

Certificate of Analysis

Productname:

Cholesterolum pulv.

Number of analysis/Inspection Code:

2 / KEUR-110915B

Batchnumber:

14B27-B05-295239

Reference code / No.:

1383 / 17642

Analysed according to:

PH.EUR8.0+

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Prejel: FUJS DRAGO

CC

Datum prejema 4-3/1
Pregledal: MIROL Robert, mag. farm., spec.

Datum pregleda: 4.3.1012

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	147 - 150	149	°C	Melting point
Identification B	Conform	Conform		TLC
Identification C	Conform	Conform		
Solubility in alcohol	Clear	Conform		1%m/V in alcohol
Acidity	Conform	Conform	and the state of the	
Loss on drying	<=0,3	0,2	%	4 h 60 °C; 670 Pa
Sulphated ash	<=0,1	Conform	%	
Cholest-5- and 3ß-ol	>=95,0	97,2	%m/m	Dried
Total sterols	97,0 - 103,0	99,7	%m/m	Dried
Total aerobic microbial count (TAMC)	<=200	Conform	CFU/g	
Total yeasts and moulds (TYMC)	<=20	Conform	CFU/g	
Ps. aeruginosa	Negative / gram	Conform		
S. aureus	Negative / gram	Conform		
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform	Section of the section of	Data producer

Analyse performed by the authorized lab Eurofins Parijs + Microbiol.

Release:

Drs. M.V. Garcia Alia

Pharmacist - QA Manager / QP

08/08/14

Expiration: 01-2017

Conclusion: APPROVED

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