

CERTIFICATE OF ANALYSIS

Product Name	Ursodeoxycholic Acid	Batch No	PY-UR20200305
Quantity	500KG	Analysis Date	Mar.08,2020
Mfg. Date	Mar.05,2020	Exp. Date	Mar.04,2022
Package	25kg/Drum	Standard	EP8.0

No.	Item	Specification	Result
1.	Appearance	White or almost white powder	Complies
2.	Solubility	Practically insoluble in water, freely soluble in ethanol(96%); slightly soluble in acetone; practically insoluble in methylene chloride.	Complies
3.	Identification	IR Identification: The infrared absorption spectrum of sample is completely in conformity with the spectrum of ursodeoxycholic acid CRS.	Complies
		TLC Identification: The principal spot in the chromatogram obtained with test solution(b) is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution.	Complies
		Colorimetric detection: The suspension obtained is greenish-blue	Complies
4.	Impurity C(by TLC)	Lithocholic acid \leq 0.1%	Complies
5.	Related Substance (by HPLC)	Chenodeoxycholic acid \leq 1% Any unspecified single Impurities \leq 0.1% Total Impurity: \leq 1.5%	0.15% 0.06% 0.42%
6.	Specific Rotation Optical	+58.0° ~ +62.0°	+60.4°
7.	Melting Point	About 202°C	Complies
8.	Loss on Drying	\leq 1.0%	0.58%
9.	Sulphated Ash	\leq 0.1%	Complies
10.	Heavy Metals	\leq 20ppm	<20ppm
11.	Assay	99.0%~101.0%	100.15%
12.	Conclusion	Conform to the EP8.0 Standard.	

Analyst: xuli

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