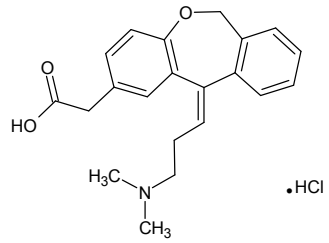
HPLC DATA SHEET

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)

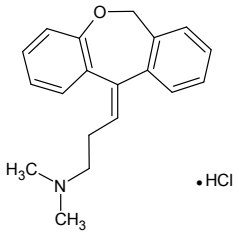
U120724B

1



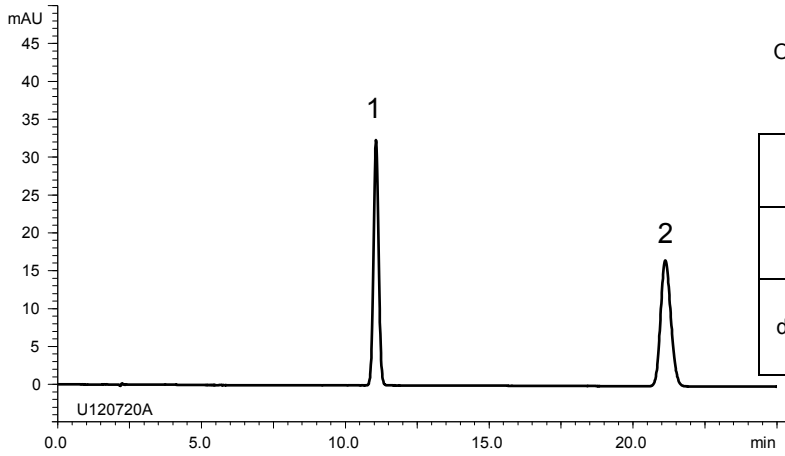
Olopatadine hydrochloride

2



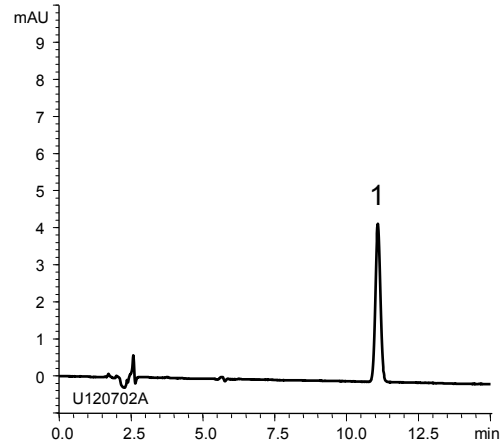
Doxepine hydrochloride (I.S.)

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	≦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)	≦1.5%	0.07%

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℃

Detection : UV at 299 nm

Injection : 20 μL

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

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