

Certificate of Analysis

Page 1 of 2
Printed on 09.03.2021 at 14:42

Material : 906102003200 Fitalite 500g BE
Customer : Fagron Belgium NV
Customer ref.number : 9715605
Batch number : 20009544
Bulk batch number : 20009544
Expiration date : 30-SEP-2023

Parameter	Specification	Result	Method
Appearance	Semi-viscous gel cream	Conform	ANALAB012
Colour	Off-white to light yellow	Conform	ANALAB012
Odour	Specific, not perfumed	Conform	ANALAB012
Agglomerates	Absent	Conform	ANALAB013
Density	0,99 - 1,02 g/ml	0,99 g/ml	APPLAB004
Viscosity	75000 - 200000 mPa.s	105200 mPa.s	APPLAB006
pH	3,5 - 5,5	4,9	APPLAB034
Sorbic acid identity	Conform standard	Conform	ANALAB027
Sorbic acid content	0,070 - 0,140 %	0,105 %	ANALAB027
Benzoic acid content	0,130 - 0,260 %	0,201 %	ANALAB027
Benzoic acid identity	Conform standard	Conform	ANALAB027
Primary packaging	White plastic jar # Ref.nr. - 4306	Conform	ANALAB014
Closure	Red plastic top with guarantee closure 4370	Conform	ANALAB014
Label	Label with print Artikelnr Fagron: 9715605	Conform	ANALAB014
Primary packaging weight	500 g	Conform	ANALAB014
Code	Batchnumber/BI number, expirydate and manufacturing date conform batchdoc on label	Conform	ANALAB014
Total Aerobic Microbial Count	<= 100 CFU/G	< 10 CFU/G	EXTLAB001
Total Yeast and Mould Count	<= 10 CFU/G	< 10 CFU/G	EXTLAB001
S. aureus	Absent	Conform	EXTLAB001
P. aeruginosa	Absent	Conform	EXTLAB001

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Expiration date : 30-SEP-2023

Parameter	Specification	Result	Method
Manufacturing date bulk		20200929	ALGLAB000
Inspection date		20201015	ALGLAB000
External analysis by Bactimm	Present, conform and copy added Digital copy send to HSC	Conform	ALGLAB999
External analysis by Quercus	Present, conform and copy added Digital copy send to HSC	Conform	ALGLAB999
Appearance	Semi-viscous gel cream	Conform	EXTLAB006
Colour	Off-white to light yellow	Conform	EXTLAB006
Odour	Specific, not perfumed	Conform	EXTLAB006
Agglomerates	Absent	Conform	EXTLAB006
Density	0,99 - 1,02 g/ml	1,00 g/ml	EXTLAB006
pH	3,5 - 5,5	5,0	EXTLAB006
Viscosity	75000 - 200000 mPa.s	107600 mPa.s	EXTLAB006
Sorbic acid identity	Conform standard	Conform	EXTLAB006
Sorbic acid content	0,070 - 0,140 %	0,094 %	EXTLAB006
Benzoic acid identity	Conform standard	Conform	EXTLAB006
Benzoic acid content	0,130 - 0,260 %	0,202 %	EXTLAB006

Remark:

This product has been manufactured in accordance with the current GMP requirements. It complies with the Marketing Authorisation and with the client agreed specifications.

Released by:
 Lucienne Knol

Release date:
 09-MAR-2021

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