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
12LIS08	41 400 L	For sale	2017-09-12	2017-09	2020-09

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
Sub-visible particles			
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:

Lene Andersen 02 Oct. 2017

Lene Andersen — Date

Approved by:

Trond Frost 05 OCT 2017

Authorised Person — Date