

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 Almirall Hermal GmbH

Manufacturer: 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.

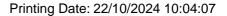
Position of Authorised Person : QP Almirall Hermal GmbH/QA Manager

Signature of Authorised Person: Julia Grewe Borras

Date Certificate Issued: Mar.26.2024

Printed On: 22/10/2024 Printed By: eboerche Page 1 of 2

This document has been electronically signed and is valid without manual signature. The electronic signature complies to the relevant EU-/US-regulations.





Certificate of Analysis

	00	rimoate	of Allalysis	Page 2 of 2	
Site / Address					
Almirall Hermal GmbH	Scholtzstrasse 3, 214 Reinbek	165			
Product type	Product Code		Product Name		
Drug Product	00175300		Decoderm® Basiscreme 100 g DE		
Batch number	per Batch size		Certificate Number	Manufacture Date	
408551	9506 UN		B-240228-128663	02/2024	
Parameter	Specification		Result	Units	
Appearance	solid cream		solid cream		
olour white			white		
Odour	faint characteristic o	dour	faint characteristic odour		
Identification of sorbic acid	positive		positive		
Microscopic examination crystals about 100% nm		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	C) Not more than 10 ² C	CFU/g	Not more than 10 ² CFU / g		
Total yeast/mould count (TYMC	Not more than 10 ¹ C	CFU/g	Not more than 10 ¹ CFU / g		
Absence of Pseudomonas aeru	ginosa Absence in 1 g		Absence in 1 g		
Absence of Staphylococcus aur	eus Absence in 1 g		Absence in 1 g		
Notes:					
Expiry Date: 02/2029					
RELEASED	26/03/2024 13:38:57 Sandra		Letters, Quality Control Manager QC-F		
Result RELEASED	Approval Date 26/03/2024 13:38:57		Approved by Sandra Letters, Quality Control Manager QC-F		