

Certificate of Analysis

Productname: Unguentum emulsificans/Hydrophile Salbe DAB

Inspection No: I02425/0321/536

Sample Unit: 1 x 250 g

Batchnumber: 21B12-T05-086358

Batch Size: 114 x 250 g

Expiration date: 31.03.2024

Analysed according to: DAB 2008

Original Manuf. Date: 12.3.2021

Identification of producer: V01454

Batch no. of vendor: 21B12-T05

	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	$\leq 2 \times 10^2$	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: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA

Date: 29.03.2021

Conclusion: APPROVED

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