

## Certificate of Analysis

**Productname:** **Cremor Basalis/Basiscreme**

**Inspection No:** I06099/0721/536

**Sample Unit:** 1 x 500 g

**Batchnumber:** **21B15-T27-086446**

**Batch Size:** 157 x 5 kg

**Expiration date:** 31.07.2024

**Analysed according to:** DAC 2019

	Requirement	Result	Unit	Standard remark	Insp. Site
<b>CHARACTERS</b>					
Appearance	White soft creme, washable with water.	Conform			
Odour (2.3.4)	Slight odour.	Conform			
<b>IDENTIFICATION</b>					
A.TLC (2.2.27)	see the test	Conform			
B. bluer upper layer	see the test	Conform			
C. purple colour	see the test	Conform			
<b>TESTS</b>					
Saponification value (2.5.6)	30 - 42	34			
Unsaponifiable matter (2.5.7)	25,0 - 35,0	29,0	%		
Water (2.5.12, KF)	38,0 - 42,0	38,3	%		
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:** 29.07.2021

**Conclusion:** APPROVED 

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