



This document certifies that G Production Inc. approves the following lot of product. Product Description: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR **Product Code:** 052010 PIC Number: N/Ap Lot Number: 328314 **Expiration Date:** 11/2022 Quantity released: 7560 units Manufacturing date: 06-May-20 N/Ap Comments: The product specified above has been manufactured, packaged, tested and approved based on Division 2. Part C of the Food and Drug Regulations of Health Canada and on Current Good Manufacturing Practices Part 210 and 211, Title 21, of the FDA Code of Federal Regulations and with accordance to G Production Inc. Standard Operating Procedures, Master Production and Control Documents. All current procedures have been followed, all incoming material have been evaluated and approved, all quality inspections have met specifications, all testing has been completed and approved, all documentation has been reviewed for completeness and accuracy and any discrepancies / deviations which occurred have been properly investigated, documented and approved by G Production Inc. Quality Assurance. The following documents are attached to this form and sent to Galderma Affiliate only. Certificate of analysis Non-Conformity Yes (Summary Attached) Certified by: Signature, date - Quality Assurance





# **QC** Chemistry Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: 052010 <u>EFFECTIVE DATE</u>: 15-10-2019

GALDERMA LOT NUMBER: 328314 LIMS LOT NUMBER: B-20200511-00018

**SAMPLE:** S-200511-00427 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:

Sabrina Marmouz, QC Chemistry Analyst

Date: 14-05-2020



# **QC** Microbiology Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: 052010 <u>EFFECTIVE DATE</u>: 15-10-2019

GALDERMA LOT NUMBER: 328314 LIMS LOT NUMBER: B-20200511-00018

**SAMPLE: S-200511-00426 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: 328314 LIMS LOT NUMBER: B-20200511-00018

SAMPLE: S-200511-00426 Composite

Test Method Limits Results

This document was electronically approved by:

Suzie Robert, QC Microbiology Specialist

Date: 20-05-2020



# **Quality Assurance Department**

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: 052010 <u>EFFECTIVE DATE</u>: 15-10-2019

GALDERMA LOT NUMBER: 328314 LIMS LOT NUMBER: B-20200511-00018

**SAMPLE:** S-200511-00429 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: 13-05-2020