



CERTIFICATE OF COMPLIANCE

PRODUCT DESCRIPTION: EXCIPIAL® - HYDROCREME 50gBATCH NUMBER: 1767003MANUFACTURING SITE: LABORATOIRES GALDERMA, ZI MONTDESIR, ALBY SUR CHERAN, 74540, FRANCEAUTHORIZATION NUMBER: M 20/018 - February 12, 2020IMPORTING COUNTRY (DESTINATION): FRANCEFORMULA NUMBER: 0767MANUFACTURING DATE (MM/DD/YYYY): 12/17/2021PRODUCT CODE: 023565SHELF LIFE: 36 MONTHSEXPIRY DATE (MM/YYYY): 11/2024REFERENCE SPECIFICATION: MT.09.DOC.1473.R01ANALYSIS NUMBER: B-20211220-00017ANALYSIS TYPE: FullRELEASED UNITS QUANTITY: 18522 UnitsMEAN FILL (>= Nominal value of label claim AC.02.SOP.5005) : 50.4 g

TESTS	METHODS	SPECIFICATIONS	RESULTS
Macroscopic appearance	Visual examination		
Form		Semisolid emulsion	Complies
Color		White	Complies
Other Properties		Homogeneous	Complies
Odor	Smell Examination	Almost odorless	Complies
Structure	Visual examination (Microscope)	No crystals visible	corresponds
pH	Ph. Eur 2.2.3 *	3.5 - 6.5	5.7
Total aerobic microbial count (TAMC)	Ph. Eur 2.6.12/USP 1111,61/JP G4,4.05*	NMT 100 CFU/g	< 100 CFU/g
Total combined yeast/mould count (TYMC)	Ph. Eur 2.6.12/USP 1111,61/JP G4,4.05*	NMT 10 CFU/g	< 10 CFU/g
Specific microorganisms	Ph. Eur 2.6.13/USP 1111,62/JP G4,4.05*		
Pseudomonas aeruginosa		Absence per gram	Absence per gram
Staphylococcus aureus		Absence per gram	Absence per gram

*All pharmacopoeia methods are carried out according to the current edition.



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NOTES: N/A

Certification:

I hereby certify that the above information is authentic and accurate.

This batch of product has been manufactured, including packaging/labelling 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 or product specification file for Investigational Medicinal Products.

The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

This document has been electronically signed by a qualified person :

GAUTIER Céline

Date: January 26, 2022