## **European Pharmacopoeia method**



Atomoxetine hydrochloride :Isomeric purity



Column	: CHIRALCEL <sup>®</sup> OD-H 0.46cmΦ × 25cmL
Mobile phase	: Diethylamine R / Trifluoroacetic acid R / 2-Propanol R / Heptane R = 1.5 / 2.0 / 150 / 846.5 (v / v / v / v)
Flow rate	: 1.0mL/min.
Injection volume	: 10µL
Column temperature	: 25°C
UV detection	: 273nm
System suitability	: Dissolve 3.5 mg of Atomovating impurity B.C.P.S and 1 mg of Atomovating

- Reference solution (a): Dissolve 3.5 mg of Atomoxetine impurity *B CRS* and 1 mg of Atomoxetine impurity *D CRS* in 5 mL of Anhydrous Ethanol *R*, sonicate until dissolution is complete and dilute to 20.0 mL with Heptane *R*. Reference solution (b): Dissolve 35.0 mg of the substance to be examined in 2.5 mL of Anhydrous
  - Ethanol *R*. Add 1.0 mL of reference solution (a) and dilute to 10.0 mL with Heptane *R*.

Relative retention with reference to Atomoxetine (retention time = about 12 min): impurity B = about 0.5; impurity D = about 0.6.

Reference solution (b)



	Requirement	Result
Resolution	Minimum 1.8 between the peaks due to Impurities	2.25
	B and D (reference solution (b))	2.20

For details of monograph, please check pharmacopoeia.