



Certificate of Analysis

FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejel: IUJS DRAGO 7- Datum prejema: <u>28.8.14</u> Prejedat: <u>MAROLT Robert, mag. farm. spec.</u> Datum pregleda: <u>28.8.2014</u>

Productname: Cholesterolum pulv.
Number of analysis/Inspection Code: 1 / KEUR-107814B
Batchnumber: 14A07-B03-292236 ✓
Reference code / No.: 1383 / 16771
Analysed according to: PH.EUR8.0+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	147 - 150	147	°C	Melting point
Identification B	Conform	Conform		TLC
Identification C	Conform	Conform		
Solubility in alcohol	Clear	Conform		1% <i>m/V</i> in alcohol
Acidity	Conform	Conform		
Loss on drying	<=0,3	<0,1	%	4 h 60 °C; 670 Pa
Sulphated ash	<=0,1	Conform	%	
Cholest-5- and 3β-ol	>=95,0	96,8	% <i>m/m</i>	Dried
Total sterols	97,0 - 103,0	101,5	% <i>m/m</i>	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 Proxylabs+Microb..

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

05/09/14

Expiration: 08-2016 ✓

Conclusion: APPROVED

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