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CERTIFICATE OF ANALYSIS

Product Name:

Abacavir Sulfate

Batch No.:

2004001

Manufacturing Date:

Apr.11, 2020

Retest Date:

Apr.10, 2022

Storage:

Preserve in well-closed containers. Store at room temperature

Tests and Methods	Specifications		Results
Appearance	White to off white powder		Conforms
Solubility	Sparingly soluble in water; very slightly soluble in acetonitrile and		Conforms
	in methanol, practically insoluble in	heptane	
Identification A. IR	Both the test sample and the reference standard exhibit the same		Conforms
	intensity of absorption at the same wave number		
B. HPLC	The retention time of the major peak of the Sample solution		Conforms
	corresponds to that of the System suitability solution, obtained as		
	directed in the test for Enantiomeric Purity		
C. Sulfate	The aqueous solution yields the rea	actions characteristic of Sulfate	Conforms
Water Determination	Not more than 0.5%		0.17%
Residue on Ignition	Not more than 0.2%		0.03%
Related Compounds	Descyclopropyl abacavir	N.M.T. 0.2%	0.02%
	trans-Abacavir	N.M.T. 0.2%	0.09%
	O-Pyrimidine derivative abacavir	N.M.T. 0.2%	Not detected
	t-Butyl derivate abacavir	N.M.T. 0.2%	Not detected
	Any unspecified impurity	N.M.T. 0.1%	0.05%
	Total Impurities	N.M.T. 0.8%	0.26%
Enantiomeric purity	Abacavir enantiomer	N.M.T. 0.3%	Not detected
Residual solvents	Methanol	N.M.T. 200ppm	17ppm
	Ethanol	N.M.T. 5000ppm	4018ppm
	Isopropyl alcohol	N.M.T. 500ppm	Not detected
Assay	97.0%~102.0% (calculated on anhydrous and solvent free basis)		99.59%
Conclusion	Conforms to the requirement of US	P39	

Check by:

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Analyzed by:

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