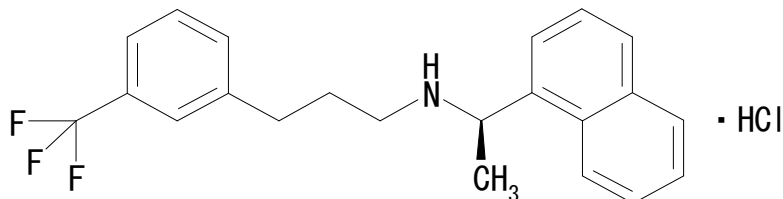


# U.S. Pharmacopeia method

## Cinacalcet Hydrochloride :Enantiomeric and Isomeric Purity

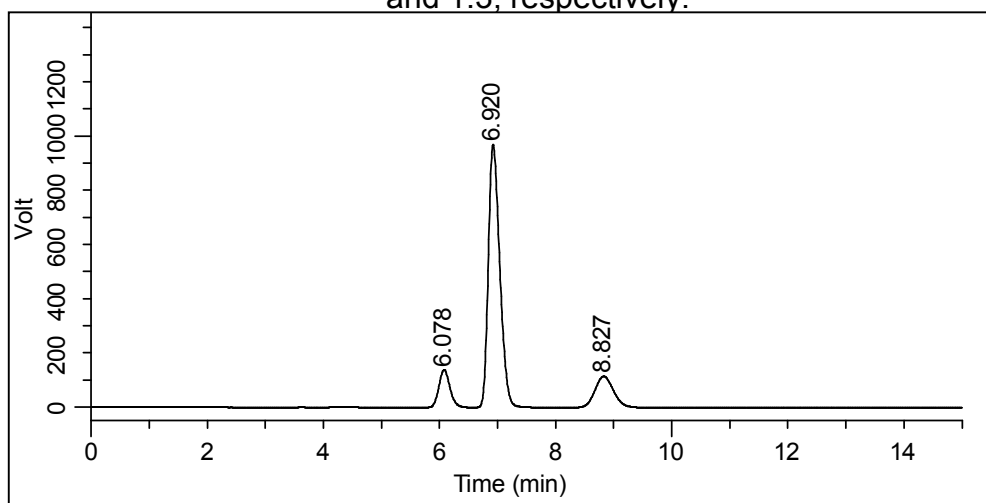


Column : CHIRALPAK® AD-H 0.46cmΦ × 25cmL (L51)  
Mobile phase : Hexane / *n*-Butanol / Isopropyl alcohol / Diethylamine = 1000 / 4 / 4 / 2 (v / v / v / v)  
Flow rate : 1.0mL/min.  
Injection volume : 20μL  
Column temperature : 10°C  
UV detection : 280nm

### System suitability

Sample: 0.5 mg/mL of USP Cinacalcet Hydrochloride RS and 0.1 mg/mL each of  
USP Cinacalcet Related Compound C RS and  
USP Cinacalcet Related Compound D RS.

Relative retention times: Compound D, Cinacalcet, and Compound C are 0.82, 1.0,  
and 1.3, respectively.



	Requirement	Result
Resolution	$\geq 1.5$	2.4