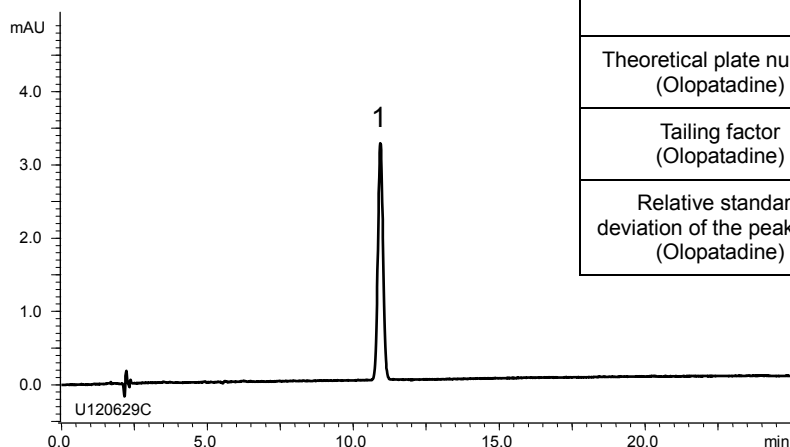


オロパタジン塩酸塩（日本薬局方収載原案記載条件）

Olopatadine hydrochloride (The draft for the Japanese Pharmacopoeia)

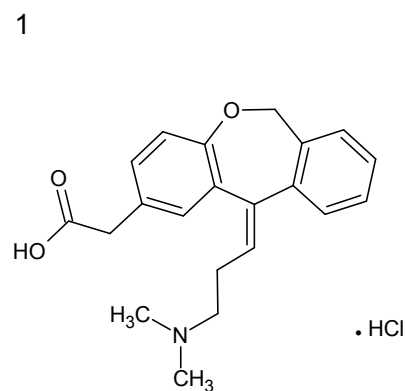
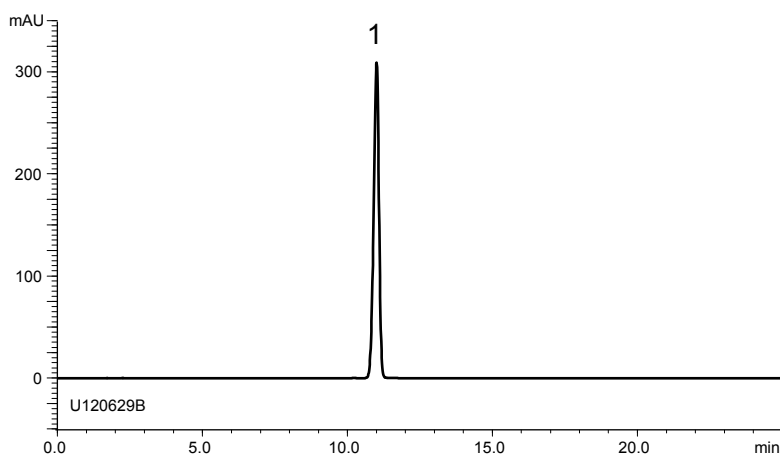
U120724A

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)	$\leq 1.0\%$	0.07%

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



Olopatadine hydrochloride

Column : YMC-Triart C8 (5 μ m, 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 μ L

(The draft for the Japanese Pharmacopoeia; Related substances)

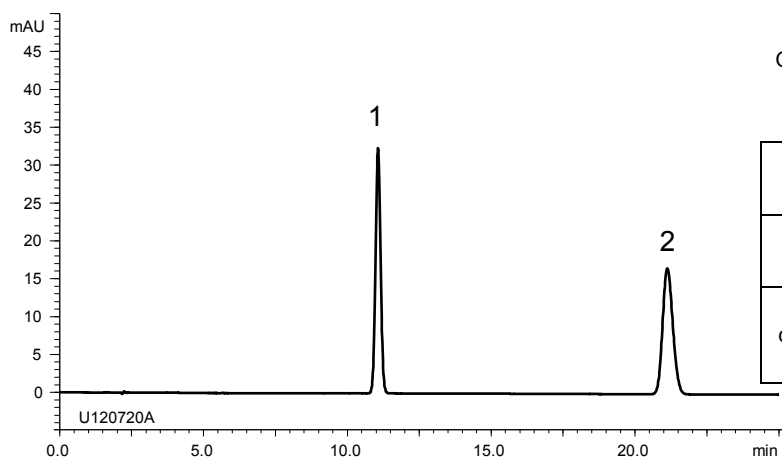
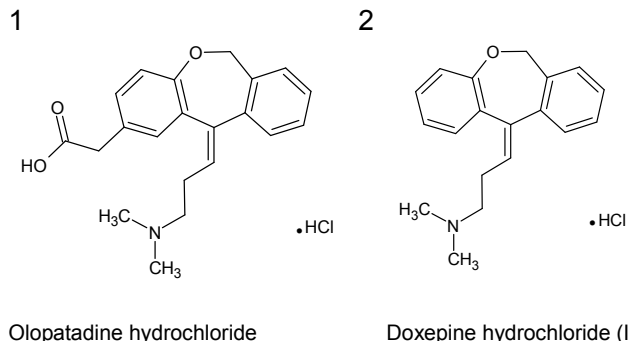
*¹ All standard and sample solutions were prepared from Olopatadine hydrochloride supplied as a reagent for laboratory use.

オロパタジン塩酸塩錠（日本薬局方収載原案記載条件）

Olopatadine hydrochloride tablets (The draft for the Japanese Pharmacopoeia)

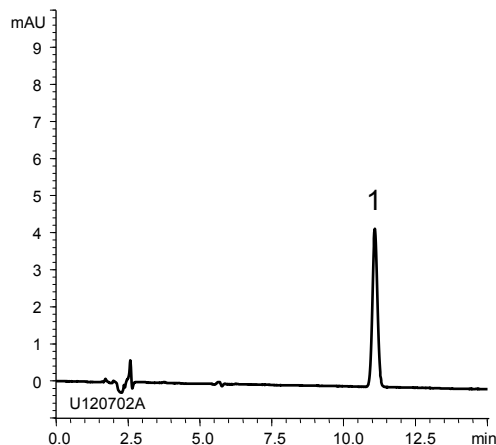
U120724B

A) Assay: Standard solution*1
(0.05 mg/mL Olopatadine HCl, 0.035 mg/mL Doxepine HCl)



	System suitability requirement	Result
Resolution (1, 2)	≥ 13	20.5
Relative standard deviation of the peak area ratio of 1 to 2	$\leq 1.0\%$	0.07%

B) Dissolution: Standard solution*1
(0.0028 mg/mL Olopatadine HCl)



	System suitability requirement	Result
Theoretical plate number (Olopatadine)	≥ 10000	18700
Tailing factor (Olopatadine)	≤ 2.0	1.08
Relative standard deviation of the peak area (Olopatadine)	$\leq 1.5\%$	0.07%

Column : YMC-Triart C8 (5 μ m, 12 nm)
250 X 4.6 mm I.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 μ L

(The draft for the Japanese Pharmacopoeia; Assay, Dissolution)

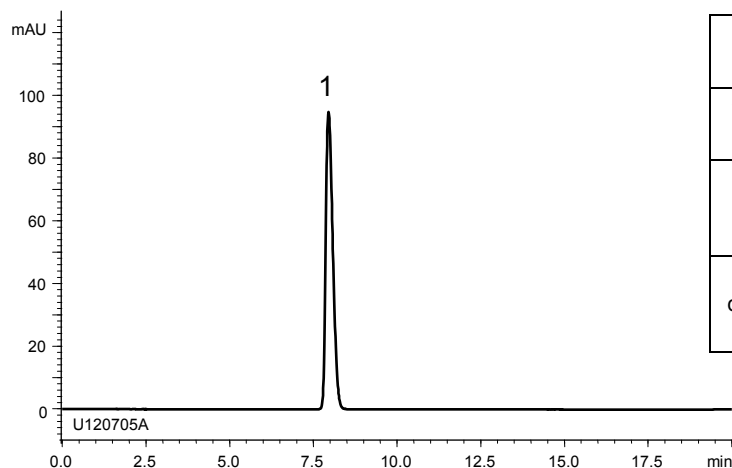
*1 All standard solutions were prepared from Olopatadine hydrochloride supplied as a reagent for laboratory use.

オロパタジン塩酸塩点眼薬（米国薬局方記載条件）

Olopatadine hydrochloride ophthalmic solution (The United States Pharmacopeia)

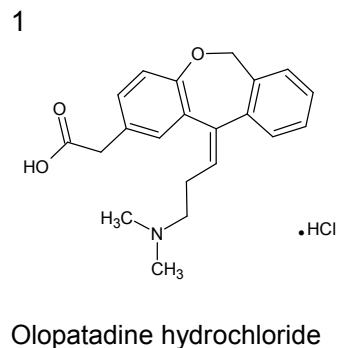
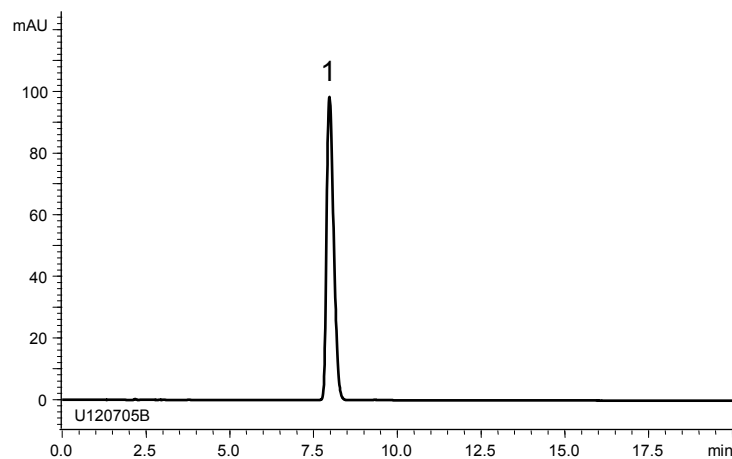
U120706C

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



	System suitability requirement	Result
Theoretical plate number (Olopatadine)	≥ 2000	6700
Tailing factor (Olopatadine)	≤ 2.0	1.43
Relative standard deviation of the peak area (Olopatadine)	$\leq 2.0\%$	0.26%

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



Column : YMC-Triart C8 (5 μ m, 12 nm)
150 X 4.6 mm I.D.

Eluent : phosphate buffer (pH 3.0)*²/acetonitrile (18/7)
*² Dissolve 13.6 g of KH_2PO_4 in 1000 mL of water, add 1 mL triethylamine, adjust pH 3.0 with H_3PO_4

Flow rate : 1.0 mL/min

Temperature : 25°C

Detection : UV at 299 nm

Injection : 30 μ L

(The United States Pharmacopeia 34th; Assay)

*¹ Standard solution was prepared from Olopatadine hydrochloride supplied as a reagent for laboratory use.
Sample solution was prepared from Olopatadine hydrochloride ophthalmic solution.