

Certificate of Analysis

Analytical Laboratory Site
Almirall Hermal GmbH

Scholtzstrasse 3, 21465
Reinbek

Product type Bulk	Product Code 98610501	Product Name Ecocel Lösung	Sample S-211005-425676
Batch number 98610501/14020	Batch size 497 KG	Certificate Number B-211005-92577	Manufacture Date 12/10/2021

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	1.366	

Notes:

Valid to: 01/12/2021

Result Conforms	Approval Date 13/10/2021 13:14:00	Approved by Sandra Letters, Quality Control Manager QC-F
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Scholtzstrasse 3, 21465
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Product type Drug Product	Product Code 60006002	Product Name Sililevo 5% Nail Lacq 3,3 ml DE	Sample S-211019-427672
Batch number 60006002/140203	Batch size 47754 UN	Certificate Number B-211019-93145	Manufacture Date 12/10/2021

Parameter	Specification	Result	Units
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: 10.2024

Result Conforms	Approval Date 29/11/2021 11:05:50	Approved by Sandra Letters, Quality Control Manager QC-F
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Certificate of Analysis

Analytical Laboratory Site

Almirall Hermal GmbH

Scholtzstrasse 3, 21465
ReinbekProduct type
Drug ProductProduct Code
60006002Product Name
Sililevo 5% Nail Lacq 3,3 ml DESample
S-211019-427671Batch number
60006002/140203Batch size
47754 UNCertificate Number
B-211019-93145Manufacture Date
12/10/2021

Parameter

Specification

Result

Units

Compliance with FPV

meets requirements

meets requirements

Labeling / packaging

meets requirements

meets requirements

Compliance with the reference
sample

in compliance

in compliance

Notes:

Expiry Date: 10.2024

Result
ConformsApproval Date
29/11/2021 11:05:50Approved by
Sandra Letters, Quality Control Manager QC-F