

Certificate of Analysis

Productname: **Pasta Zinci/Zinkpaste**Inspection No: **H07258/0720/536**Batchnumber: **20E12-T11-080179**Expiration date: **31.07.2023**Analysed according to: **DAB 2008**Sample Unit: **2 x 250 g**Batch Size: **200 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	24,8	%		
White soft paraffin	47,0 - 53,0	47,5	%	2 h 105 °C	

Performed by: **Jitka Spáčilová**Responsible: **Mgr. Kateřina Jokešová, QC**
PharmDr. Ivana Urbánková, QA

Date: **14.08.2020**Conclusion: **APPROVED**

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