



CERTIFICATE OF COMPLIANCE



GALDERMA

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


Product Description: EXCIPIAL LIPOLOTION NEUTRE 400ML 6 FR  
Product Code: 052011 PIC Number: 0  
Lot Number: 303063  
Expiration Date: 06/2021  
Quantity released: 3 846 units  
Manufacturing date: 12-Dec-18  
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 :

 02-01-2019  
Signature, date - Quality Assurance





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**FINISHED PRODUCT  
CERTIFICATE OF ANALYSIS**

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 GALDERMA

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**QC Chemistry Department**

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ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 400ML 6 FR

ITEM NUMBER: 052011

EFFECTIVE DATE: 20-07-2018

GALDERMA LOT NUMBER: 303063

LIMS LOT NUMBER: B-20181218-00012

SAMPLE: S-181218-00340 Begin

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

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This document was electronically approved by :

Pierre-Luc Reid, QC Chemistry Supervisor

Date : 19-12-2018

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**FINISHED PRODUCT  
CERTIFICATE OF ANALYSIS**

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 GALDERMA

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**QC Chemistry Department**

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ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 400ML 6 FR

ITEM NUMBER: 052011

EFFECTIVE DATE: 20-07-2018

GALDERMA LOT NUMBER: 303063

LIMS LOT NUMBER: B-20181218-00012

SAMPLE: S-181218-00341 End

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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 :

Pierre-Luc Reid, QC Chemistry Supervisor

Date : 19-12-2018

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**FINISHED PRODUCT  
CERTIFICATE OF ANALYSIS**

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 GALDERMA

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**QC Microbiology Department**

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**ITEM DESCRIPTION:** EXCIPIAL LIPOLOTION NEUTRE 400ML 6 FR

**ITEM NUMBER:** 052011

**EFFECTIVE DATE:** 20-07-2018

**GALDERMA LOT NUMBER:** 303063

**LIMS LOT NUMBER:** B-20181218-00012

**SAMPLE:** S-181218-00339 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	< 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 400ML 6 FR

GALDERMA LOT NUMBER: 303063

LIMS LOT NUMBER: B-20181218-00012

SAMPLE: S-181218-00339 Composite

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Test	Method	Limits	Results
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This document was electronically approved by :  
Louise Pineault, QC Supervisor - Microbiology & STC  
Date : 02-01-2019

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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 400ML 6 FR

**ITEM NUMBER:** 052011

**EFFECTIVE DATE:** 20-07-2018

**GALDERMA LOT NUMBER:** 303063

**LIMS LOT NUMBER:** B-20181218-00012

**SAMPLE:** S-181218-00343 Analyse

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Test	Method	Limits	Results
<b>Number of containers sampled</b>	2.BD.05.SOP.5405	For information only	8
<b>Inspection by attributs and final packaging</b>	2.BD.05.SOP.5337 / PMO en vigueur	Conforms	Conforms

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This document was electronically approved by :

Sylvie Ducasse, Quality Assurance Analyst

Date : 19-12-2018

