Certificate of Analysis

Client

E&O Laboratories Ltd
Burnhouse
Bonnybridge
Scotland
FK4 2HH

E&O Laboratories Ltd

Burnhouse, Bonnybridge
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Telephone: 01324 840404
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Sample: PP8020 - TSA - IRR (VHP)

Batch Number: 04154428

Expiry Date: 2021-10-01

Date Received: 2021-02-26

Date Tested: 2021-02-26

Sample Condition: Satisfactory

Sample Number: 397906

The RGI is a calculation of the % growth on the test media compared with the growth on a control media. The test medium must achieve an RGI between 70-120% for non-selective media / ≥ 50% for selective media.
Accredited Test Method: ED/SOP/008 Quantitative evaluation using spread inoculum technique (solid media)

Productivity	RGI (%)	Colonial Appearance	Colonial Appearance Specification
Escherchia coli ATCC 8739	96	Cream colonies	Cream colonies
Aspergillus brasiliensis ATCC 16404	71	White colonies. Reverse side is pale yellow	White colonies. Reverse side is pale yellow
Candida albicans ATCC 10231	75	White colonies	White colonies
Pseudomonas aeruginosa ATCC 9027	94	Cream colonies	Cream colonies
Bacillus subtilis ATCC 6633	92	Opaque/Grey colonies	Opaque/Grey colonies
Staphylococcus aureus ATCC 6538	92	White colonies	White colonies

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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 ≥ 0.4% of the batch and the reject level ≤ 7 units depending on batch size.			
pH	7.3	7.3 +/- 0.2	ED/SOP/003 measurement by pH meter
Colour	Conforms	2-8 - 6-8 Straw	ED/SOP/009 by visual observation. Range measured using Pantone® 4 colour process guide
Fill Quantity	Conforms	25ml	ED/SOP/054 by gravimetric determination
Moisture	Conforms	95% +/- 3%	ED/SOP/053 with drying and gravimetric determination

Growth promotion testing conducted in accordance with the requirements of the Harmonised United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP).

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

Test specifications are based on ISO 11133:2014/Amd/:2020 and internal product specifications
*Sterility sampling is outwith scope of accreditation.

UKAS TESTING 1894

Douglas Cameron
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