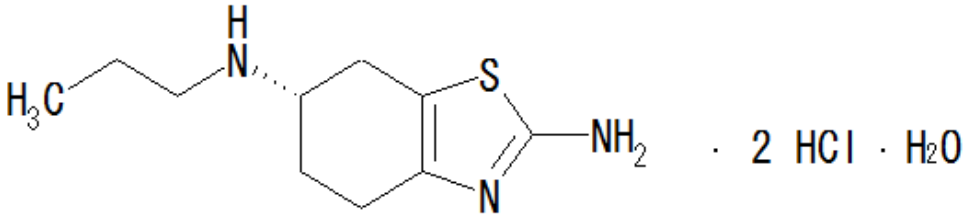
U.S. Pharmacopeia method

DAICEL CORPORATION

Pramipexole Dihydrochloride :Enantiomeric purity

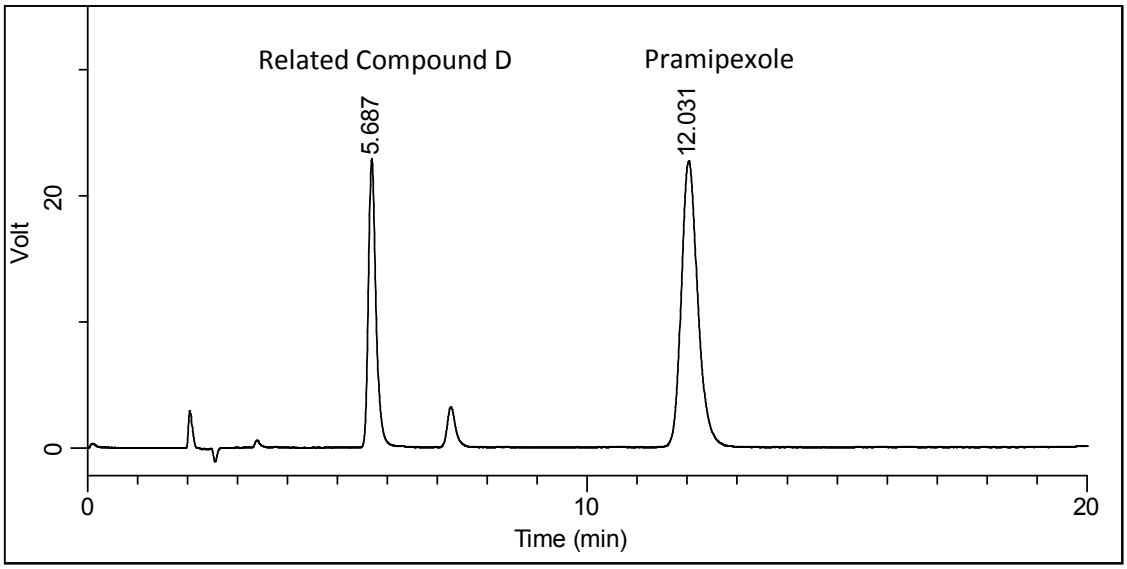


Column	: CHIRALPAK® AD 0.46cmΦ × 25cmL (L51)
Mobile phase	: *n*-Hexane / dehydrated alcohol / Diethylamine = 850 / 150 / 1 (v / v / v)
Flow rate	: 1.5mL/min.
Injection volume	: 75μL
UV detection	: 254nm

System suitability
Sample:
(System suitability stock solution)
1 mg/mL each of USP Pramipexole Dihydrochloride RS and USP Pramipexole Related Compound D RS in dehydrated alcohol.

(System suitability solution)
0.01 mg/mL each of USP Pramipexole Dihydrochloride RS and USP Pramipexole Related Compound D RS from *System suitability stock solution* in *Mobile phase.*

Relative retention time: Pramipexole Related Compound D (*R*-enentiomer) and Pramipexole (*S*-enentiomer) are 0.5 and1.0, respectively.



	Requirement	Result
Resolution	≧5.0	14.9
Tailing factor for Pramipexole	≦2.4	1.22