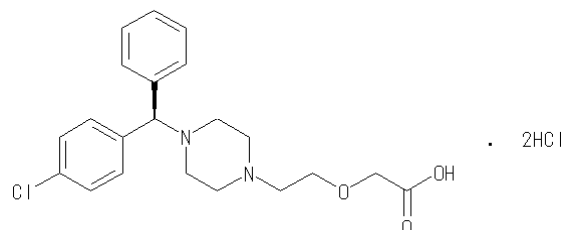


# U.S. Pharmacopeia method

## Levocetirizine Dihydrochloride : Enantiomeric purity

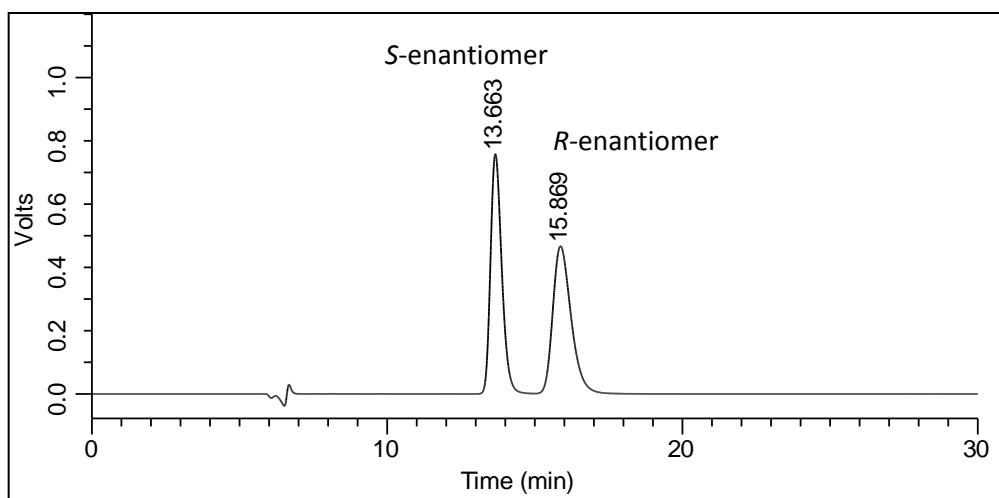


Column : CHIRALPAK® AS-H 0.46cmΦ × 25cmL (L90)  
 Mobile phase : Acetonitrile / Buffer = 30 / 70 (v / v)  
 ※Buffer: 1.5g/L of Ammonium acetate in water. Adjust with glacial acetic acid to a pH of 4.8.  
 Flow rate : 0.5mL/min.  
 Injection volume : 20μL  
 Column temperature : 30°C  
 UV detection : 230nm

### System suitability

System suitability solution: 0.5 mg/mL of USP Cetirizine Hydrochloride RS in water.

Relative retention times: The *S*-enantiomer (of Cetirizine) and Levocetirizine, which is the *R*-enantiomer (of Cetirizine), are about 0.83 and 1.0, respectively.



	Requirement	Result
Resolution (System suitability solution)	$\geq 1.4$	4.9
Tailing factor	$\leq 2.0$	1.29( <i>S</i> -enantiomer) 1.33( <i>R</i> -enantiomer)