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CERTIFICATE OF ANALYSIS

Product Name	Obeticholic acid	CAS No.	459789-99-2
Batch No.	P010562717A	Mfg. Date	May 06, 2017
Quantity	2kg	Retest Date	May 05, 2019
Packing	2kg/Drum	Report Date	May 15, 2017
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	≤0.15%	0.05%
Impurity 2	≤0.15%	0.04%
Impurity 3	≤0.15%	0.03%
Impurity 5(CDCA)	≤1.0%	0.2%
Impurity 6	≤0.15%	0.06%
Any Other Individual Impurity	≤0.15%	0.05%
Total Impurities	≤1.0%	0.58%
Residual Solvents		
-Ethanol	≤5000ppm	164ppm
-Methanol	≤3000ppm	150ppm
-Ethyl Acetate	≤5000ppm	300ppm
-Tetrahydrofuran	≤720ppm	Undetected
Conclusion	The product conforms to Enterprise Standard.	
Remarks	N/A	

Analyst:

QC Manager:

QA: