

Product Description: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR



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

Product Code:	052010	PIC Number:	N/Ap	
Lot Number:	321964			
Expiry Period:	30 months			
Quantity released:	7452 units			
Manufacturing date:	12-Dec-19			
Comments: N/Ap				
2, Part C of the Formattices Part 210 a Production Inc. Star All current procedur quality inspections documentation has which occurred have	ood and Drug R and 211, Title 21 ndard Operating res have been fo have met spe been reviewed e been properly i	egulations of Health (, of the FDA Code of F Procedures, Master Pr llowed, all incoming m ecifications, all testing for completeness and nvestigated, document	caged, tested and approcanada and on Current Federal Regulations and oduction and Control Dotaterial have been evaluated has been completed accuracy and any discountied and approved by G I form and sent to Galdern	t Good Manufacturing with accordance to Gocuments. ated and approved, all d and approved, all repancies / deviations Production Inc. Quality
Certificate of analys	is 🗸			
Non-Conformity	☐ Yes (S	Summary Attached)		
Certified by : Signa	iture, date - Quality	/ Assurance		





QC Chemistry Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: 052010 <u>EFFECTIVE DATE</u>: 15-10-2019

GALDERMA LOT NUMBER: 321964 LIMS LOT NUMBER: B-20191219-00025

SAMPLE: S-191219-00514 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: 02-01-2020



QC Microbiology Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: 052010 <u>EFFECTIVE DATE</u>: 15-10-2019

GALDERMA LOT NUMBER: 321964 LIMS LOT NUMBER: B-20191219-00025

SAMPLE: S-191219-00513 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

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GALDERMA LOT NUMBER: 321964 LIMS LOT NUMBER: B-20191219-00025

SAMPLE: S-191219-00513 Composite

Test Method Limits Results

This document was electronically approved by:

Suzie Robert, QC Microbiology Specialist

Date: 06-01-2020

Quality Assurance Department

ITEM DESCRIPTION: EXCIPIAL LIPOLOTION NEUTRE 200ML 18 FR

<u>ITEM NUMBER</u>: 052010 <u>EFFECTIVE DATE</u>: 15-10-2019

GALDERMA LOT NUMBER: 321964 LIMS LOT NUMBER: B-20191219-00025

SAMPLE: S-191219-00516 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: 19-12-2019