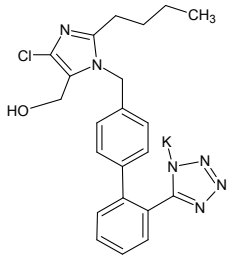
YMC SEPARATION TECHNOLOGY

HPLC DATA SHEET

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)

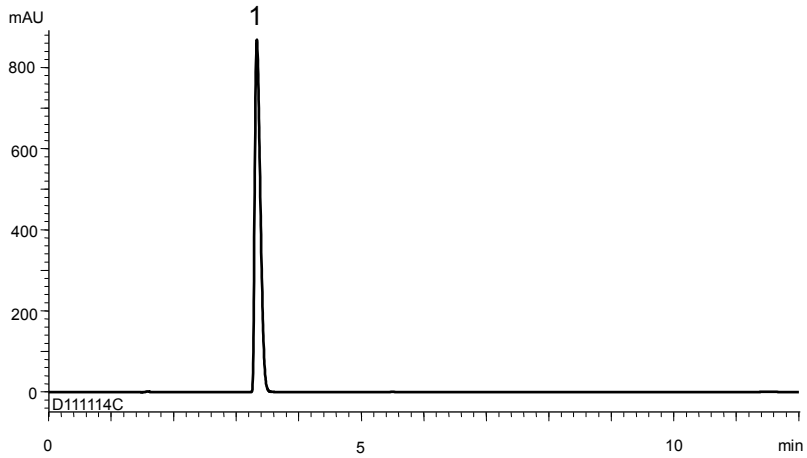
D111229B

1



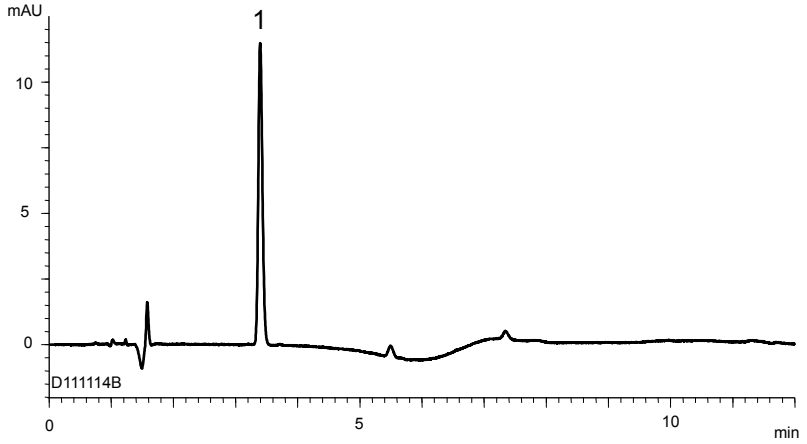
Losartan Potassium

(A) Assay: Standard solution*1 (0.25 mg/mL 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*1 (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 mmI.D.
Eluent	: A) phosphate buffer (pH 6.7)*2/acetonitrile (85/15)
	B) acetonitrile
	20-60%B (0-10 min)
	*2 *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℃
Detection	: UV at 250 nm
Injection	: 10 μL

(The United States Pharmacopeia 34th)

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