# GALDERMA

EST. 1981

#### CERTIFICATE OF COMPLIANCE

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This document cer	tifies that (	G Production	on Inc. approves the	e following lot of pr	roduct.
Product Description:	EXCIPIAL	LIPOLOTIO	ON NEUTRE 200ML 1	8 FR	
Product Code:	052010		PIC Number:	N/Ap	
Lot Number:	367181		FIL Number:	0806	
Expiration Date:	10/2024				
Quantity released:	14598	units			
Manufacturing date:	12	-May-22			
Comments: N/Ap	)				
Practices Part 210 Production Inc. Sta  All current procedu quality inspections documentation has which occurred have	and 211, undard Ope ures have in s have no s been rev ue been pr	Title 21, of erating Probeen follownet specificiewed for operly inve	the FDA Code of F cedures, Master Pro wed, all incoming ma cations, all testing completeness and estigated, document	ederal Regulations oduction and Contr aterial have been e has been com accuracy and any ed and approved b	urrent Good Manufacturis and with accordance to rol Documents.  evaluated and approved, pleted and approved, discrepancies / deviation Grown Grown Affiliate only.
Certificate of analy	sis 🗸				
Non-Conformity		Yes (Sun No	nmary Attached)		
Certified by : Sign	ature, date	- Quality As	surance		



## **QC** Chemistry Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: 052010 <u>EFFECTIVE DATE</u>: 08-04-2022

GALDERMA LOT NUMBER: 367181 LIMS LOT NUMBER: B-20220517-00115

**SAMPLE:** S-220520-00338 Begin

Test	Method	Limits	Results
Description	1.BD.05.MET.9000.R00	White, slightly pink homogeneous fatty liquid emulsion.	Conforms

This document was electronically approved by:

Ginette Garon, Chem. PF Reviewing & Investigation Spc.

Date: 25-05-2022



### **QC** Microbiology Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: **052010** <u>EFFECTIVE DATE</u>: **08-04-2022** 

GALDERMA LOT NUMBER: 367181 LIMS LOT NUMBER: B-20220517-00115

SAMPLE: S-220520-00337 Composite

Test	Method	Limits	Results
Microbial Examination of Non Sterile products: Harmonized method EP and USP	1.BD.05.MET.8015.R05		
Total Aerobic Microbial Count Section 9.1 Parameter A		Not more than 10^2 CFU/g	Conforms CFU/g
Total Combined Yeasts and Molds Count Section 9.2 Parameter A		Not more than 10^1 CFU/g	Conforms CFU/g
Absence of S.aureus and P. aeruginosa Section 9.3 and 9.4 Parameter B		Absence of S. aureus and P.aeruginosa / g	Conforms
Bile Tolerant Gram Negative Bacteria Qualitative Section 9.5 Parameter A		Absence of Bile Tolerant Gram Negative Bacteria, includes E.coli, Total and Fecal coliforms / g	Conforms
Microbial Examination of Non Sterile products: Harmonized method EP and USP	1.BD.05.AUD.6023.R00		
Absence of C. albicans		Absence of C.albicans / g	Conforms



### **QC** Microbiology Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

GALDERMA LOT NUMBER: 367181 LIMS LOT NUMBER: B-20220517-00115

SAMPLE: S-220520-00337 Composite

Test Method Limits Results

**COMMENTS:** Based on Risk Analysis: 2.BD.05.AUD.6022

This document was electronically approved by:

Suzie Robert, QC Microbiology Specialist

Date: 20-05-2022



### **Quality Assurance Department**

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: 052010 <u>EFFECTIVE DATE</u>: 08-04-2022

GALDERMA LOT NUMBER: 367181 LIMS LOT NUMBER: B-20220517-00115

**SAMPLE:** S-220520-00340 Analyse

Test	Method	Limits	Results
Number of containers sampled	2.BD.05.SOP.5405	For information only	4
Inspection by attributs and final packaging	2.BD.05.SOP.5337 / PMO en vigueur	Conforms	Conforms

This document was electronically approved by:

Christiane Bédard, Quality Assurance Analyst

Date: 25-05-2022