

Career Henan Chemical Co.

Certificate of Analysis

Product name: Ursodeoxycholic acid

Packing: 25kg/drum

Batch No.: C180701

Mfg Date: 2018.07.05

CAS No.: 128-13-2

Quantity: 500kg

Analysis Standard: EP 8.0

Items	Specification	Results
Description	White or light yellow color powder	Comply with the provisions
Solubility	Insoluble in water,insoluble in methylene chloride,freely soluble in ethanol,soluble in ethanol,slightly soluble in acetone	Comply with the provisions
Identification IR	Complies with reference	Comply with the provisions
Loss on drying	≤1.0%	0.75%
Melting point	200-204℃	202-204℃
Specific optical rotation	+58.0°~ +62.0°	+59.5°
Sulphated Ash	≤0.10%	0.06%
Heavy Metals	≤20ppm	12ppm
Burned Residue	≤0.10%	0.07%
Chloride	≤0.10%	0.06%
Related Substances(By HPLC)		
Chenodeoxycholic Acid	≤1.00%	0.15%
Lithocholic Acid	≤0.10%	0.01%
Single Impurity	≤0.10%	0.05%
Total Impurities	≤1.50%	0.45%
Assay(On dried basis)	99%-101%	99.44%
Residual solvent		
Isopropanol	≤0.50%	None
Methanol	≤0.30%	0.14%
Acetone	≤0.50%	0.09%
Ethyl acetate	≤0.50%	0.12%

Conclusion: We certify that the quality of this product conforms to EP8.0.

Analyst: Dr.LIAN

Checked by: LI

Date: 2018.07.06

