



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

Certificate of Analysis

Lipoderm Lotio (Formel 2006)

Article 375400

Lot F011
Batch size 2'179 kg
Order number 8192/1
Date of manufacture 03.01.2008
Expiry date JUL 2010
Analytical method 827-001
Preservative Chlorhexidine hydrochloride WE 00024715
Preservative Triclosan WE 00024491
Release 15.01.2008

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/m3	955 - 975	962
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

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test	unit	requirement	result
total viable aerobic count	CFU/g	max. 100	< 10
enterobacteria and certain other gram-negative bacteria	CFU/g	max. 10	< 1
pseudomonas aeruginosa		absent	absent
staphylococcus aureus		absent	absent

Comments

test

comments

Excipial Lipolotion neutre, PE bottle 200 ml

meets specification

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