Logistic batch number

9769021-3566

GALDERMA

CERTIFICATE OF COMPLIANCE

PRODUCT DESCRIPTION : EXCIPIAL® - LIPOCREME 50g

BATCH NUMBER : 9769021

MANUFACTURING SITE : LABORATOIRES GALDERMA, ZI MONTDESIR, ALBY SUR CHERAN, 74540, FRANCE

AUTHORIZATION NUMBER : MM 18/037 - February 16, 2018

IMPORTING COUNTRY (DESTINATION) : FRANCE

FORMULA NUMBER : 0769

PRODUCT CODE : 023566

MANUFACTURING DATE (MM/DD/YYYY) : 08/27/2019

SHELF LIFE : 36 MONTHS

EXPIRY DATE (MM/YYYY) : 07/2022

REFERENCE SPECIFICATION : MT.09.DOC.1433.R00.1

ANALYSIS TYPE : Full

ANALYSIS NUMBER : B-20190905-00006

RELEASED UNITS QUANTITY : 13040 Units

MEAN FILL (>= Nominal value of label claim AC.02.SOP.5005) : 50.5 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
ASSAYS (LC)	AL.74.ATP.1158		
Benzyl Alcohol		0.450 – 0.550 % w/w (0.500 % w/w ± 10%)	0.502 % w/w
Phenoxyethanol		0.360 – 0.440 % w/w (0.400 % w/w ± 10%)	0.401 % w/w
Potassium Sorbate		0.180 – 0.220 % w/w (0.200 % w/w ± 10%)	0.199 % w/w
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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TESTS	METHODS	SPECIFICATIONS	RESULTS

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 :

Aurélie GARREAU

Date : September 23, 2019