

Certificate of Analysis

Productname: Lanolin/Lanolinum

Inspection No: H08109/0820/536

Batchnumber: 20E12-T07-080152

Expiration date: 31.08.2022

Analysed according to: DAB 2008

Sample Unit: 2 x 100 g

Batch Size: 719 x 250 g

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Pale yellow, unctuous substance.	Conform			
Odour (2.3.4)	Slight characteristic odour.	Conform			
IDENTIFICATION					
Identification A	Conform	Conform		Cholesterol	
TESTS					
Water-soluble acid or alkaline subst.	Conform	Conform			
Saponification value (2.5.6)	58 - 69	66			
Soap	Conform	Conform			
Water - soluble oxidisable substances	Conform	Conform			
Water soluble substances	$\leq 0,1$	0,03	%		
Chlorides	≤ 100	Conform	$\mu\text{g/g}$		
Water (2.5.12, KF)	18,0 - 21,0	19,4	%		
Rancidity	Conform	Conform			
Peroxide value (2.5.5)	≤ 15	2,3			
Water-absorption capacity	Conform	Conform			
Microbiology	Conform	Conform			
TAMC	$\leq 2 \times 10^2$	Conform	CFU/g		
TYMC	$\leq 2 \times 10^1$	Conform	CFU/g		
Pseudomonas aeruginosa	negative/1g	Conform			
Staphylococcus aureus	negative/1g	Conform			
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			
Residual solvents	CPMP/ICH/82 260/2006	Conform			

Performed by: Jitka Spáčilová

Responsible: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA



Date: 02.09.2020

Conclusion: APPROVED

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