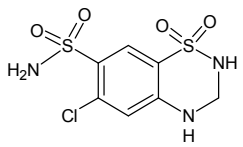
HPLC DATA SHEET

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)

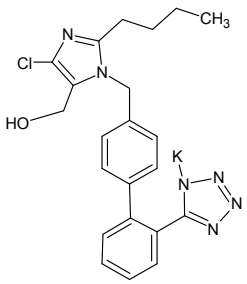
D111229A

1



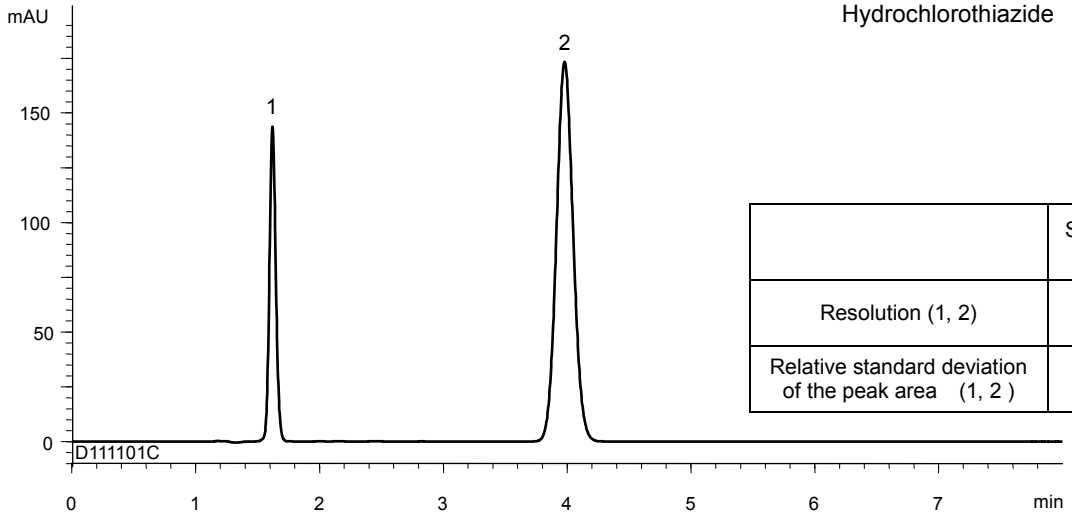
Hydrochlorothiazide

2



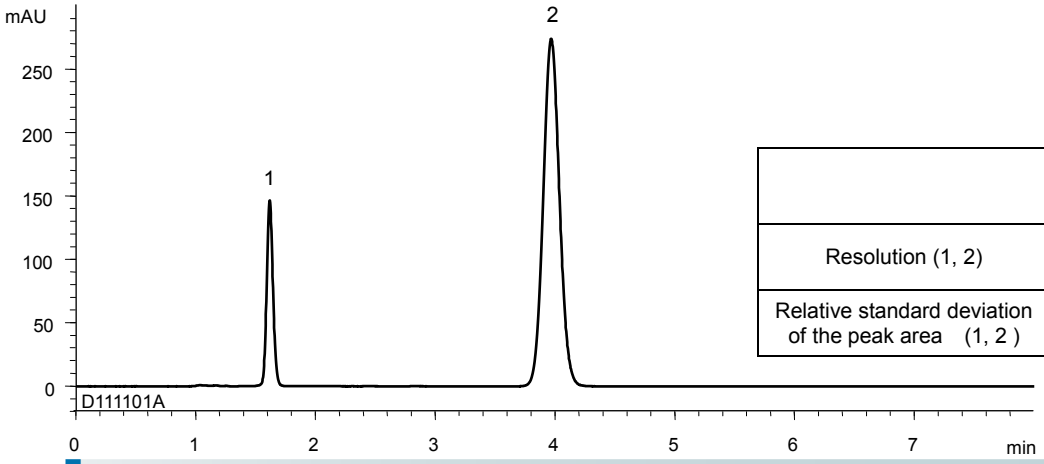
Losartan potassium

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)	≦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)	≦2.0%	0.02%

Column : YMC-Pack C_8 (10 μm, 12 nm)
250 X 4.6 mmI.D.
Eluent : phosphate buffer (pH 2.5)*2 /acetonitrile (60/40)
*2*Dissolve 1.36 g of KH_2PO_4 in 1000 mL of water, and adjust pH 2.5 with H_3PO_4*
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.