



## Certificate of Analysis

**Productname:** Unguentum emulsificans/Hydrophile Salbe DAB

**Inspection No:** G07366/0719/536  
**Batchnumber:** 19D25-T12-066644  
**Expiration date:** 31.07.2022  
**Analysed according to:** DAB 2008

**Sample Unit:** 2 x 250 g  
**Batch Size:** 196 x 250 g

	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	61			
Microbiology	Conform	Conform			
TAMC	$\leq 2 \times 10^2$	Conform	CFU/g		
TYMC	$\leq 2 \times 10^1$	Conform	CFU/g		
Pseudomonas aeruginosa	absent/1g	Conform			
Staphylococcus aureus	negative/1g	Conform			
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. Ivana Urbánková, QA

**Date:** 05.08.2019

**Conclusion:** APPROVED

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