

Certificate of Analysis

Product name: **Cholesterolum**
Batch number / Weight: **21C18-B01-213250 / 100 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 | 148,8 | °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 | <=0,3 | 0,02 | % | |
| Sulphated ash | <=0,1 | 0,01 | % | |
| Cholest-5-en 3β-ol | >=95,0 | 96,37 | %m/m | |
| Total sterols | 97,0 - 103,0 | 100,76 | %m/m | |
| Total aerobic microbial count (TAMC) | <=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

23-08-2021

Expiration: 11-01-2024

Conclusion: APPROVED

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