

Certificate of Analysis

Product name: Acidum ursodeoxycholicum
Batch number / Weight: 25C07-B10-009694 / 50 g
Producer / Producer Batch Number: ICE S.p.A. / UDCA 0225039
Analyzed according to: Ph. Eur. 11.7
Number of Analysis / Certificate no.: 25C07-B10 / QO0014868

	Requirement	Result	Unit	Standard remark
Appearance	White or almost white powder	Conform		
Identification	A	Conform		
Specific optical rotation	(+58,0) - (+62,0)	+60,07		
Impurity C	<=0,1	<0,1	%	
Related substances	Conform	Conform		
Impurity A	<=1,0	<1,0	%	
Unspecified impurities	<=0,10	<0,10	%	
Total impurities	<=1,5	<1,5	%	
Loss od drying	<=1,0	0,2	%	
Sulfated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	99,0 - 101,0	99,6	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE lab

Release:

27-5-2025
 Dominika Sottysik
 Qualified Person

Expiration: 31-12-2029

Conclusion: APPROVED

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