 mL/min

Temperature : 35°C

Detection : UV at 230 nm

Injection : 20 μL

(The United States Pharmacopeia 34th)

*1 Standard solutions were prepared from Hydrochlorothiazide and Losartan potassium supplied as a reagent for laboratory use.