

Certificate of Analysis

Client

E&O Laboratories Ltd
Burnhouse
Bonnybridge
Scotland
FK4 2HH



Sample: BM0384 - Saline (0.45%)
Batch Number: 04075566
Expiry Date: 2020-02-15
Date Received: 2018-02-16
Data Tested: 2018-02-16
Sample Condition: Satisfactory
Sample Number: 327594

Burnhouse, Bonnybridge
Scotland, FK4 2HH
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The log difference between inocula pre and post a 45 minute retention in the diluent should be ≤ 0.3 .
Accredited Test Method: See table below

Productivity	Result	Specification
Escherichia coli NCTC 12241	Conforms	≤ 0.3
Staphylococcus aureus NCTC 12981	Conforms	≤ 0.3

Physical	Result	Specifications	Accredited Test Method
Sterility	Conforms	Within acceptable limits	ED/SOP/005 Visual check and growth assessment following incubation for 3 days at 15-25°C and 37°C
Sterility sampling is performed in accordance with ISO 2859-1:1999. The inspection level is $\geq 0.4\%$ of the batch and the reject level ≤ 7 units depending on batch size.			
pH	N/A	N/A	ED/SOP/003 measurement by pH meter
Colour	Conforms	Colourless	ED/SOP/009 by visual observation. Range measured using Pantone® 4 colour process guide
Fill Quantity	Conforms	3ml +/- 0.3	ED/SOP/054 by gravimetric determination

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Accredited Test Method for Solid Media	Accredited Test Method for Liquid Media	Accredited Test Method for Diluents
ED/SOP/008 Quantitative evaluation using spread inoculum technique	ED/SOP/008 Semi quantitative inoculation with growth assessment from subculture	ED/SOP/008 Semi quantitative evaluation of viability maintenance after a holding time of 45 minutes

All of the results on this certificate of analysis relate only to the samples submitted.



Douglas Cameron
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