



## CERTIFICATE OF ANALYSIS

Product name	Entecavir monohydrate		
Batch No.	20160801	Expiry date	2019.08
Report Date	2016.08.09	Quantity	1350g

Inspection Items	Accepted Standard	Results
Appearance	White to off-white powder	Complies
Optical rotation	+24.0 °—+28.0 °(DMF:MeOH=1:1 c=1%)	+27.2 °
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%	6.2%
Related Substances	Single impurity $\leq 0.1\%$	0.01%
	Total impurities $\leq 0.3\%$	0.03%
Residue on ignition	$\leq 0.1\%$	0.04%
Heavy metals	$\leq 10\text{ppm}$	Complies
Residual solvents	Should complies	Complies
Assay	$\geq 99.5\%$	99.9%
Conclusion : Complies to the enterprise standard		

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