GALDERMA

EST. 1981

CERTIFICATE OF COMPLIANCE

This document certifies that G Production Inc. approves the following lot of product.

Product Description:	EXCIPIAL LIPOLOTION NEUTRE 400ML 12 FR		
Product Code:	052011	PIC Number:	N/Ap
Lot Number:	380017	FIL Number:	0806
Expiration Date:	06/2025		
Quantity released:	7404 units		

Manufacturing date: 16-Jan-23

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, 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)
☑ No

Certified by : Christiane Bédard Signature numérique de Christiane Bédard
Date : 2023.01.20 10:23:07 -05'00'
Signature, date - Quality Assurance

19400 Transcanadienne, Baie d'Urfé, (Québec), H9X 3S4, CANADA Phone : (514) 457-3366

0806

FINISHED PRODUCT
CERTIFICATE OF ANALYSIS

GALDERMA
EST. 1981

QC Chemistry Department

ITEM DESCRIPTION : **EXCIPIAL LIPOLOTION NEUTRE 400ML 12 FR**

ITEM NUMBER : **052011**

EFFECTIVE DATE : **11-04-2022**

GALDERMA LOT NUMBER : **380017**

LIMS LOT NUMBER : **B-20230119-00008**

SAMPLE : **S-230119-00486 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 : 19-01-2023

FINISHED PRODUCT
CERTIFICATE OF ANALYSIS

GALDERMA
EST. 1981

QC Microbiology Department

ITEM DESCRIPTION : **EXCIPIAL LIPOLOTION NEUTRE 400ML 12 FR**

ITEM NUMBER : **052011**

EFFECTIVE DATE : **11-04-2022**

GALDERMA LOT NUMBER : **380017**

LIMS LOT NUMBER : **B-20230119-00008**

SAMPLE : **S-230119-00485 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

FINISHED PRODUCT
CERTIFICATE OF ANALYSIS

GALDERMA
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QC Microbiology Department

ITEM DESCRIPTION : **EXCIPIAL LIPOLOTION NEUTRE 400ML 12 FR**

GALDERMA LOT NUMBER : **380017** LIMS LOT NUMBER : **B-20230119-00008**

SAMPLE : **S-230119-00485 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 : 19-01-2023

FINISHED PRODUCT
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GALDERMA
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Quality Assurance Department

ITEM DESCRIPTION : **EXCIPIAL LIPOLOTION NEUTRE 400ML 12 FR**

ITEM NUMBER : **052011**

EFFECTIVE DATE : **11-04-2022**

GALDERMA LOT NUMBER : **380017**

LIMS LOT NUMBER : **B-20230119-00008**

SAMPLE : **S-230119-00488 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 :

Christiane Bédard, Quality Assurance Analyst

Date : 20-01-2023