

Certificate of Analysis

Product name: **Cholesterolum**

Batch number / Weight: **22J03-B01-229331 / 100 G**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **22J03-B01 / INS-22-8665**

Reference Code / No.: **V01134 / 040396**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	147 - 150	149,4	°C	
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Solubility	acc. to Ph. Eur.	Conform		
Solubility in alcohol	Clear	Conform		
Acidity	Conform	Conform	ml	
Loss on drying	<=0,3	0,02	%	
Sulphated ash	<=0,1	0,04	%	
Cholest-5-en 3β-ol	>=95,0	96,30	%m/m	
Total sterols	97,0 - 103,0	101,61	%m/m	
Total aerobic microbial count (TA)	<=10 ³	<10	CFU / g	
Total yeasts and moulds (TYMC)	<=10 ²	<10	CFU / g	
Ps. aeruginosa	Negative / gram	Conform		
St. aureus	Negative / gram	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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,CBMiA

Release:
Dominika Soltysik
Qualified Person

19-04-2023

Expiration: 10-07-2025

Conclusion: APPROVED

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