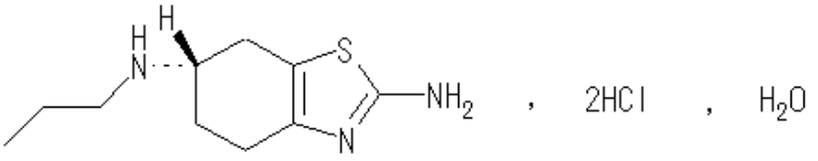
European Pharmacopoeia method

DAICEL CORPORATION

Pramipexole dihydrochloride monohydride :Enantiomeric purity



Column	: CHIRALPAK® AD 0.46cmΦ × 25cmL
Mobile phase	: Diethylamine *R* / Anhydrous ethanol *R* / Hexane *R* = 0.1 / 15 / 85 (V / V / V)
Flow rate	: 1.5mL/min.
Injection volume	: 75μL
UV detection	: 254nm

System suitability

Reference solution (a):

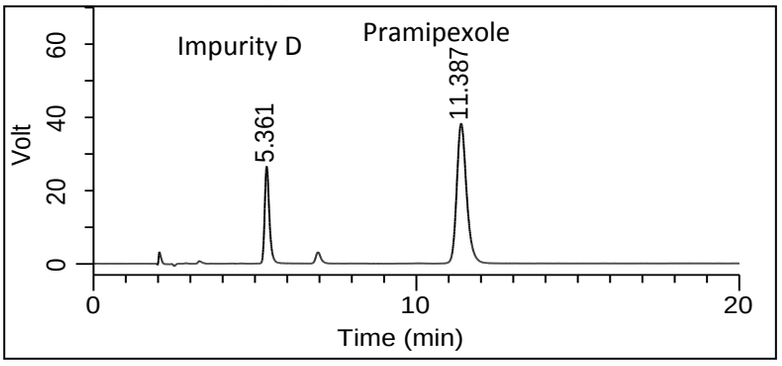
Dissolve 2 mg of *Pramipexole impurity D CRS* in the mobile phase and dilute to 10 mL with the mobile phase. To 1 mL of this solution add 1 mL of the test solution and dilute to 20 mL with the mobile phase.

Reference solution (b):

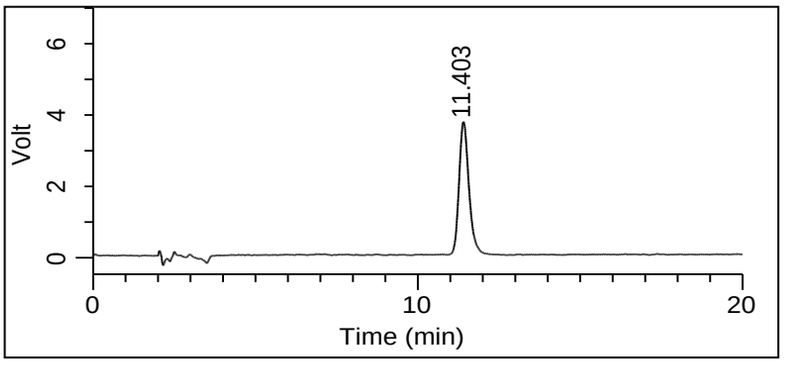
Dilute 1.0 mL of the test solution to 20.0 mL with the mobile phase. Dilute 1.0 mL of this solution to 10.0 mL with the mobile phase.

Relative retention with reference to Pramipexole (retention time = about 11 min.):
impurity D = about 0.5

Reference solution (a)



Reference solution (b)



	Requirement	Result
Resolution	Minimum 5 between the peaks due to impurity D and Pramipexole (reference solution (a))	15.2
Symmetry factor	Maximum 2.4 for the peak due to Pramipexole (reference solution (b))	1.24

For details of monograph, please check pharmacopoeia.