

## Certificate of Analysis

**Productname:** Cremor Basalis/Basiscreme

**Inspection No:** I06614/0821/536  
**Batchnumber:** 21E24-T20-088655  
**Expiration date:** 31.07.2024  
**Analysed according to:** DAC 2019

**Sample Unit:** 1 x 500 g  
**Batch Size:** 23 x 10 kg

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	White soft creme, washable with water.	Conform			
Odour (2.3.4)	Slight odour.	Conform			
IDENTIFICATION					
A.TLC (2.2.27)	see the test	Conform			
B.bluer upper layer	see the test	Conform			
C.purple colour	see the test	Conform			
TESTS					
Saponification value (2.5.6)	30 - 42	35			
Unsaponifiable matter (2.5.7)	25,0 - 35,0	28,4	%		
Water (2.5.12, KF)	38,0 - 42,0	40,0	%		
Homogeneous distribution of componen	see the test	Conform			
Microbiology	Conform	Conform			
TAMC	<=2 x 10 <sup>2</sup>	Conform	CFU/g		
TYMC	<=2 x 10 <sup>1</sup>	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. Pavel Mišák, QC  
 PharmDr. Ivana Urbánková, QA

**Date:** 18.08.2021

**Conclusion:** APPROVED

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