



CERTIFICATE OF COMPLIANCE

PRODUCT DESCRIPTION : EXCIPIAL® - HYDROCREME 50gBATCH NUMBER : 1767002MANUFACTURING 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) : 04/24/2021PRODUCT CODE : 023565SHELF LIFE : 36 MONTHSEXPIRY DATE (MM/YYYY) : 03/2024REFERENCE SPECIFICATION : MT.09.DOC.1473.R01ANALYSIS TYPE : FullANALYSIS NUMBER : B-20210510-00012RELEASED UNITS QUANTITY : 37296 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	5.4
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 certified that above information is authentic and accurate.

This batch has been manufactured (including packaging and quality control), at the above mentioned site in full compliance with the GMP requirements of the local regulatory authorities and with the specification in the marketing authorization of the importing country.

The batch processing, packaging and analysis records were reviewed and found to be in compliance with the GMP. All major processes (manufacturing and analytical) have been validated. All deviation or changes have been properly investigated, evaluated and approved by authorized personal.

This document has been electronically signed by a qualified person :

GOEHRY Calvin

Date: June 16, 2021