

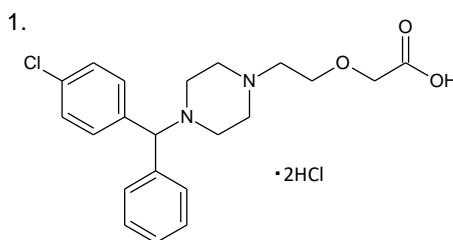
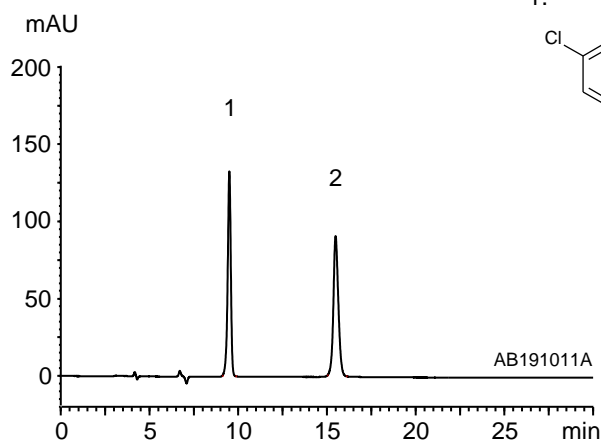
セチリジン塩酸塩 (日本薬局方記載条件)

Cetirizine Hydrochloride (The Japanese Pharmacopoeia)

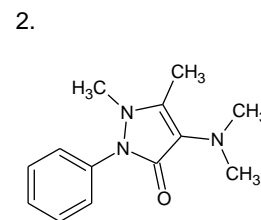
AB191015A

(A) System performance test solution*

(50 µg/mL Cetirizine dihydrochloride, 60 µg/mL Aminopyrine)



Cetirizine dihydrochloride

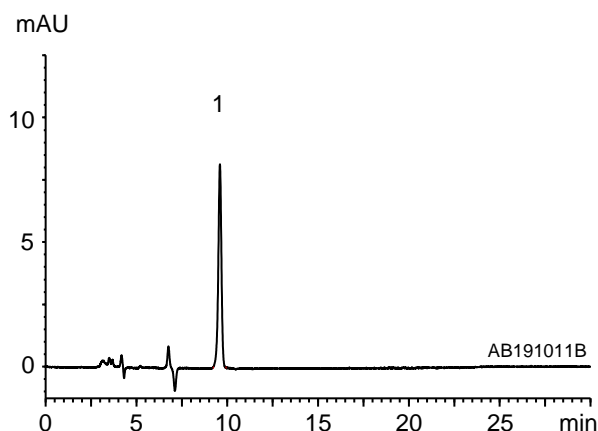


Aminopyrine

	System suitability requirement	Result
Elution order	1, 2	1, 2
Resolution (1,2)	≥7	14.8

(B) Standard solution*

(4.0 µg/mL Cetirizine dihydrochloride)



	System suitability requirement	Result
Relative standard deviation of the peak area (n=6) (Cetirizine)	≤2.0%	0.14%

Column : YMC-Triart SIL (5 µm, 12 nm)

250 X 4.0 mmI.D.

Eluent : acetonitrile/0.04 M sulfuric acid (94/6)

Flow rate : 0.75 mL/min (adjust the flow rate so that the retention time of Cetirizine is about 9 min)

Temperature : 25°C

Detection : UV at 230 nm

Injection : 10 µL

(The Japanese Pharmacopoeia 17th; Purity (2) Related substances)

*All system performance test and standard solutions were prepared from Cetirizine dihydrochloride supplied as a reagent for laboratory use.

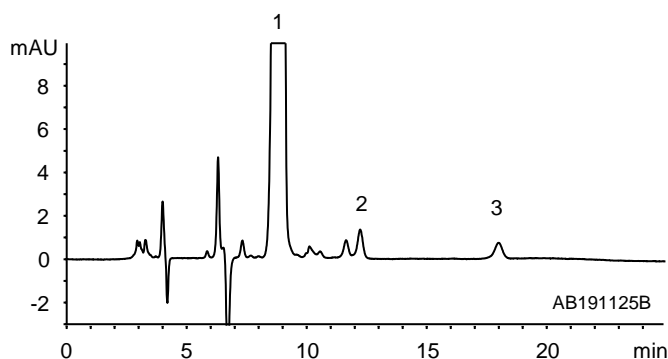
レボセチリジン二塩酸塩 (米国薬局方記載条件)

Levocetirizine Dihydrochloride (The United States Pharmacopeia)

AB191123A

(A) System suitability solution*

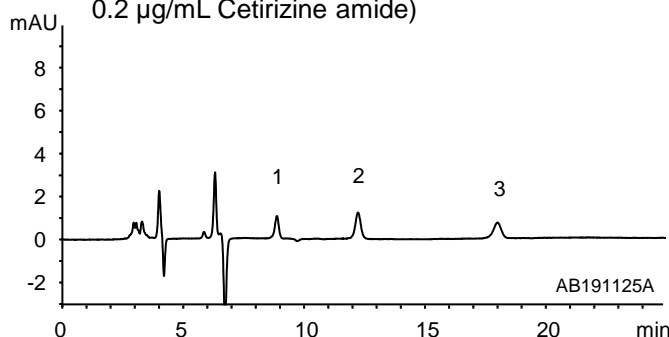
(0.2 mg/mL Levocetirizine dihydrochloride, 0.2 µg/mL Chlorobenzhydryl piperazine, 0.2 µg/mL Cetirizine amide)



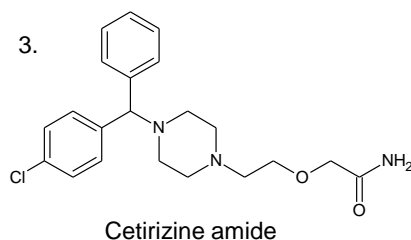
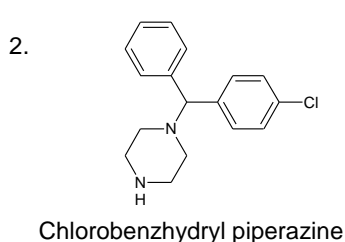
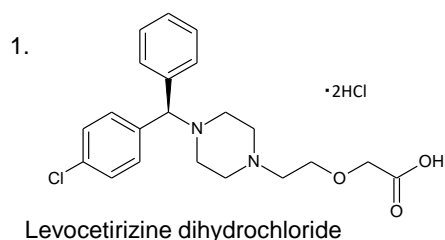
	System suitability requirement	Result
Resolution (1, 2)	≥ 3.0	9.0
Tailing factor (Levocetirizine)	≤ 2.0	0.9

(B) Standard solution*

(0.2 µg/mL Levocetirizine dihydrochloride, 0.2 µg/mL Chlorobenzhydryl piperazine, 0.2 µg/mL Cetirizine amide)



	System suitability requirement	Result
Relative standard deviation of the peak area (Levocetirizine)	≤ 5.0%	3.96%



Column : YMC-Triart SIL (5 µm, 12 nm)
250 X 4.6 mm I.D.
Eluent : acetonitrile/water/1 M sulfuric acid (93/6.6/0.4)
Flow rate : 1.0 mL/min
Temperature : 30°C
Detection : UV at 230 nm
Injection : 20 µL

(The United States Pharmacopeia 42th; Impurities)

*All system suitability and standard solutions were prepared from Levocetirizine Dihydrochloride supplied as a reagent for laboratory use.