

Certificate of Analysis

Productname: **Cremor basalis hydrophobicus/Hydrophobe Basiscreme DAC**

Inspection No: I09914/1221/536
Batchnumber: **21H10-T01-090851**
Expiration date: 31.05.2023
Analysed according to: DAC 2019
Original Manuf. Date: 23.11.2021

Sample Unit: 1 x 500 mg
Batch Size: 21 x 5 kg

Identification of producer: V01454
Batch no. of vendor: 21H10-T01

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	White or almost white, soft preparation not washable with water from skin.	Conform			
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	4,8			
Saponification value (2.5.6)	7 - 12	8			
Water (2.5.12)	61,0 - 67,0	64,3	%		
Homogeneous distribution of componen	Conform	Conform		DAC 2019	
Tocopherol	Calculated value	<4,92	ppm		
Microbiology	Conform	Conform			
TAMC	<=2 x 10 ²	Conform	CFU/g		
TYMC	<=2 x 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	0,11	%	DAC 2019	

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Performed by: Jitka Spáčilová

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 13.12.2021



Conclusion: APPROVED

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