



Certificate of Analysis

FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejel: PUJS DRAGO QA: H
Datum prejava: 1.4.14
Prejedal: MAROLT Robert, mag. farm. spec.
Datum pregleda: 2.4.2014

Productname: Cholesterolum pulv.
Number of analysis/Inspection Code: 1 / KEUR-95641B
Batchnumber: 13A03-B04-281229
Reference code / No.: 1383 / 14249
Analysed according to: PH.EUR7.6+

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	Pink / green	Conform		
Solubility in alcohol	Clear	Conform		1% <i>m</i> /V in alcohol
Acidity	Conform	Conform		
Loss on drying	<=0,3	0,0	%	4 h 60 °C; 670 Pa
Sulphated ash	<=0,1	Conform	%	
Cholest-5- and 3β-ol	>=95,0	95,8	% <i>m</i> /m	Dried
Total sterols	97,0 - 103,0	98,0	% <i>m</i> /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 Synergy Health+Microbiologie.

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

15-05-13

Expiration: 01-2016

Conclusion: APPROVED

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