

Certificate of Analysis

Productname: Cremor basalis hydrophobicus/Hydrophobe Basiscreme DAC
Inspection No: H04403/0420/536 **Sample Unit:** 0 x 50 g
Batchnumber: 20D01-T09-078346 **Batch Size:** 83 x 1 kg
Expiration date: 31.10.2021
Analysed according to: DAC 2011

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	White or almost white, soft preparation not washable with water from skin.	Conform			
Odour	Slight	Conform		DAC 2003	
IDENTIFICATION					
A.TLC (2.2.27)	Conform	Conform			
B.bluer upper layer	Conform	Conform			
C.mixture of phases	Conform	Conform		DAC 2011	
TESTS					
pH (2.2.3)	3,5 - 5,0	4,9			
Saponification value (2.5.6)	7 - 12	10			
Water (2.5.12)	61,0 - 67,0	64,8	%		
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			
Residual solvents	CPMP/ICH/82 260/06	Conform			
ASSAY					
Sorbic acid (2.2.29)	0,09 - 0,12	0,104	%		

Performed by: Jitka Spáčilová
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 PharmDr. Ivana Urbánková, QA 
Date: 19.05.2020
Conclusion: APPROVED

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