

Certificate of Analysis

Productname: Unguentum emulsificans/Hydrophile Salbe DAB
Inspection No: H00466/0120/536 **Sample Unit:** 2 x 250 g
Batchnumber: 19J10-T11-072625 **Batch Size:** 196 x 250 g
Expiration date: 31.12.2022
Analysed according to: DAB 2008
Identification of producer: V01454
Batch no. of vendor: 19J10-T11

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Soft ointment.	Conform			
Odour	Slight characteristic odour.	Conform			
IDENTIFICATION					
Identification A	Conform	Conform		Crystalline precipitate	
Identification B	Conform	Conform		Hydrophilic ointment	
TESTS					
Acidity or alkalinity	Conform	Conform			
Hydroxyl value	55 - 70	63			
Microbiology	Conform	Conform			
TAMC	<=2 x 10 ²	Conform	CFU/g		
TYMC	<=2 x 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: Mgr. Kateřina Jokešová, QC
 Ing. Martina Zemanová, QP 

Date: 02.03.2020

Conclusion: APPROVED

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