

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: 0
Lot Number: 170612
Expiration Date: 01/2021
Quantity released: 2 448 units
Manufacturing date: 12-Jul-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 :  12-09-2018
Signature, date - Quality Assurance

**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS**

 GALDERMA

QC Chemistry Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

ITEM NUMBER: 052010

EFFECTIVE DATE: 20-07-2018

GALDERMA LOT NUMBER: 170612

LIMS LOT NUMBER: B-20180906-00009

SAMPLE: S-180906-00069 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 :

Sabrina Marmouz, QC Chemistry Analyst

Date : 10-09-2018

**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS**



QC Chemistry Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

ITEM NUMBER: 052010

EFFECTIVE DATE: 20-07-2018

GALDERMA LOT NUMBER: 170612

LIMS LOT NUMBER: B-20180906-00009

SAMPLE: S-180906-00070 End

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

This document was electronically approved by :

Sabrina Marmouz, QC Chemistry Analyst

Date : 10-09-2018

**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS**

 GALDERMA

QC Microbiology Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

ITEM NUMBER: 052010

EFFECTIVE DATE: 20-07-2018

GALDERMA LOT NUMBER: 170612

LIMS LOT NUMBER: B-20180906-00009

SAMPLE: S-180906-00068 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	< 10 CFU/g
Total Combined Yeasts and Molds Count Section 9.2 Parameter A		Not more than 10 ¹ 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
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

QC Microbiology Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

GALDERMA LOT NUMBER: 170612

LIMS LOT NUMBER: B-20180906-00009

SAMPLE: S-180906-00068 Composite

Test	Method	Limits	Results
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This document was electronically approved by :

Suzie Robert, QC Microbiology Specialist

Date : 11-09-2018

**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS**

 GALDERMA

Quality Assurance Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

ITEM NUMBER: 052010

EFFECTIVE DATE: 20-07-2018

GALDERMA LOT NUMBER: 170612

LIMS LOT NUMBER: B-20180906-00009

SAMPLE: S-180906-00072 Analyse

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

This document was electronically approved by :

Sylvie Ducasse, Quality Assurance Analyst

Date : 07-09-2018

