

# Certificate of Analysis

Site / Address			
Almirall Hermal GmbH		Scholtzstrasse 3, 21465 Reinbek	
Product type Drug Product	Product Code 00175300	Product Name Decoderm® Basiscreme 100 g DE	
Batch number 239432	Batch size 8134 UN	Certificate Number B-221115-109105	Manufacture Date 09/2022

Parameter	Specification	Result	Units
Appearance	solid cream	solid cream	
Colour	white	white	
Odour	faint characteristic odour	faint characteristic odour	
Identification of sodium hydroxide	positive	positive	
Identification of anhydrous silica	positive	positive	
Identification of sorbic acid	positive	positive	
Ident. of medium-chain triglycerides	positive	positive	
Identification of glyceryl monostearate	positive	positive	
Identification of propylene glycole	positive	positive	
Ident. of PEG-sorbitan monopalmitate	positive	positive	
Identification of cetostearyl alcohol	positive	positive	
Identification of liquid paraffin	positive	positive	
Identification of white petrolatum	positive	positive	
Microscopic examination	crystals about 100% nmt 50 µm	crystals about 100% nmt 50 µm	
Emulsiontype	oil in water	oil in water	
Relative density D20/20	0.950 - 0.964	0.959	
pH-Value	3.6 - 4.8	4.6	
Viscosity EP 2.2.10	5 - 12	8	Pas
Water (NIR)	35.0 - 42.0	38.6	%

**Notes:**

Expiry Date: 09/2027

Result RELEASED	Approval Date 21/12/2022 09:44:47	Approved by Sandra Letters, Quality Control Manager QC-F
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## Certificate of Analysis

## Site / Address

Almirall Hermal GmbH

Scholtzstrasse 3, 21465  
ReinbekProduct type  
Drug ProductProduct Code  
00175300Product Name  
Decoderm® Basiscreme 100 g DEBatch number  
239432Batch size  
8134 UNCertificate Number  
B-221115-109105Manufacture Date  
09/2022

## Parameter

## Specification

## Result

## Units

Content of sorbic acid

0.18 - 0.22

0.19

%

Compliance with FPV

meets requirements

meets requirements

Labeling / packaging

meets requirements

meets requirements

Total aerobic micr. count (TAMC)

Not more than 10<sup>2</sup> CFU / gNot more than 10<sup>2</sup> CFU / g

Total yeast/mould count (TYMC)

Not more than 10<sup>1</sup> CFU / gNot more than 10<sup>1</sup> CFU / g

Absence of Pseudomonas aeruginosa

Absence in 1 g

Absence in 1 g

Absence of Staphylococcus aureus

Absence in 1 g

Absence in 1 g

## Notes:

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Approved by

Sandra Letters, Quality Control Manager QC-F