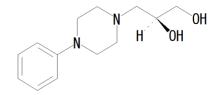
European Pharmacopoeia method



Levodropropizine :Enantiomeric purity



Column : CHIRALCEL[®] OD 0.46cmΦ × 25cmL

Mobile phase : Diethylamine R / Anhydrous ethanol R / Hexane R = 0.2 / 5 / 95 (v / v / v)

Flow rate : 0.8mL/min.
Injection volume : 20µL
UV detection : 254nm

System suitability

Test Solution:

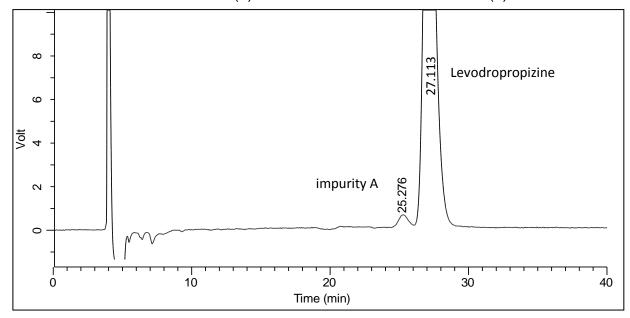
Dissolve 10.0 mg of the substance to be examined in 10.0 mL of the solvent mixture. Dilute 1.0 mL of this solution to 50.0 mL with the solvent mixture.

Reference solution (a):

Dissolve 10.0 mg of *Levodropropizine CRS* in 10.0 mL of the solvent mixture. Dilute 1.0 mL of this solution to 50.0 mL with the solvent mixture.

Reference solution (d):

Dilute 0.5 mL of reference solution (b) to 25 mL with reference solution (a).



	Requirement	Result
Retention time		27.1min.
	The retention times of the principal peaks in the	(reference solution
	chromatograms obtained with the test solution and	(a))
	reference solution (a) are similar	27.1min.
		(test solution)
Resolution	Minimum 1.3 between the peaks due to impurity A and Levodropropizine (reference solution (d))	1.34

For details of monograph, please check pharmacopoeia.