

Certificate of Analysis

Productname: Pasta Zinci/Zinkpaste

Inspection No: I09867/1221/536
Batchnumber: 21H09-T36-090842
Expiration date: 30.11.2023
Analysed according to: DAB 2008

Sample Unit: 2 x 250 g
Batch Size: 103 x 250 g

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	White, at room temperature spreadable, homog.paste.	Conform			
Odour	Practically without odour.	Conform			
Solubility	Conform	Conform			
IDENTIFICATION					
Identification A	Conform	Conform		Zinc	
Identification B	Conform	Conform		Zinc	
Identification C	Conform	Conform		Starch	
TESTS					
Colour of ointment - base	Conform	Conform		2 h 105 °C	
Reaction with H ₂ SO ₄	Conform	Conform			
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			
ASSAY					
Zinc oxide	23,5 - 26,5	25,2	%		
White soft paraffin	47,0 - 53,0	49,4	%	2 h 105 °C	

Performed by: Jitka Spáčilová

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

Date: 10.12.2021

Conclusion: APPROVED

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