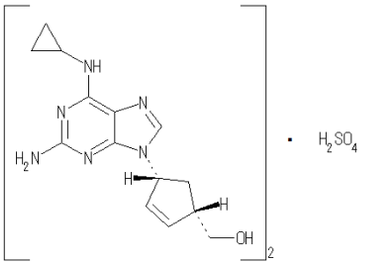
European Pharmacopoeia method

DAICEL CORPORATION

Abacavir sulfate :Enantiomeric purity



Column	: CHIRALPAK® AD 0.46cmΦ × 25cmL
Mobile phase A	: Diethylamine *R* / 2-Propanol *R* / Heptane *R* = 0.1 / 15 / 85 (v / v / v)
Mobile phase B	: Heptane *R* / 2-Propanol *R* = 50 / 50 (v / v)
Flow rate	: 1.0mL/min.
Injection volume	: 20μL
Column temperature	: 30℃
UV detection	: 286nm

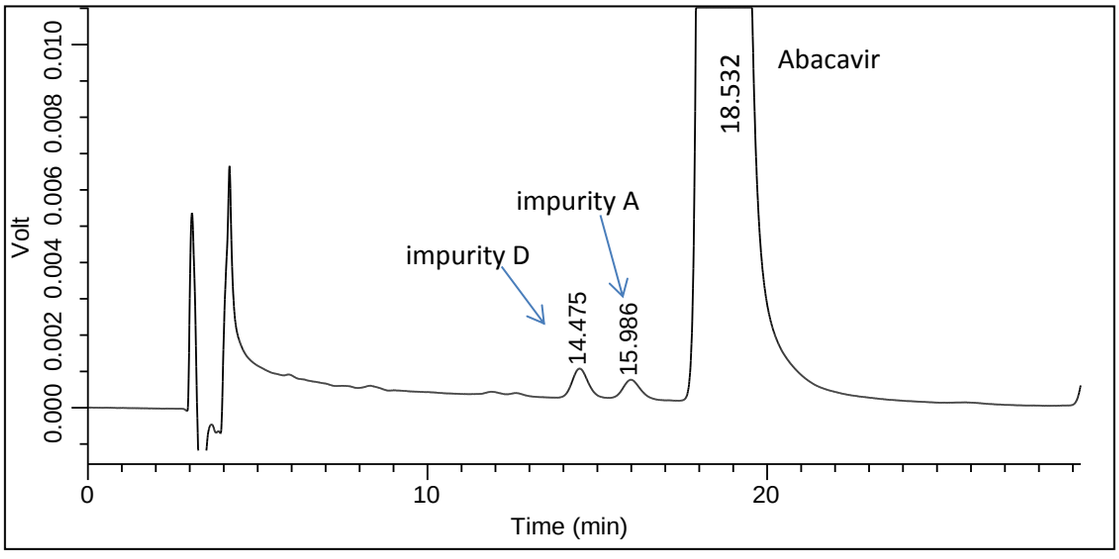
Time (min.)	Mobile phase A (per cent *V/V*)	Mobile phase B (per cent *V/V*)
0–25	100	0
25–27	100 → 0	0 → 100
27–37	0	100

System suitability

Reference solution (a):

Dissolve 2 mg of *Abacavir for system suitability CRS* (containing impurities A and D) in 1.5 mL of solution A. Sonicate until dissolution is complete. Add 1.5 mL of *2-propanol R* and dilute to 5.0 mL with *heptane R*.

Relative retention with reference to Abacavir (retention time = about 17 min):
impurity D = about 0.8 ; impurity A = about 0.9



	Requirement	Result
Resolution	Minimum 1.5 between the peaks due to impurities D and A (reference solution (a))	1.7
	Minimum 1.5 between the peaks due to impurity A and Abacavir (reference solution (a))	2.5

For details of monograph, please check pharmacopoeia