



成都百特万合医药科技有限公司

Chengdu Better Pharmaceutical Technology Co.Ltd

Add.:Tianhe Incubation Park,Hi-tech Zone,Chengdu City, Sichuan Province

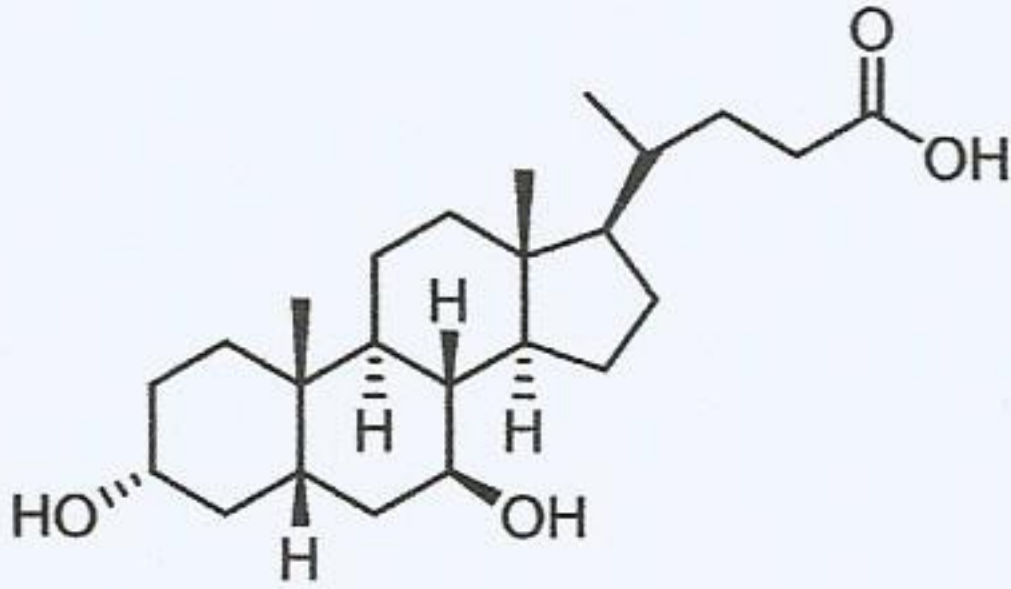
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CERTIFICATION OF ANALYSIS

Product Name:	Ursodeoxycholic Acid
CAS NO	128-13-2
Structure	
Formula	C ₂₄ H ₄₀ O ₄
Molecular Weight	392.57
Batch No	UD-180301
Manufacture date	2018.03.20
Report Date	2018.04.21



Testing Items	Specifications	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	201.5°C~202.5°C
Identification	A. 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, colour 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%	0.54%
Specific Optical Rotation	$[\alpha]D^{20}$: +58.0°~+62.0°	60.4°
Heavy Metals	≤ 20PPM	Complies
Sulphated Ash	≤0.1%	Complies
Assay	99.0%~101.0%	100.15%
Impurity C (by TLC)	Lithocholic acid≤0.1%	Complies
Related Substance (by HPLC)	Chenodeoxycholic acid≤1.0%	0.15%
	Any unspecified single impurity≤0.1%	0.06%
	Total impurities ≤1.5%	0.42%
Conclusion	Pass	
Specification Standard	EUROPEAN PHARMACOPOEIA 8.0	
Storage	Be stored in special airtight containers, numbered, timely registered and properly kept.	

QC: 高博

QA: 刘国凤

Quality Assurance Department
Chengdu Better Pharmaceutical Technology Co.Ltd