



BOC Sciences

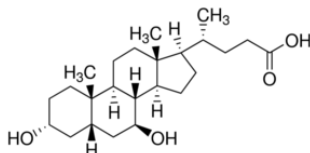
BOC Sciences

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Certificate of Analysis Ursodeoxycholic acid



CAS	128-13-2	Batch No.	B15YH0314
Product Name	Ursodeoxycholic acid	Batch size	100kg
MFG. Date	Mar. 14, 2015	Retest Date	Mar. 13, 2017
TESTING ITEM	SPECIFICATION	RESULT	
Appearance	White or almost white powder	Conforms	
Solubility	Practically insoluble in water, freely soluble in ethanol (96%), slightly soluble in acetone, Practically insoluble in methylene chloride.	Conforms	
Identification	Infrared absorption, TLC and chrominance test	Conforms	
Melting Point	200~204 °C	202.5 °C	
Specific Optical Rotation	$[\alpha]_D^{20} +58.0^\circ \sim +62.0^\circ$	+60.0°	
Loss on drying	≤1.0%	0.05%	
Heavy metals	≤20ppm	Conforms	
Sulphated ash	≤0.1%	0.05%	
Residual solvents	Acetone ≤0.5%	0.24%	
	Methanol ≤0.3%	None	
	Secondary butyl alcohol ≤0.5%	None	
Assay(Titration)	99.0%~101.0% (on the dried basis)	99.9%	
Related substance (TLC)	Lithocholic acid: ≤0.1%	Conforms	
	Cholic acid: ≤0.5%	Conforms	
	Chenodeoxycholic acid: ≤1.0%	Conforms	
	Other: ≤0.25%	Conforms	
Conclusion	Correspond to EP 6.0		

QA:

Peter Shaw

QC:

Linder Main

Date:

Mar. 14, 2015