# GALDERMA

EST. 1981

### CERTIFICATE OF COMPLIANCE

This document certifies that G Production Inc. approves the following lot of product.					
Product Description:	EXCIPIAL	. LIPOLOTIOI	N NEUTRE 200ML 1	8 FR	
Product Code:	052010		PIC Number:	N/Ap	
Lot Number:	348423		FIL Number:	0806	
Expiration Date:	11/2023				
Quantity released:	7092	units			
Manufacturing date: Comments: N/Ap		-Jun-14			
2, Part C of the F Practices Part 210 Production Inc. Sta All current procedu quality inspections documentation has	ood and and 211, indard Operation of the control of	Drug Regula Title 21, of the erating Processing seen followers net specificativiewed for contractive	ations of Health C he FDA Code of F edures, Master Pro ed, all incoming ma ations, all testing ompleteness and	Canada and on Curederal Regulations oduction and Contraction and Contraction and Contraction have been end accuracy and any	approved based on Division urrent Good Manufacturing and with accordance to Good Documents.  Evaluated and approved, all pleted and approved, all discrepancies / deviations by G Production Inc. Quality
Assurance. The fol	lowing dod	cuments are	attached to this fo	rm and sent to Ga	lderma Affiliate only.
Certificate of analys	sis 🔽				
Non-Conformity	✓	Yes (Sumr No	mary Attached)		
Certified by : Sign	ature, date	- Quality Assu	urance		





## **QC** Chemistry Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: 052010 <u>EFFECTIVE DATE</u>: 17-08-2020

GALDERMA LOT NUMBER: 348423 LIMS LOT NUMBER: B-20210630-00050

**SAMPLE: S-210630-00458 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:

Bouchra Rissafi, QC Chemistry Analyst

Date: 01-07-2021



## FINISHED PRODUCT CERTIFICATE OF ANALYSIS

## **QC** Microbiology Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: 052010 <u>EFFECTIVE DATE</u>: 17-08-2020

<u>GALDERMA LOT NUMBER</u>: 348423 <u>LIMS LOT NUMBER</u>: **B-20210630-00050** 

**SAMPLE: S-210630-00457** 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	< 10 CFU/g
Total Combined Yeasts and Molds Count Section 9.2 Parameter A		Not more than 10^1 CFU/g	< 10 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	Absent
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	Absent
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: 348423 LIMS LOT NUMBER: B-20210630-00050

SAMPLE: S-210630-00457 Composite

Test Method Limits Results

This document was electronically approved by:

Suzie Robert, QC Microbiology Specialist

Date: 06-07-2021





## **Quality Assurance Department**

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: 052010 <u>EFFECTIVE DATE</u>: 17-08-2020

GALDERMA LOT NUMBER: 348423 LIMS LOT NUMBER: B-20210630-00050

**SAMPLE: S-210630-00460 Analyse** 

Test	Method	Limits	Results
Number of containers sampled	2.BD.05.SOP.5405	For information only	6
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: 01-07-2021