GALDERMA

EST. 1981

CERTIFICATE OF COMPLIANCE

| This document certifies that G Production Inc. approves the following lot of product. | | | | | | |
|--|--------------------------|---------------------------------|-----------------------------------|---|---|--|
| Product Description: | EXCIPIAL | . LIPOLOTION | NEUTRE 400ML 12 | 2 FR | | |
| Product Code: | 052011 | | PIC Number: | N/Ap | | |
| Lot Number: | 349021 | | FIL Number: | 0975 | | |
| Expiration Date: | 11/2023 | | | | | |
| Quantity released: | 3 624 | units | | | | |
| Manufacturing date: Comments: N/Ap | | -Jun-21 | | | | |
| 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 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 | | | | | | |
| documentation has which occurred have | s been rev ve been pr | viewed for co operly investi | mpleteness and a gated, documente | has been completed accuracy and any discreped and approved by G Prom and sent to Galderma | pancies / deviations oduction Inc. Quality | |
| Certificate of analys | sis 🗸 | | | | | |
| Non-Conformity | ✓ | Yes (Summ | ary Attached) | | | |
| Certified by : Sign | ature, date | - Quality Assu | rance | | | |





QC Chemistry Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 400ML 12 FR

<u>ITEM NUMBER</u>: 052011 <u>EFFECTIVE DATE</u>: 17-08-2020

GALDERMA LOT NUMBER: 349021 LIMS LOT NUMBER: B-20210623-00005

SAMPLE: S-210623-00036 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:

Bouchra Rissafi, QC Chemistry Analyst

Date: 23-06-2021



FINISHED PRODUCT CERTIFICATE OF ANALYSIS

QC Microbiology Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 400ML 12 FR

<u>ITEM NUMBER</u>: 052011 <u>EFFECTIVE DATE</u>: 17-08-2020

<u>GALDERMA LOT NUMBER</u>: **349021** <u>LIMS LOT NUMBER</u>: **B-20210623-00005**

SAMPLE: S-210623-00035 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 |





QC Microbiology Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 400ML 12 FR

GALDERMA LOT NUMBER: 349021 LIMS LOT NUMBER: B-20210623-00005

SAMPLE: S-210623-00035 Composite

Test Method Limits Results

This document was electronically approved by:

Suzie Robert, QC Microbiology Specialist

Date: 28-06-2021





Quality Assurance Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 400ML 12 FR

<u>ITEM NUMBER</u>: 052011 <u>EFFECTIVE DATE</u>: 17-08-2020

GALDERMA LOT NUMBER: 349021 LIMS LOT NUMBER: B-20210623-00005

SAMPLE: S-210623-00038 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:

Christiane Bédard, Quality Assurance Analyst

Date: 25-06-2021