



Certificate of Analysis-Entecavir

CAS: 142217-69-4

Batch Number: *FTF0231226* Batch Quantity: 600kg

Manufacture Date: Dec.24th,2023 Analysis Date: Dec.25th,2023 Certificate Date: Dec.26th,2023

Storage Store in cool & dry place. Store in well-closed containers.
Shelf life 3 years when properly stored.

Items	Standards	Results
Appearance	White or off-white solid powder	White solid powder
Identification	By IR	Complies
	By HPLC	Complies
Specific Rotation	+24.0°~+28.0°(DMF:MeOH=1:1 c=1%)	+9.5°
pH	5.5~7.5	6.8
Water Content	5.6%~7.2%	6.1%
Heavy Metal	≤20ppm	Complies
Residue on Ignition	≤0.10%	0.04%
Enantiomer	≤0.20%	ND
	M'ethanol: ≤3000ppm	ND
	D'ichloromethane: ≤600ppm	ND
	T'etrahydrofuran: ≤720ppm	ND
	T'oluene: ≤890ppm	ND
	H'exane: ≤290ppm	ND
	DMF: ≤880ppm	ND
Related Substances	Any single impurity: ≤0.10%	0.05%
	Total Impurities: ≤0.30%	0.07%
Assay (HPLC basis on drying)	98.0%~102.0%	99.90%

Conclusion: Conform with enterprise specification .

QC MANAGER: 刘娟 INSPECTOR: 黄子烨

