

Certificate of Analysis

Productname: Zinci pasta mollis/Weiche Zinkpaste DAB

Inspection No: H07477/0820/536

Batchnumber: 20D30-T01-079790

Expiration date: 31.07.2023

Analysed according to: DAB 2008

Sample Unit: 1 x 500 g

Batch Size: 42 x 5 kg

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	White or almost white homogenous soft paste.	Conform			
Odour (2.3.4)	Slight beewax odour.	Conform			
IDENTIFICATION					
A.Zinc (2.3.1)	Conform	Conform			
B.TLC (2.2.27)	Conform	Conform			
TESTS					
Lead (2.2.23/II, AAS)	≤30,0	<3	µg/g		
Cadmium (2.2.23/II, AAS)	≤3,0	<0,3	µg/g		
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 - complexometric titration	28,0 - 32,0	29,9	%		

Performed by: Jitka Spáčilová

Responsible: Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA



Date: 14.08.2020

Conclusion: APPROVED

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