



杭州海蓝化工有限公司  
HANGZHOU HAILAN CHEMICAL CO.,LTD

Certificate of Analysis

Name	Ursodeoxycholic Acid	CAS	128-13-2
(Chemical formula)	C <sub>24</sub> H <sub>40</sub> O <sub>4</sub>	(Packing)	Negotiable
(Order number)	20250530	(Detection time)	20250603
(Testing Items)	(Specification)	(Results)	
(Identification)	The infrared absorption spectrum of sample is completely in conformity with the spectrum of ursodeoxycholic acid CRS.	Complies	
	The principle 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.		
	Colorimetric Detection: The suspension obtained in greenish-blue.		
(Appearance)	White or Off-white powder	White powder	
(Content)	≥98.0%	99.6%	
(Solubility)	Practically insoluble in water, freely soluble in ethanol (96%), slightly soluble in acetone, practically insoluble in methylene chloride.	Complies	
(Melting Point)	200°C~ 204°C	202.2°C~ 203.7°C	
(Loss on Drying)	≤1.0%	0.13%	
(Optical Rotation)	+58.0°~ +62.0°	59.7°	
(Heavy Metals)	≤20PPM	Complies	
(Sulphated Ash)	≤0.1%	Complies	
(Impurity)	Lithocholic acid≤0.1%	Complies	

(Related Substance)	Chenodeoxycholic acid $\leq$ 1.0%	Not Detected	
	(Any unspecified single impurity ) $\leq$ 0.1%	0.09%	
	(Total impurities ) $\leq$ 1.5%	0.53%	
The quality inspection standard is in accordance with EP8.0			
Inspector	弭兆红	Re-examiner	韩凌