

Certificate of Analysis

Productname: Cremor Basalis/Basiscreme Tube

Inspection No: H09310/0920/536
Batchnumber: 20F18-T02-081202
Expiration date: 30.09.2023
Analysed according to: DAC 2019

Sample Unit: 5 x 100 g
Batch Size: 5 000 x 100 g

	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	28,9	%		
Water (2.5.12, KF)	38,0 - 42,0	38,3	%		
Homogeneous distribution of componen	see the test	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: Lenka Morávková, QC
 PharmDr. Ivana Urbánková, QA

Date: 14.10.2020

Conclusion: APPROVED

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