

Certificate of Analysis

Site / Address			
Almirall Hermal GmbH		Scholtzstrasse 3, 21465 Reinbek	
Product type Drug Product	Product Code 60006001	Product Name Sililevo 5% Nail Lacq 6,6 ml DE	
Batch number 346271	Batch size 34499 UN	Certificate Number B-231109-124116	Manufacture Date 11/2023

Parameter	Specification	Result	Units
Appearance	clear liquid	clear liquid	g/ml
Colour	pale yellow	pale yellow	
Odour	characteristic	characteristic	
Homogeneity	homogeneous	homogeneous	
Particulate matter in the solution	essentially free from particles (precipitates or others) that can be observed on visual inspection	essentially free from particles (precipitates or others) that can be observed on visual inspection	
Density	0.94 - 0.97 at 20°C	0.95	
Refractive index	1.360 - 1.370 at 20°C	1.367	
Compliance with FPV	meets requirements	meets requirements	
Compliance with the reference sample	in compliance	in compliance	
Labeling / packaging	meets requirements	meets requirements	
Total aerobic micr. count (TAMC)	Not more than 10 ² CFU / g	Not more than 10 ² CFU / g	
Total yeast/mould count (TYMC)	Not more than 10 ¹ CFU / g	Not more than 10 ¹ CFU / g	
Absence of Staphylococcus aureus	Absent in 1 g	Absent in 1 g	
Absence of Pseudomonas aeruginosa	Absent in 1 g	Absent in 1 g	

Notes:

Expiry Date: 11/2026

Result RELEASED	Approval Date 02/01/2024 13:34:14	Approved by Katrin Müller-Landré, QP Almirall Hermal GmbH Sandra Letters, Quality Control Manager QC-F
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