

Certificate of Analysis

Productname: Unguentum emulsificans/Hydrophile Salbe DAB
Inspection No: I02426/0321/536 **Sample Unit:** 0 x 1 kg
Batchnumber: 21B12-T05-086359 **Batch Size:** 19 x 1 kg
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		
<i>Pseudomonas aeruginosa</i>	negative/1g	Conform			
<i>Staphylococcus aureus</i>	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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Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521