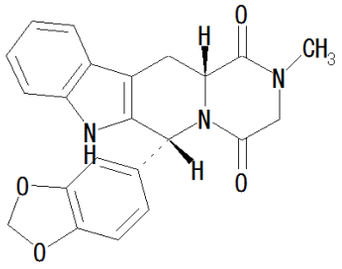
European Pharmacopoeia method

DAICEL CORPORATION

Tadalafil :Limit of impurity A



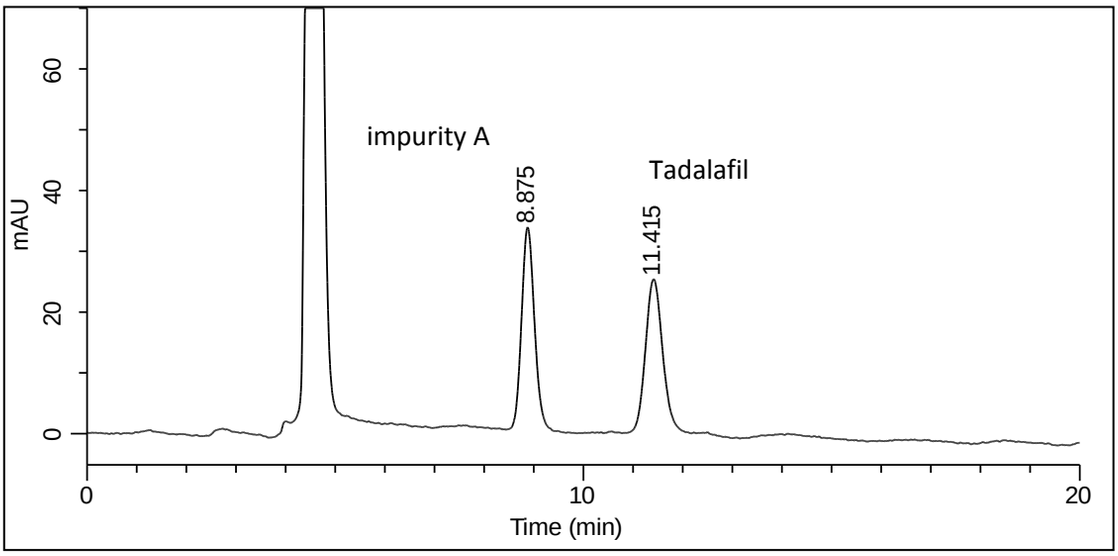
Column	: CHIRALPAK® AD 0.46cmΦ × 25cmL
Mobile phase A	: Hexane *R* / 2-Propanol *R* = 50 / 50 (v / v)
Flow rate	: 0.75mL/min.
Injection volume	: 20μL
Column temperature	: 30℃
UV detection	: 222nm

System suitability

Reference solution (d):

To 1.0 mL of the test solution add 1.0 mL of reference solution (c) and dilute to 50.0 mL with the solvent mixture.

Relative retention with reference to Tadalafil (retention time = about 11 min):
impurity A = about 0.8 .



	Requirement	Result
Resolution	Minimum 2.0 between the peaks due to impurity A and Tadalafil (reference solution (d))	4.6

For details of monograph, please check pharmacopoeia