



CERTIFICATE OF ANALYSIS

Product name	Entecavir		
Batch No.	20190201	Expiry date	2022.01
Report Date	2019.02.12	Quantity	1200g

Inspection Items	Accepted Standard	Results
Appearance	White or almost white powder.	Complies
solubility	Slightly soluble in water, methanol, Ethanol.	Complies
Optical rotation	+24.0°~+28.0°	+26.8°
Identification	A:Specific optical rotation	Complies
	B: By IR, To match with working standard	Complies
Water	5.8%~7.0%	6.2%
Impurity F	≤0.1%	Not found
Related Substances	Unspecified impurity ≤0.1%	0.01%
	Total impurities ≤0.3%	0.03%
Sulfated ash	≤0.1%	0.07%
Heavy	≤10ppm	Complies
Residual solvents	Dichloromethane≤600ppm.	Not detected
	Methanol≤3000ppm	Not detected
	Ethyl acetate≤5000ppm	200 ppm
	Toluene≤890ppm	Not detected
Particle size	95% of the particles should be within 125um	Complies
Assay	98.0%~102.0%	99.9%
Conclusion : Complies with EP9.0.		

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