

GALDERMA

EST. 1981

CERTIFICATE OF COMPLIANCE

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: 403521 FIL Number: 806
Expiration Date: 10/2026
Quantity released: 15120 units
Manufacturing date: 21/May/24
Comments: N/Ap

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 and all testing has been completed and approved. The net weight results are in conformance with local regulations and administrations of their respective countries. 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)
 No

Certified by : _____
Signature, date - Quality Assurance

**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS**

GALDERMA
EST. 1981

QC Chemistry Department

ITEM DESCRIPTION : **EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR**

ITEM NUMBER : **052010**

EFFECTIVE DATE : **08-04-2022**

GALDERMA LOT NUMBER : **403521**

LIMS LOT NUMBER : **B-20240524-00002**

SAMPLE : **S-240524-00009 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 :

François Perreault, Chemist, Quality Control Manager

Date : 24-05-2024

**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS**

GALDERMA
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QC Microbiology Department

ITEM DESCRIPTION : EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

ITEM NUMBER : 052010

EFFECTIVE DATE : 08-04-2022

GALDERMA LOT NUMBER : 403521

LIMS LOT NUMBER : B-20240524-00002

SAMPLE : S-240524-00008 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

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QC Microbiology Department

ITEM DESCRIPTION : **EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR**

GALDERMA LOT NUMBER : **403521**

LIMS LOT NUMBER : **B-20240524-00002**

SAMPLE : **S-240524-00008 Composite**

Test	Method	Limits	Results
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COMMENTS : Based on Risk Analysis : 2.BD.05.AUD.6022

This document was electronically approved by :

Chantal Crevier, QC Microbiology Analyst

Date : 27-05-2024

**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS**

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Quality Assurance Department

ITEM DESCRIPTION : **EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR**

ITEM NUMBER : **052010**

EFFECTIVE DATE : **08-04-2022**

GALDERMA LOT NUMBER : **403521**

LIMS LOT NUMBER : **B-20240524-00002**

SAMPLE : **S-240524-00011 Analyse**

Test	Method	Limits	Results
Number of containers sampled	2.BD.05.SOP.5405	For information only	3
Inspection by attributs and final packaging	2.BD.05.SOP.5337 / PMO en vigueur	Conforms	Conforms

This document was electronically approved by :

Lydia Bessai, Quality Assurance Analyst

Date : 27-05-2024