

Spirig Pharma Ltd., CH-4622 Egerkingen, Switzerland
Quality Control

Certificate of Analysis

Excipial Lipolotion neutre (F)

PE bottle 400 ml

Article 385302

Lot M045
Batch size 2'202 kg
Order number 12353/5
Date of manufacture 17.08.2012
Expiry date 02-2015
Analytical method 827-002
Preservative Chlorhexidine hydrochloride WE 00040522
Preservative Triclosan WE 00039575
Bulk-Release 24.08.2012 14:24

test	unit	requirement	result
form		liquid emulsion	liquid emulsion
color		slightly pink, white	white
other properties		homogeneous, fatty	homogeneous, fatty
odor		faint characteristic	faint characteristic
crystals		corresponds	corresponds
density 20°C	kg/m ³	955 - 975	964
identity chlorhexidine hydrochloride (color reaction or HPLC)		corresponds (HPLC), corresponds (color)	corresponds (color)
identity triclosan (TLC or HPLC)		corresponds (HPLC), corresponds (TLC)	corresponds (TLC)

meets specification

finished product approved: 07.09.2012 14:18

Cornelia Baltuschus
Deputy Lab Manager Bulk Materials
Spirig Pharma Ltd.

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test	unit	requirement	result
total aerobic microbial count	CFU/g	max. 100	< 10
total combined yeasts/moulds count	CFU/g	max. 10	< 10
staphylococcus aureus		absent	absent
pseudomonas aeruginosa		absent	absent

meets specification

approved: 13.09.2012 09:39
Sandra von Ah
Lab Manager Microbiology
Spirig Pharma Ltd.

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