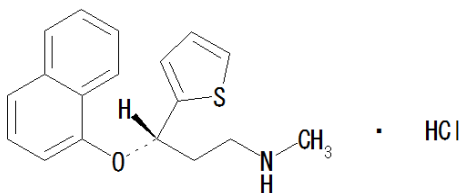


Duloxetine hydrochloride : Enantiomeric purity



Column : CHIRALCEL® OD-H 0.46cmΦ × 25cmL
 Mobile phase : Diethylamine *R* / 2-Propanol *R* / Hexane *R* = 0.2 / 17 / 83 (v / v / v)
 Flow rate : 1.0mL/min.
 Injection volume : 20μL
 Column temperature : 40°C
 UV detection : 230nm

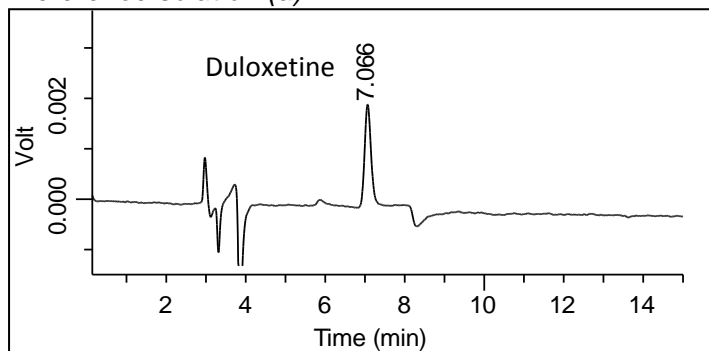
System suitability

Reference solution (a): Dilute 1.0 mL of the test solution to 200.0 mL with the mobile phase.

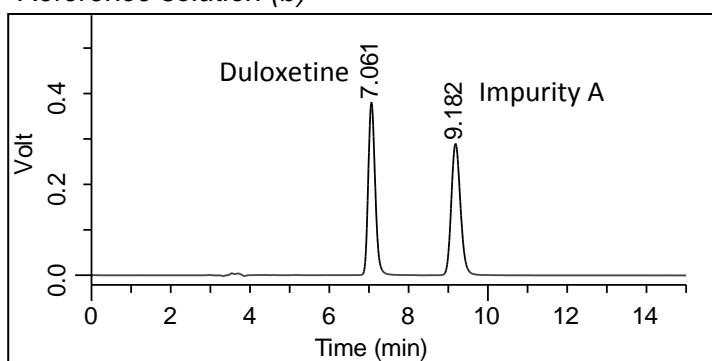
Reference solution (b): Dissolve 5 mg of *Duloxetine impurity A CRS* and 5 mg of the substance to be examined in 100.0 mL of the mobile phase.

Relative retention with reference to Duloxetine (retention time = about 7 min):
 impurity A = about 1.3

Reference solution (a)



Reference solution (b)



	Requirement	Result
Resolution	Minimum 3.5 between the peaks due to Duloxetine and impurity A (reference solution (b))	5.65
Signal-to-noise ratio	Minimum 10 for the principal peak (reference solution (a))	50.4

For details of monograph, please check pharmacopoeia.