

CERTIFICATE OF ANALYSIS

Product Name:	Ursodeoxycholic acid		
Batch No.	20230805	CAS No.	128-13-2
Manufacturing Date	August 5, 2023	Expiry Date TO	August 4, 2025
Quantities/Spec.	230KG	Reference	In house
Packaging format	Internal PE bag/external aluminum foil bag		
Analytical results			
Items	Specifications		Results
Appearance	White to Off-white powder		White powder
Solubility	Practically insoluble in water, freely soluble in ethanol(96%), slightly soluble in acetone.		Conform
Identification	The infrared absorption spectrum of sample is completely in conformity with the spectrum of ursodeoxycholic acid CRS		Conform
	The principal spot in the chromatogram obtained with test solution is similar in position color and size to the principal spot in the chromatogram obtained with reference solution		Conform
Specific Rotation	+58.0°~+62.0°		+61.2°
Melting Point	200~204°C		202.4°C
Loss on Drying	NMT 1.0%		0.09%
Residue on ignition	NMT 0.1%		0.03%
Heavy Metals	NMT 20ppm		Conform
Related Substance	Impurity A(Chenodeoxycholic Acid):NMT1.0%		0.06%
	Impurity C: NMT 0.1%		Conform
	Any unspecified single Impurity:NMT 0.1%		0.03%
	Total Impurities: NMT 1.5%		0.15%
Assay	99.0%~101.0%		100.20%
Storage	Preserve in well closed container, store in a cool and dry place, and keep away from strong light and heat. When the product stored under above condition, the retest date is 2 years from the manufacture date		
Conclusion	The material complies with in-house standard.		

Inspector: Carlifor Wu

Verifier: Jack He