



Certificate of Analysis

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Prizel: FUJS DRAGO
Zei: 
Datum presmeta: 
Pregledal: MAROLT Robert, mag. farm., spec.
Datum pregleda: 17. 4. 2015

Productname: Cholesterolum pulv.
Number of analysis/Inspection Code: 2 / KEUR-110925B
Batchnumber: 14B27-B05-295825 ✓
Reference code / No.: 1383 / 17642
Analysed according to: PH.EUR8.0+

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		
Loss on drying	<=0,3	0,2	%	4 h 60 °C; 670 Pa
Sulphated ash	<=0,1	Conform	%	
Cholest-5- and 3β-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		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.