



Certificate of Analysis

Productname: Cremor Basalis/Basiscreme

Inspection No: F04190/0418/536
Batchnumber: 18C19-T22-053970
Expiration date: 30.04.2021
Analysed according to: DAC 2011

Sample Unit: 2 x 50 g
Batch Size: 24 x 5 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	29.3	%		
Water (2.5.12, KF)	38.0 - 42.0	39.4	%		
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			
Residual solvents	CPMP/ICH/82 260/06	Conform			

Performed by: Jitka Spáčilová

Responsible: Mgr. Kateřina Jokešová, QC
 PharmDr. Hana Běhalová, QP

Date: 27.04.2018

Conclusion: APPROVED

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