Certificate of Analysis

Compound Name	Obeticholic acid		
CAS No.	459789-99-2	Manufacturing Date	2020-02-10
Batch No.	20200201	Re-test Date	2022-02-09
Batch quantity	5kg	Reference Standard	In-house
Structure	но,,	H OH	

Items	Specifications	Results
Appearance	White powder	Conforms
Loss on drying	3.0%~4.5%	1.6%
Residue on ignition	NMT 0.2%.	0.05%
Identification	1H NMR spectrum of sample corresponds to that	Conforms
	of standard preparation	
	MS spectrum of sample corresponds to that of standard preparation	Conforms
, NG	The retention time of the major peak in the chromatogram of sample corresponds to that in the chromatogram of standard preparation	Conforms
Solubility	70 mg/mL in DMSO	Conforms
C), ,	5 mg/mL in H2O	Conforms
Residual Solvent	Ethanol: NMT 5000ppm	N.D
Heavy Metal	NMT 20ppm	Conforms
Max Single impurity	NMT 0.2%	0.19%
Total impurity	NMT 1.0%	0.48%
Particle size	D90: NMT 20um	Conforms
Assay (HPLC)	99.0%~101.0%	99.40%

Storage condition: Store in a tightly closed container, at controlled 25°C.

Analyst: Lee Checker: Sue QA Approved: ChenSheng

