

Certificate of Analysis

Productname: Unguentum emulsificans/Hydrophile Salbe DAB

Inspection No: I06799/0821/536
Batchnumber: 21F16-T05-087690
Expiration date: 31.07.2024
Analysed according to: DAB 2008
Original Manuf. Date: 28.7.2021

Sample Unit: 1 x 250 g
Batch Size: 47 x 1 kg

Identification of producer: V01454
Batch no. of vendor: 21F16-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	<=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: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
 MVDr. Zdenka Borská, QA

Date: 18.08.2021

Conclusion: APPROVED

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