

CERTIFICATE OF ANALYSIS

Product Name	Ursodeoxycholic acid		
CAS No.	128-13-2		
Molecular formula	C ₂₄ H ₄₀ O ₄		
Batch Number	20221025	Manufacture Date	20221025
Report Date	20221025	Expiry Date	20241024

Item of Analysis		Specification	Results
Assay		99.0 ~ 101.0%	99.4 %
Appearance		White or off-white powder	Conform
Identification IR		Complies with reference	Conform
Solubility		insoluble in water, insoluble in methylene chloride, freely soluble in ethanol, slightly soluble in acetone.	Conform
Loss On Drying		≤1.0%	0.8%
Melting Point		200 ~ 204 °C	202-204 °C
Heavy Metal		≤20ppm	None
Burned Residue		≤0.1%	0.03%
Specific Optical Rotation		+58.0° ~ +62.0°	+59.0°
Chenodeoxycholic acid		≤1.0%	None
Lithocholic acid		1.0mg/kg Max.	Conform
Single Impurity		≤0.1%	0.09%
Total Impurities		≤1.5%	0.57%
Residual Solvent	Isopropanol	≤0.5%	None
	Methanol	≤0.3%	29.7ppm
	Ethyl Acetate	≤0.5%	26ppm
	Acetone	≤0.3%	None
Conclusion		We certify that the quality of this product conforms to EP 7.0	

Storage: Store in tight, light-resistant containers, avoid exposure to direct sunlight, moisture and excessive heat.

Shelf Life: 24 months if store under the conditions above and stay in original packaging.

