

Certificate of Analysis

Product name: Acidum ursodeoxycholicum
Batch number / Weight: 24C07-B17-004511 / 50 g
Producer / Producer Batch Number: ICE S.p.A. / UDCA 0224035
Analyzed according to: Ph. Eur.
Number of Analysis / Certificate no.: 24C07-B17 / QO0008170

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification A	Conform	Conform		
Specific optical rotation	+58,0 - +62,0	60,3		
Impurity C	<=0,1	<0,1	%	
Related substances	Conform	Conform		
Impurity A	<=1,0	0,28	%	
Unspecified impurities	<=0,10	0,046	%	
Total impurities	<=1,5	0,33	%	
Loss on drying	<=1,0	0,09	%	
Sulfated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	99,0 - 101,0 (dried substance)	100,48	% m/m	
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 Fagron PL lab

Release:

2-12-2024
 Agnieszka Pszczółka
 Qualified Person

Expiration: 31-12-2028

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.