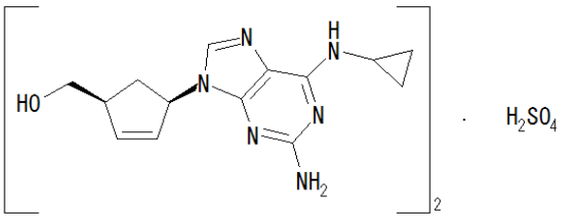
U.S. Pharmacopeia method

DAICEL CORPORATION

Abacavir Sulfate :Enantiomeric Purity



Column	: CHIRALPAK® AD 0.46cmΦ × 25cmL (L51)
Mobile phase	: See the gradient table
Solution A	: Heptane / 2-Propanol / Diethylamine = 850 / 150 / 1 (v / v / v)
Solution B	: Heptane / 2-Propanol = 1 / 1 (v / v)
Injection volume	: 20μL
Column temperature	: 30℃
UV detection	: 286nm

(gradient table)

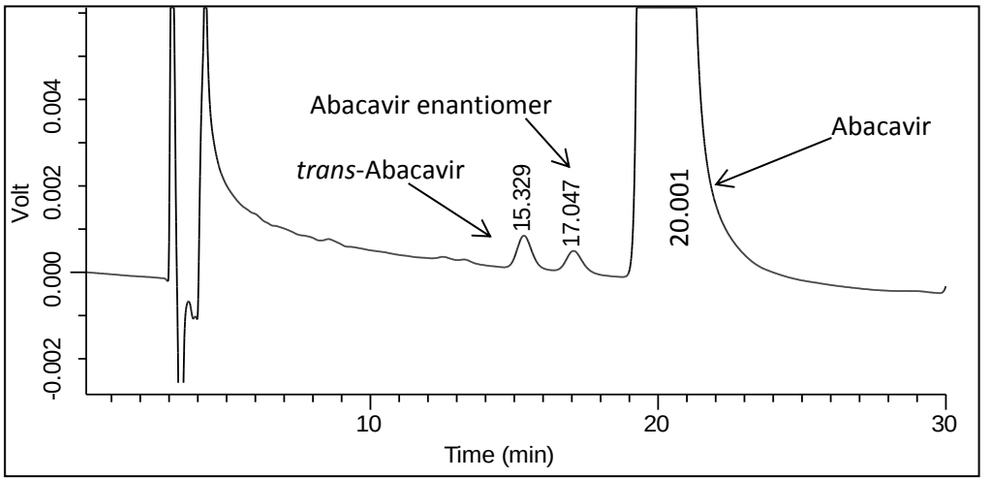
Time(min)	Solution A (%)	Solution B (%)	Flow Rate (mL/min.)
0	100	0	1.0
25	100	0	1.0
27	0	100	0.8
37	0	100	0.8
39	100	0	1.0
55	100	0	1.0

System suitability

Sample: Transfer a quantity of USP Abacavir Stereoisomers Mixture RS to a suitable volumetric flask, add a volume of *Diluent* equivalent to 30% of the final volume, and sonicate until the solid is fully dissolved. Add a volume of 2-propanol equivalent to about 30% of the final volume, mix, and dilute with heptane to volume to obtain 0.4 mg/mL of USP Abacavir Stereoisomers Mixure RS.

Dilute: Methanol and trifluoroacetic acid (200:1)

Relative retention times: *trans*-Abacavir, Abacavir enantiomer, and Abacavir are 0.8, 0.9 and 1.0, respectively.



		Requirement	Result
Resolution	between *trans*-Abacavir and Abacavir enantiomer	≧1.0	1.7
	between Abacavir enantiomer and Abacavir	≧1.5	2.6