



# Certificate of analysis

Productname: Emtricitabine

Cas number: 143491-57-0

Molecular Formula: C<sub>8</sub>H<sub>10</sub>FN<sub>3</sub>O<sub>3</sub>S

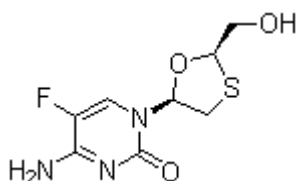
Molecular Weight: 247.25

Date of production: Mar. 25, 2019

Batch NO: 20190325

Exp Date: Mar. 24, 2021

Chemical structure:



Items	Specifications	Results
<b>Appearance</b>	White to off-white crystalline powder	Conforms
<b>Identification</b>	IR,HPLC	Conforms
<b>Solubility</b>	Free soluble in water Freely soluble in Methanol	Conforms
<b>Specific rotation</b>	-125 °~-142 °	-140 °
<b>Loss On Drying</b>	≤0.5%	0.10%
<b>Residue on ignition</b>	≤0.1%	0.04%
<b>Heavy metals</b>	≤20ppm	Conforms
<b>Related Substances</b>		
<b>Ethanol</b>	≤ 5000PPM	600PPM
<b>Isopropy alcohol</b>	≤ 5000PPM	Undetected
<b>Dichloromethane</b>	≤ 600PPM	Undetected
<b>n-Hexane</b>	≤ 290PPM	Undetected
<b>Toluene</b>	≤ 890PPM	Undetected
<b>Dimethyl formamide</b>	≤ 880PPM	Undetected
<b>Ethyl acetate</b>	≤ 5000PPM	300PPM
<b>Chromatographic purity</b>		
<b>Carboxylic acid and its isomer</b>	≤0.30%	0.08%
<b>Isomer of Emtricitabine</b>	≤ 0.15%	< 0.05%
<b>Unspecified Impurity</b>	≤ 0.10%	0.02%
<b>Content of FCME</b>	≤ 0.15%	< 0.05%
<b>Assay (HPLC)</b>	98.0%-102.0%	99.9%

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

Analyst:Zhao

Checker:Liu

Q.C Director. Fang F