

CERTIFICATE OF ANALYSIS

Product name	Entecavir monohydrate		
Batch No.	QYB180705	Expiry date	2021.07
Report Date	2018.07.10	Quantity	1.5kg

Inspection Items	Accepted Standard	Results
Appearance	White to off-white powder	Complies
Optical rotation	+24.0°—+28.0°(DMF:MeOH=1:1 c=1%)	+26.0°
Identification	A: By IR, To match with working standard	Complies
	B:By HPLC, retain time should match with working standard	Complies
Water	5.8%—6.5%	6.0%
Isomer	Single $\leq 0.1\%$	0.04%
	Total $\leq 0.5\%$	0.10%
Related Substances	Single impurity $\leq 0.1\%$	0.06%
	Total impurities $\leq 0.3\%$	0.11%
Residue on ignition	$\leq 0.1\%$	0.04%
Heavy metals	$\leq 20\text{ppm}$	Complies
Residual solvents	Should complies	Complies
Assay	$\geq 99.7\%$	99.95%
Conclusion : Complies to the enterprise standard		