

Certificate of Analysis

Product name: **Cholesterolum**

Batch number / Weight: **22C05-B02-222049 / 25 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	147 - 150	148,81	°C	
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Solubility	acc. to Ph. Eur.	Conform		
Solubility in alcohol	Clear	Conform		
Acidity	Conform	C	ml	
Loss on drying	$\leq 0,3$	0,03	%	
Sulphated ash	$\leq 0,1$	0,02	%	
Cholest-5-en 3 β -ol	$\geq 95,0$	96,72	%m/m	
Total sterols	97,0 - 103,0	100,76	%m/m	
Total aerobic microbial count (TA)	$\leq 10^3$	Conform	CFU / g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	Conform	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

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

06-06-2022

Expiration: 15-11-2024

Conclusion: APPROVED

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