

# 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 200ML 18 FR  
Product Code: 052010 PIC Number: N/Ap  
Lot Number: 346459 FIL Number: 0975  
Expiration Date: 10/2023  
Quantity released: 8 046 units

Manufacturing date: 02-May-21

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, 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 : \_\_\_\_\_  
Signature, date - Quality Assurance

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**FINISHED PRODUCT  
CERTIFICATE OF ANALYSIS**

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**QC Chemistry Department**

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

ITEM NUMBER : **052010**

EFFECTIVE DATE : **17-08-2020**

GALDERMA LOT NUMBER : **346459**

LIMS LOT NUMBER : **B-20210506-00001**

SAMPLE : **S-210506-00035 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 :

Bouchra Rissafi, QC Chemistry Analyst

Date : 07-05-2021

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**FINISHED PRODUCT  
CERTIFICATE OF ANALYSIS**

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**QC Microbiology Department**

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

**ITEM NUMBER :** 052010

**EFFECTIVE DATE :** 17-08-2020

**GALDERMA LOT NUMBER :** 346459

**LIMS LOT NUMBER :** B-20210506-00001

**SAMPLE :** S-210506-00034 Composite

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	< 10 CFU/g
Total Combined Yeasts and Molds Count Section 9.2 Parameter A		Not more than 10 <sup>1</sup> 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
<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 200ML 18 FR**

GALDERMA LOT NUMBER : **346459**

LIMS LOT NUMBER : **B-20210506-00001**

SAMPLE : **S-210506-00034 Composite**

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<b>Test</b>	<b>Method</b>	<b>Limits</b>	<b>Results</b>
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This document was electronically approved by :

Suzie Robert, QC Microbiology Specialist

Date : 11-05-2021

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**FINISHED PRODUCT  
CERTIFICATE OF ANALYSIS**

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**Quality Assurance Department**

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ITEM DESCRIPTION : EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

ITEM NUMBER : 052010

EFFECTIVE DATE : 17-08-2020

GALDERMA LOT NUMBER : 346459

LIMS LOT NUMBER : B-20210506-00001

SAMPLE : S-210506-00037 Analyse

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Test	Method	Limits	Results
Number of containers sampled	2.BD.05.SOP.5405	For information only	6
Inspection by attributes and final packaging	2.BD.05.SOP.5337 / PMO en vigueur	Conforms	Conforms

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This document was electronically approved by :

Christiane Bédard, Quality Assurance Analyst

Date : 07-05-2021