

## 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
<b>CHARACTERS</b>					
Appearance	Soft ointment.	Conform			
Odour	Slight characteristic odour.	Conform			
<b>IDENTIFICATION</b>					
Identification A	Conform	Conform		Crystalline precipitate	
Identification B	Conform	Conform		Hydrophilic ointment	
<b>TESTS</b>					
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:** Mgr. Kateřina Jokešová, QC  
Ing. Martina Zemanová, QP



**Date:** 02.03.2020

**Conclusion:** APPROVED

This document has been produced electronically from our quality system and is valid without signature.