

No.: BPAP-627-A-00/3.0

CERTIFICATE OF ANALYSIS

Product Name	Obeticholic acid	CAS No.	459789-99-2
Batch No.	P010662719A	Mfg. Date	Jun. 25, 2019
Quantity	2kg	Retest Date	Jun. 24, 2021
Packing	As appropriate	Report Date	Jun. 30, 2019
Specification	Enterprise Standard		

ITEM	SPECIFICATION	RESULT
Appearance	White to light yellow powder	Complies
Identification	A) HPLC: The principal peak in the chromatogram obtained with the test solution is similar in position to the principal peak in the chromatogram obtained with reference solution. B) IR: Conform to the spectrum obtained with the reference standard.	Complies
Loss on Drying	≤3.0%	1.3%
Residue on Ignition	≤0.2%	0.06%
Heavy Metals	≤20ppm	Complies
Assay(Anhydrous basis)	98.5%-102.0%	99.6%
Related Substances		
Impurity 1 and Impurity 4	≤0.30%	0.15%
Impurity 2	≤0.30%	0.14%
Impurity 3	≤0.30%	0.13%
Impurity 5(CDCA)	≤1.0%	0.2%
Impurity 6	≤0.30%	0.06%
Any Other Individual Impurity	≤0.30%	0.05%
Total Impurities	≤1.0%	0.68%
Residual Solvents		
-Ethanol	≤5000ppm	164ppm
-Methanol	≤3000ppm	150ppm
-Ethyl Acetate	≤5000ppm	300ppm
-Tetrahydrofuran	≤720ppm	Undetected
Conclusion	Comply with the specification.	
Storage	Preserve in tight containers, protected from strong light and high heat.	

Analyst:

Reviewed by:

Approved by: