



SWAPNROOP DRUGS & PHARMACEUTICALS

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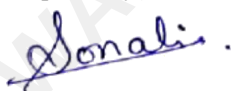
CERTIFICATE OF ANALYSIS

Product Name	ENTECAVIR MONOHYDRATE	CAS No:	209216-23-9
Batch No.	2605001	Manufactured by	Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White or almost white powder.	Almost white powder.
2	Solubility	Practically insoluble in water, in anhydrous ethanol and in heptane, slightly soluble in Methanol.	Complies
3	Identification – By IR	The Infrared absorption spectrum of the sample should be concordant with the IR spectrum obtained from Entecavir monohydrate CRS.	Complies
4	Identification – By Specific optical rotation	+24 to +30 (anhydrous substance, measured at 25°C)	25.010
5	Impurity F by LC	maximum 0.10%	Not detected
6	Related substances by LC Unspecified impurities	maximum 0.10% (for each impurity)	0.08
7	Related substances by LC Total impurities	maximum 0.3%	0.15
8	Water	5.5% to 7.0%, determined on 30.0 mg by direct sample introduction.	6.3
9	Sulfated ash	Maximum 0.1%	0.07
10	Assay by HPLC	98.0% to 102.0% (anhydrous substances)	100.6

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026
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