

CERTIFICATE OF ANALYSIS

GALDERMA

Excipial Lipocrème (F)

ITEM NUMBER : 385701

MATERIAL TYPE : Finished Product

BATCH NUMBER : V051

BULK BATCH NUMBER : V051

SIZE : aluminium membrane tube 50 g

FORMULA NUMBER : 352600

LIMS BATCH : B-20170706-00013

BULK LIMS BATCH : B-20170510-00025

Test	Method	Requirements	Results
aspect			
form		semisolid emulsion	semisolid emulsion
color		white	white
other properties		smooth, supple	smooth, supple
odor		characteristic (perfumed)	characteristic
structure		no crystals visible; shiny structures max. 50 µm visible	corresponds
microbial quality (ISO 17516)			
total viable aerobic count		max. 200 CFU/g	< 100 CFU/g
staphylococcus aureus		absent in 1 g	absent in 1 g
pseudomonas aeruginosa		absent in 1 g	absent in 1 g
candida albicans		absent in 1 g	absent in 1 g
total coliforms and fecal coliforms (incl. e.coli and salmonella)		absent in 1 g	absent in 1 g

COMMENTS :

N/Ap

MFD : 05. Mai 2017

EXP : 05-2020

This document was electronically approved by :
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Date : 16/May/2017

Jutta ANTKOWIAK, Expert QC Lab Microbiology

Date : 06/Jul/2017

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Date : 10/Jul/2017

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CERTIFICATE OF ANALYSIS

GALDERMA

Excipial Pommade (F)

ITEM NUMBER : 385801

SIZE : aluminium membrane tube 50 g

MATERIAL TYPE : Finished Product

FORMULA NUMBER : 112200

BATCH NUMBER : V031

LIMS BATCH : B-20170629-00044

BULK BATCH NUMBER : V031

BULK LIMS BATCH : B-20170531-00051

Test	Method	Requirements	Results
aspect			
form		ointment	ointment
color		slightly yellow; white	slightly yellow
other properties		greasy, opaque	greasy, opaque
odor			
		characteristic	characteristic
structure			
crystals		without crystals	corresponds
agglomerates		without agglomerates	corresponds
microbial quality			
total aerobic microbial count		max. 100 CFU/g	< 10 CFU/g
total combined yeasts/moulds count		max. 10 CFU/g	< 10 CFU/g
staphylococcus aureus		absent	absent
pseudomonas aeruginosa		absent	absent
spreadability		8 - 16 mm	11 mm

COMMENTS :

N/Ap

This document was electronically approved by :
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Date : 20/Jun/2017

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Date : 04/Jul/2017

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