

CERTIFICATE OF MANUFACTURE / COMPLIANCE

Product Identification Number : 00175300

Product Name : Decoderm® Basiscreme 100 g DE

Importing Country : Date of Manufacture : 02/2024

Date of Expiry : 02/2029

Strength/Potency : Batch Number : 408551

Formulation No. : 98701006 Batch size (units) : 9506 UN

Marketing

Authorisation No :

Manufacturing DE_SH_01_MIA_2023-0001

Authorisation No :

Name and Address of Manufacturer : Almirall Hermal GmbH
Scholtzstrasse 3, 21465
Reinbek

I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processings, packaging and analysis records were reviewed and found to be in compliance with GMP.

Position of Authorised Person : QP Almirall Hermal GmbH/QA Manager

Signature of Authorised Person : Julia Grewe Borrás

Date Certificate Issued : Mar.26.2024



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 408551	Batch size 9506 UN	Certificate Number B-240228-128663	Manufacture Date 02/2024

Parameter	Specification	Result	Units
Appearance	solid cream	solid cream	
Colour	white	white	
Odour	faint characteristic odour	faint characteristic odour	
Identification of sorbic acid	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	4.5	
Viscosity EP 2.2.10	5 - 12	10	Pas
Water (NIR)	35.0 - 42.0	38.0	%
Content of sorbic acid	0.18 - 0.22	0.20	%
Compliance with FPV	meets requirements	meets requirements	
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 Pseudomonas aeruginosa	Absence in 1 g	Absence in 1 g	
Absence of Staphylococcus aureus	Absence in 1 g	Absence in 1 g	

Notes:

Expiry Date: 02/2029

Result RELEASED	Approval Date 26/03/2024 13:38:57	Approved by Sandra Letters, Quality Control Manager QC-F
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