



## CERTIFICATE OF COMPLIANCE

PRODUCT DESCRIPTION : EXCIPIAL® - LIPOCREME 50gBATCH NUMBER : 2769003MANUFACTURING SITE : LABORATOIRES GALDERMA, ZI MONTDESIR, ALBY SUR CHERAN, 74540, FRANCEAUTHORIZATION NUMBER : M 20/018 - February 12, 2020IMPORTING COUNTRY (DESTINATION) : FRANCEFORMULA NUMBER : 0769MANUFACTURING DATE (MM/DD/YYYY) : 01/30/2022PRODUCT CODE : 023566SHELF LIFE : 36 MONTHSEXPIRY DATE (MM/YYYY) : 12/2024REFERENCE SPECIFICATION : MT.09.DOC.1433.R00.1ANALYSIS NUMBER : B-20220203-00050ANALYSIS TYPE : FullRELEASED UNITS QUANTITY : 13589 UnitsMEAN FILL (>= Nominal value of label claim AC.02.SOP.5005) : 50.4 g

TESTS	METHODS	SPECIFICATIONS	RESULTS
Macroscopic appearance	Visual examination		
Form		Semi solid emulsion	Complies
Color		White	Complies
Other Properties		Smooth, supple	Complies
Odor	Smell Examination	Characteristic (perfumed)	Complies
Structure	Visual examination (Microscope)	No crystal visible, shiny structure <= 50µm visible	corresponds
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.



## CERTIFICATE OF COMPLIANCE

---

PRODUCT DESCRIPTION: EXCIPIAL® - LIPOCREME 50g

BATCH NUMBER: 2769003

TESTS	METHODS	SPECIFICATIONS	RESULTS
-------	---------	----------------	---------

---

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 :*

REVIRIEGO Elodie

Date: February 18, 2022