



Certificate of Analysis

Productname: Cremor basalis hydrophobicus/Hydrophobe Basiscreme DAC

Inspection No: H10725/1120/536

Sample Unit: 1 x 500 mg

Batchnumber: 20G14-T01-081556

Batch Size: 36 x 5 kg

Expiration date: 30.04.2022

Analysed according to: DAC 2019

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	White or almost white, soft preparation not washable with water from skin.	Conform			
Odour	Slight	Conform		DAC 2003	
IDENTIFICATION					
A.TLC (2.2.27)	Conform	Conform		DAC 2019	
B.bluer upper layer	Conform	Conform			
C.mixture of phases	Conform	Conform		DAC 2019	
TESTS					
pH (2.2.3)	3,5 - 5,0	4,7			
Saponification value (2.5.6)	7 - 12	8			
Water (2.5.12)	61,0 - 67,0	65,7	%		
Homogeneous distribution of componen	Conform	Conform		DAC 2019	
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			
ASSAY					
Sorbic acid (2.2.29)	0,08 - 0,12	0,091	%	DAC 2019	

Performed by: Jitka Spáčilová

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

Date: 10.12.2020

Conclusion: APPROVED

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