



Zhengzhou Yuanli Biological Technology Co., Ltd.
郑州原理生物科技有限公司

Address: No. 52 Huangyang Street, Zhengzhou, 450000, Henan, China.

Phone: +86-371-63507389

Fax: +86-371-63507390

Certificate of Analysis

Product Name: Ursodeoxycholic Acid		Batch No.: 20191203
CAS No. : 128-13-2		Quantity : 100kg
Manufacturing Date: 12/14/2019		Retest Date: 12/13/2021
Sampling Date: 12/23/2019		Report Date :12/28/2019
Test Items	Requirements	Results
Appearance	White or almost white powder	White powder
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	200.0 °C ~ 202.5 °C
Identification	IR: The infrared absorption spectrum of sample is completely in conformity with the spectrum of ursodeoxycholic acid CRS.	Complies
	B. TLC: 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.	Complies
	C: Colorimetric Detection: The suspension obtained is greenish-blue.	Complies
Loss on drying	≤1.0%	0.13%
Specific Optical Rotation	$[\alpha]_D^{20}$: +58.0°~ +62.0°	59.4°
Heavy Metals	≤ 20PPM	Complies
Sulphated Ash	≤ 0.1%	Complies
Impurity C (by TLC)	Lithocholic acid ≤0.1%	Complies
Related Substance (by HPLC)	Chenodeoxycholic acid≤1.0%	ND
	Any unspecified single impurity ≤0.1%	0.07%
	Total impurities ≤1.5%	0.29%
Assay	99.0% ~ 101.0%	100.4%
Conclusion	The product complies with enterprise standard.	
Checker: Jin Jin	Rechecker: Jing Zhao	Supervisor: Xuezhe Han

