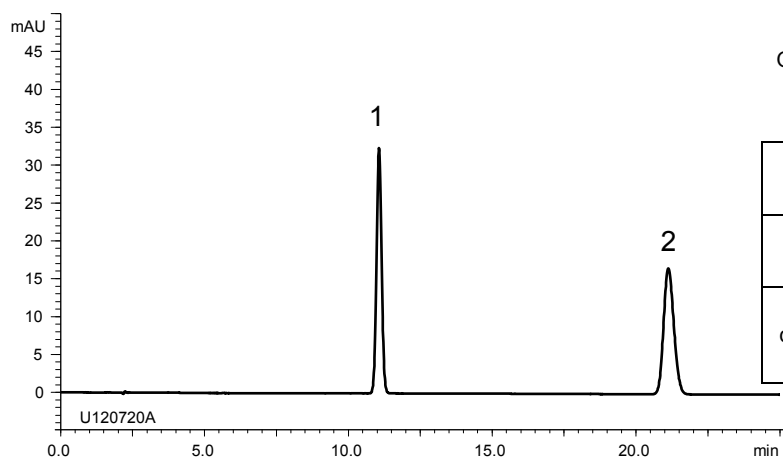
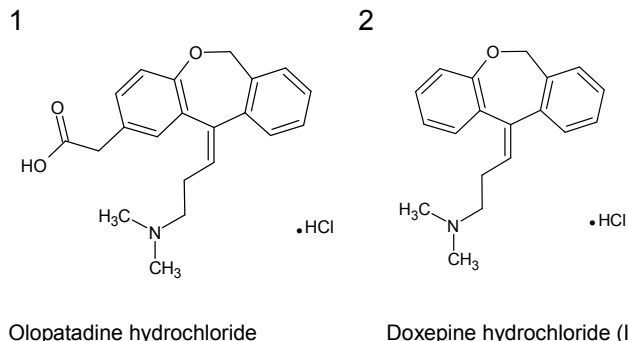


オロパタジン塩酸塩錠（日本薬局方収載原案記載条件）

Olopatadine hydrochloride tablets (The draft for the Japanese Pharmacopoeia)

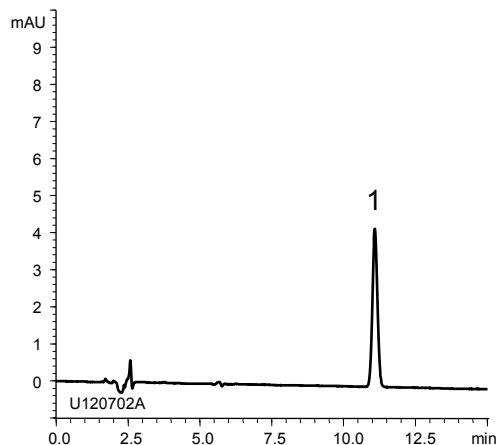
U120724B

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



	System suitability requirement	Result
Resolution (1, 2)	$\geq 13$	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)	$\geq 10000$	18700
Tailing factor (Olopatadine)	$\leq 2.0$	1.08
Relative standard deviation of the peak area (Olopatadine)	$\leq 1.5\%$	0.07%

Column : YMC-Triart C8 (5  $\mu$ 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  $\text{KH}_2\text{PO}_4$  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; Assay, Dissolution)

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