



# Certificate of analysis

Product name: Entecavir monohydrate

Cas number: 209216-23-9

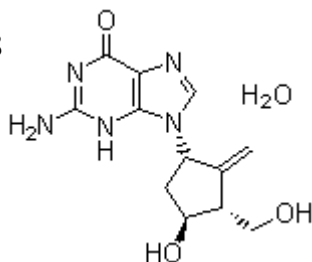
Molecular Formula: C<sub>12</sub>H<sub>15</sub>N<sub>5</sub>O<sub>3</sub>.H<sub>2</sub>O

Molecular Weight: 295.30

Date of production: Jun.28,2018

Batch NO:20180628

EXP DATE: Jun.28,2020



Chemical structure:

Items	Specifications	Results
Appearance	White or off-White powder	White powder
Identification	HPLC IR	Conforms
Water	5.8~6.5%	6.0%
Sulfated ash	≤0.10%	0.05%
Heavy metals	≤10ppm	Conforms
Related substance ETA	≤0.10%	N.D
Related substance ET-4	ET-4≤0.30%	N.D
Related substances	G ≤0.10%	N.D
	ET-1≤0.10%	0.02%
	ET-2≤0.10%	0.01%
	ET-3≤0.10%	N.D
	Individual unknown impurity≤0.10%	0.01%
	Total impurities other than Related substance ETA,ET-4≤0.20%	0.12%
Residual solvents	Methanol ≤600ppm	N.D.
	Dichloromethane≤300ppm	N.D.
	Ethyl acetate≤5000ppm	N.D.
	Tetrahydrofuran≤720ppm	N.D.
Assay	98.0%~102.0%(On anhydrous basis)	100.1%

**Conclusion: It complies with the Enterprise Standard.**

Analyst:Zhao

Checker:Liu

Q.C Director. Fang