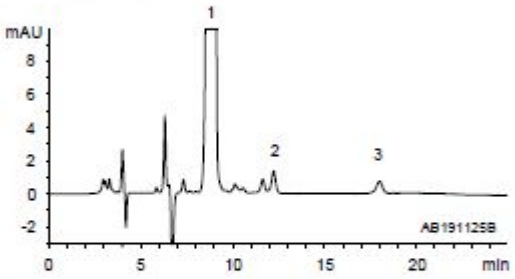
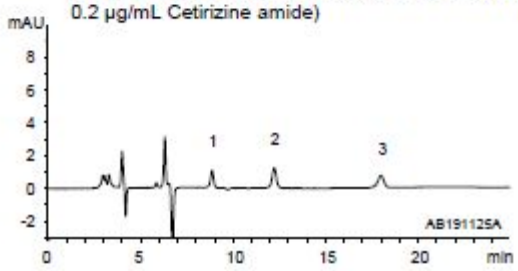
Levocetirizine Dihydrochloride (The United States Pharmacopeia) AB191123A

(A) System suitability solution*
(0.2 mg/mL Levocetirizine dihydrochloride, 0.2 µg/mL Chlorobenzhydryl piperazine, 0.2 µg/mL Cetirizine amide)

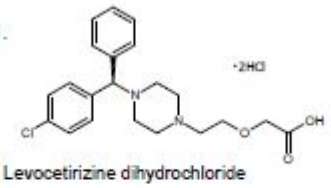


	System suitability requirement	Result
Resolution (1, 2)	≧3.0	9.0
Tailing factor (Levocetirizine)	≦2.0	0.9

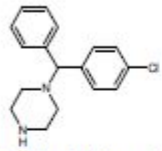
(B) Standard solution*
(0.2 µg/mL Levocetirizine dihydrochloride, 0.2 µg/mL Chlorobenzhydryl piperazine, 0.2 µg/mL Cetirizine amide)



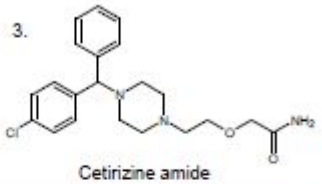
	System suitability requirement	Result
Relative standard deviation of the peak area (Levocetirizine)	≦5.0%	3.96%

1.


Levocetirizine dihydrochloride

2.


Chlorobenzhydryl piperazine

3.


Cetirizine amide

Column	: YMC-Triart SIL (5 µm, 12 nm) 250 X 4.6 mmI.D.
Eluent	: acetonitrile/water/1 M sulfuric acid (93/6.6/0.4)
Flow rate	: 1.0 mL/min
Temperature	: 30℃
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.