



CERTIFICATE OF COMPLIANCE



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: 315822
Expiration Date: 02/2022
Quantity released: 4 002 units

Manufacturing date: 19-Aug-19
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 : *Montréal 13/09/19*
Signature, date - Quality Assurance





**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS**



QC Chemistry Department

ITEM DESCRIPTION : EXCIPIAL LIPOLOTION NEUTRE 400ML 6 FR

ITEM NUMBER : 052011

EFFECTIVE DATE : 12-09-2019

GALDERMA LOT NUMBER : 315822

LIMS LOT NUMBER : B-20190906-00005

SAMPLE : S-190906-00037 Begin

| 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 : 09-09-2019

**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS**

 GALDERMA

QC Microbiology Department

ITEM DESCRIPTION : EXCIPIAL LIPOLOTION NEUTRE 400ML 6 FR

ITEM NUMBER : 052011

EFFECTIVE DATE : 12-09-2019

GALDERMA LOT NUMBER : 315822

LIMS LOT NUMBER : B-20190906-00005

SAMPLE : S-190906-00036 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**



QC Microbiology Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 400ML 6 FR

GALDERMA LOT NUMBER: 315822

LIMS LOT NUMBER: B-20190906-00005

SAMPLE: S-190906-00036 Composite

| Test | Method | Limits | Results |
|------|--------|--------|---------|
|------|--------|--------|---------|

This document was electronically approved by :

Chantal Crevier, QC Microbiology Analyst

Date : 12-09-2019

**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS**

 GALDERMA

Quality Assurance Department

ITEM DESCRIPTION : EXCIPIAL LIPOLOTION NEUTRE 400ML 6 FR

ITEM NUMBER : 052011

EFFECTIVE DATE : 12-09-2019

GALDERMA LOT NUMBER : 315822

LIMS LOT NUMBER : B-20190906-00005

SAMPLE : S-190906-00039 Analyse

| 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 |

This document was electronically approved by :

Lydia Bessai, Quality Assurance Analyst

Date : 06-09-2019