

# GALDERMA

EST. 1981

## CERTIFICATE OF COMPLIANCE

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

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Product Description:	EXCIPIAL LIPOLOTION NEUTRE 400ML 12 FR		
Product Code:	052011	PIC Number:	N/Ap
Lot Number:	408957	FIL Number:	806
Expiration Date:	02/2027		
Quantity released:	7440	units	
Manufacturing date:	09/Sep/24		
Comments:	N/Ap		

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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

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**FINISHED PRODUCT  
CERTIFICATE OF ANALYSIS**

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**GALDERMA**  
EST. 1981

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**QC Chemistry Department**

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

ITEM NUMBER : **052011**

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

GALDERMA LOT NUMBER : **408957**

LIMS LOT NUMBER : **B-20240913-00006**

SAMPLE : **S-240913-00060 Begin**

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

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This document was electronically approved by :

Ginette Garon, Chem. PF Reviewing & Investigation Spc.

Date : 13-09-2024

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**FINISHED PRODUCT  
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**GALDERMA**  
EST. 1981

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**QC Microbiology Department**

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

**ITEM NUMBER :** 052011

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

**GALDERMA LOT NUMBER :** 408957

**LIMS LOT NUMBER :** B-20240913-00006

**SAMPLE :** S-240913-00059 Composite

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Test	Method	Limits	Results
<b>Microbial Examination of Non Sterile products: Harmonized method EP and USP</b>	1.BD.05.MET.8015.R05		
Total Aerobic Microbial Count Section 9.1 Parameter A		Not more than 10 <sup>2</sup> CFU/g	Conforms CFU/g
Total Combined Yeasts and Molds Count Section 9.2 Parameter A		Not more than 10 <sup>1</sup> 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
<b>Microbial Examination of Non Sterile products: Harmonized method EP and USP</b>	1.BD.05.AUD.6023.R00		
Absence of C. albicans		Absence of C.albicans / g	Conforms

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**QC Microbiology Department**

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

GALDERMA LOT NUMBER : **408957**

LIMS LOT NUMBER : **B-20240913-00006**

SAMPLE : **S-240913-00059 Composite**

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

This document was electronically approved by :

Suzie Robert, QC Microbiology Specialist

Date : 13-09-2024

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**Quality Assurance Department**

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

ITEM NUMBER : **052011**

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

GALDERMA LOT NUMBER : **408957**

LIMS LOT NUMBER : **B-20240913-00006**

SAMPLE : **S-240913-00062 Analyse**

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

This document was electronically approved by :

Lydia Bessai, Quality Assurance Analyst

Date : 13-09-2024