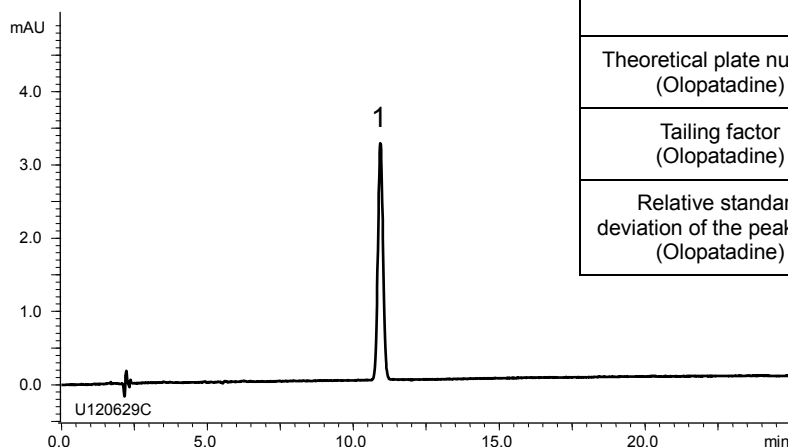


オロパタジン塩酸塩 (日本薬局方収載原案記載条件)  
Olopatadine hydrochloride (The draft for the Japanese Pharmacopoeia)

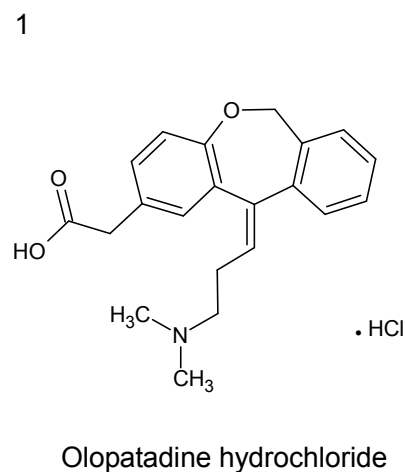
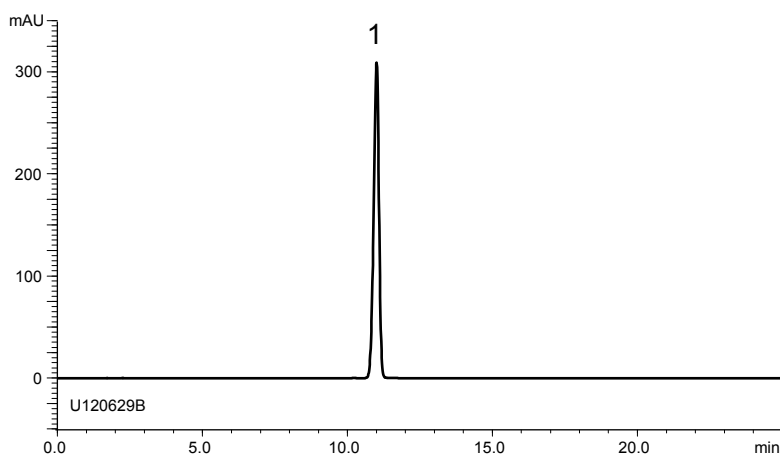
U120724A

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



|                                                            | System suitability requirement | Result |
|------------------------------------------------------------|--------------------------------|--------|
| Theoretical plate number (Olopatadine)                     | $\geq 8000$                    | 18100  |
| Tailing factor (Olopatadine)                               | $\leq 2.0$                     | 1.08   |
| Relative standard deviation of the peak area (Olopatadine) | $\leq 1.0\%$                   | 0.07%  |

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



Column : YMC-Triart C8 (5  $\mu$ m, 12 nm)  
250 X 4.6 mmI.D.

Eluent : phosphate buffer (pH 3.5)\*<sup>2</sup>/acetonitrile (11/9) containing 8 mM sodium lauryl sulfate  
\*<sup>2</sup> Dissolve 8.6 g of  $\text{KH}_2\text{PO}_4$  in 1000 mL of water, adjust pH 3.5 with  $\text{H}_3\text{PO}_4$  (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  $\mu$ L

(The draft for the Japanese Pharmacopoeia; Related substances)

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