

Certificate of Analysis

Site / Address

Almirall Hermal GmbH

 Scholtzstrasse 3, 21465
Reinbek

Product type

Drug Product

Product Code

60006002

Product Name

Sililevo 5% Nail Lacq 3,3 ml DE

Batch number

409285

Batch size

85344 UN

Certificate Number

B-240229-128762

Manufacture Date

03/2024

Parameter
Specification
Result
Units

Appearance

clear liquid

clear liquid

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

g/ml

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 10² CFU / g

 Not more than 10² CFU / g

Total yeast/mould count (TYMC)

 Not more than 10¹ CFU / g

 Not more than 10¹ 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: 03/2027

Result

RELEASED

Approval Date

22/03/2024 15:27:36

Approved by

 Julia Grewe Borrás, QP Almirall Hermal GmbH/QA Manager
Sandra Letters, Quality Control Manager QC-F