



**FRESENIUS  
KABI**

Fresenius Kabi Norge AS  
Svinesundsveien 80  
NO-1753 Halden, Norway

## CERTIFICATE OF ANALYSIS (CoA)

Batch No	Batch size	Use of batch	Date of manufacture	Date of analysis	Expiry date
12LHS01	41 400 L	For sale	2017-08-01	2017-08	2020-08

Product description

### Sterilised Water for Irrigation, 1000 mL

Test/Parameter	Unit	Specifications	Results
Appearance		Clear and colourless solution	Conforms
Acidity or alkalinity		To conform	Conforms
Conductivity	µS/cm	≤ 5.0	1.3
Oxidizable substances		To conform	Conforms
Chlorides		To conform	Conforms
Nitrates	ppm	≤ 0.2	< 0.2
Sulphates		To conform	Conforms
Ammonium	ppm	≤ 0.2	< 0.2
Calcium and magnesium		To conform	Conforms
Residue on evaporation	mg	≤ 3 (0.003 %)	< 3
<u>Sub-visible particles</u>			
particles ≥ 10 µm	/mL	≤ 25	0
particles ≥ 25 µm	/mL	≤ 3	0
Visible particles		Free from visible particles	Conforms
Bacterial endotoxins	EU/mL	< 0.25	< 0.03
Sterility assurance		To pass (parametric release)	Passes

Compiled by:

08. sept. 2017

Adrian Bykowski

Date

Approved by:

Authorised Person

Trond Frost 11 SEP 2017

Date