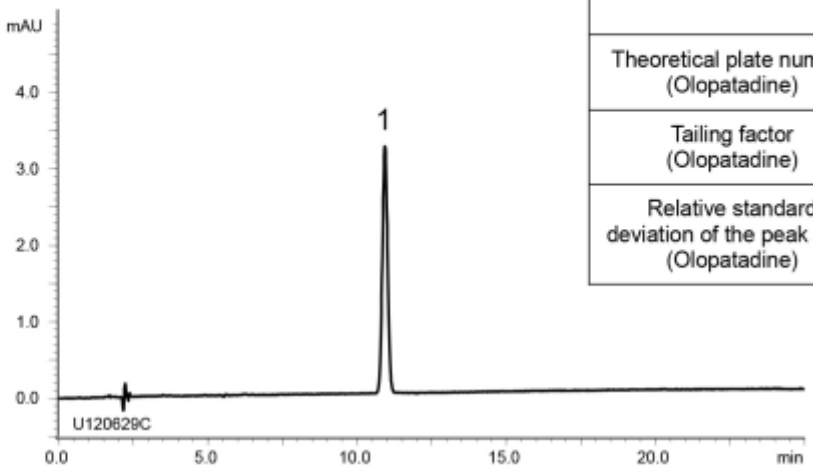
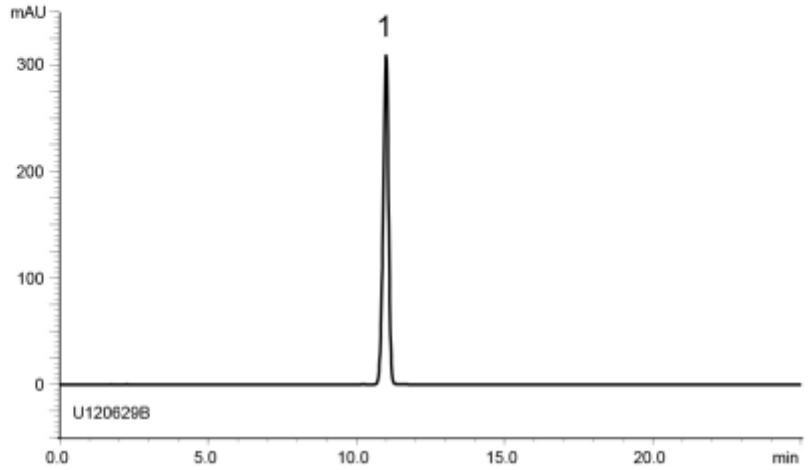
A) Standard solution*1
(0.005 mg/mL Olopatadine HCl)

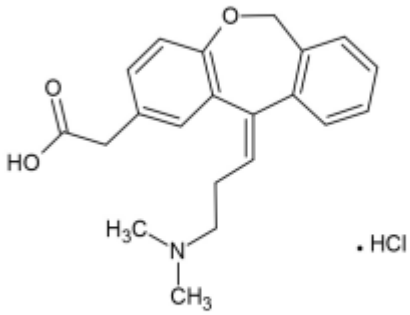


	System suitability requirement	Result
Theoretical plate number (Olopatadine)	≧8000	18100
Tailing factor (Olopatadine)	≦2.0	1.08
Relative standard deviation of the peak area (Olopatadine)	≦1.0%	0.07%

B) Sample solution*1
(0.5 mg/mL Olopatadine HCl)



1



Olopatadine hydrochloride

Column	: YMC-Triart C8 (5 μm, 12 nm) 250 X 4.6 mmI.D.
Eluent	: phosphate buffer (pH 3.5)*2/acetonitrile (11/9) containing 8 mM sodium lauryl sulfate
	*2 *Dissolve 8.6 g of KH_2PO_4 in 1000 mL of water, adjust pH 3.5 with H_3PO_4 (49→10000)*
Flow rate	: 1.1 mL/min *(adjust the flow rate so that the retention time of olopatadine is about 11 min)*
Temperature	: 40°C
Detection	: UV at 299 nm
Injection	: 20 μL

(The draft for the Japanese Pharmacopoeia; Related substances)

*1 All standard and sample solutions were prepared from Olopatadine hydrochloride supplied as a reagent for laboratory use.