



SWAPNROOP DRUGS & PHARMACEUTICALS

Address: Plot No:D-187/16, Five Star Shendra MIDC, Shendra,
Aurangabad-431154, Maharashtra, India.

Call/ WhatsApp: +91-8767062101 Email: enquiry@sdp.org.in
website: www.sdp.org.in

CERTIFICATE OF ANALYSIS

Product Name	ABACAVIR SULFATE - IP	CAS No:	188062-50-2
Batch No:	2604001	Manufactured by	-
Date of Mfg.	APR-2026	Date of Analysis	20/04/2026
Batch Quantity	-	Date of Retest	MAR-2031

Sr. No	Test	Acceptance Criteria	Results
1.	Description	A white or almost white crystalline powder	Almost white crystalline powder
2.	Solubility	Soluble in water.	Complies
3.	Identification		
	By IR	Determine by infrared Absorption by spectrophotometer compare the spectrum with that obtained with abacavir sulphate RS or with the reference spectrum of abacavir sulphate	Complies
	By HPLC	Retention time corresponds with standard preparation	Complies
	Test for Sulfates	Responds to the test for sulphates	Complies
4.	Specific Optical Rotation	Between -32.0° and -38.0°	-36.9°
5.	Water Content	Not more than 0.5% w/w	0.22%
6.	Heavy Metals (Method-B)	Not more than 20 ppm	Less than 20 ppm
7.	Sulphated Ash	Not more than 0.2% w/w	0.04%
8.	Related Substances (By HPLC)		
	Any Secondary Peak	Not more than 0.5%	0.18%
	Total Impurities	Not more than 1.5%	0.34%
9.	Assay by HPLC (on anhydrous basis)	Not less than 98.0% w/w and not more than 102.0% w/w	100.1%
10.	Residual Solvents by GC		
	Methanol	Not more than 3000 ppm	Not detected



SWAPNROOP DRUGS & PHARMACEUTICALS

Address: Plot No:D-187/16, Five Star Shendra MIDC, Shendra,
Aurangabad-431154, Maharashtra, India.

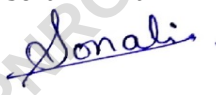
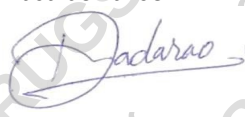
Call/ WhatsApp: +91-8767062101 Email: enquiry@sdp.org.in

website: www.sdp.org.in

	Ethanol	Not more than 5000 ppm	2358 ppm
	Isopropyl Alcohol	Not more than 5000 ppm	Not detected
11.	Enantiomeric Purity by HPLC	Not more than 0.3% w/w	0.02%
	Abacavir Enantiomer		

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By	Checked by	Approved By
Sonali Nirmal 	Dadarao kakde 	Nayna Nehete 
Date: 23/04/2026	Date: 23/04/2026	Date: 23/04/2026

