

Certificate of Analysis

Product name: Cholesterolum

Batch number / Weight: 21F08-B20-216236 / 25 G

Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	Conform	Conform		
Identification A	147 - 150	149,3	°C	
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Solubility	acc. to Ph. Eur.	Conform		
Solubility in alcohol	Clear	Conform		
Acidity	Conform	0,15	ml	
Loss on drying	<=0,3	0,06	%	
Sulphated ash	<=0,1	0,06	%	
Cholest-5-en 3ß-ol	>=95,0	95,15	%m/m	
Total sterols	97,0 - 103,0	99,73	%m/m	
Total aerobic microbial count (TA	<=10^3	Conform	CFU/g	
Total yeasts and moulds (TYMC)	<=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

03-03-2022

Expiration: 24-02-2024

Conclusion: APPROVED

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