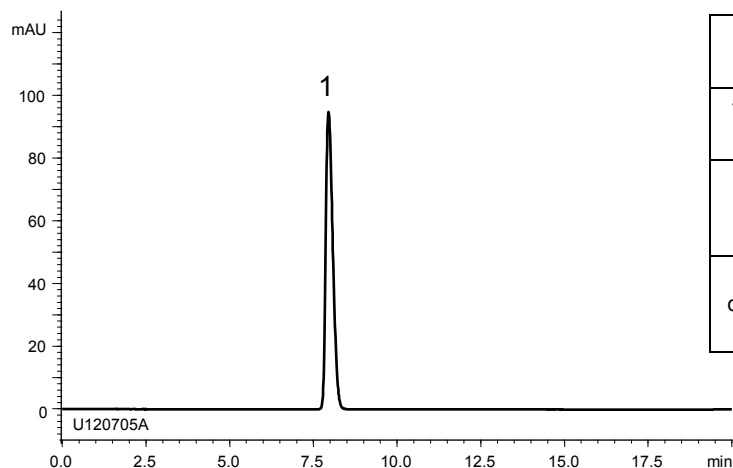


オロパタジン塩酸塩点眼薬（米国薬局方記載条件）

Olopatadine hydrochloride ophthalmic solution (The United States Pharmacopeia)

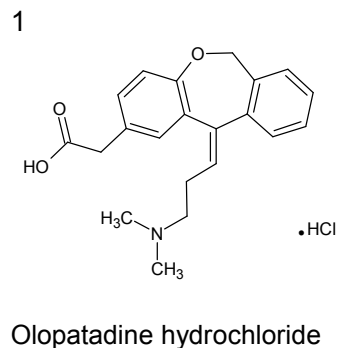
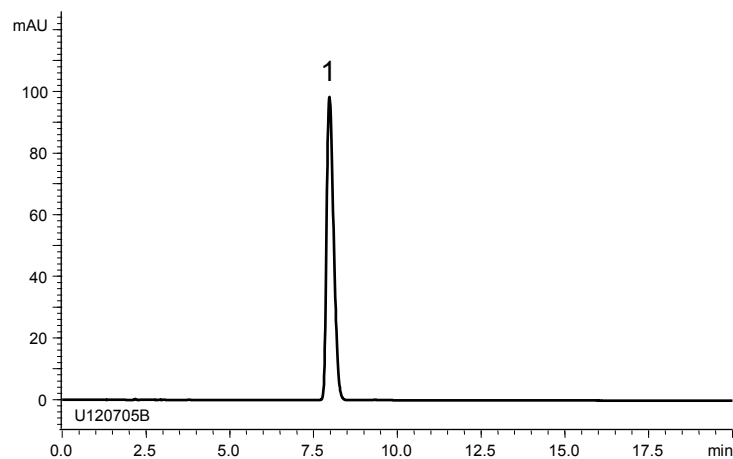
U120706C

A) Standard solution\*<sup>1</sup>  
(0.1 mg/mL Olopatadine HCl)



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

B) Sample solution\*<sup>1</sup>  
(0.1 mg/mL Olopatadine HCl)



Column : YMC-Triart C8 (5  $\mu$ m, 12 nm)

150 X 4.6 mm I.D.

Eluent : phosphate buffer (pH 3.0)\*<sup>2</sup>/acetonitrile (18/7)

\*<sup>2</sup> 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  $\mu$ L

(The United States Pharmacopeia 34th; Assay)

\*<sup>1</sup> Standard solution was prepared from Olopatadine hydrochloride supplied as a reagent for laboratory use.  
Sample solution was prepared from Olopatadine hydrochloride ophthalmic solution.