

## G & M Procter Ltd. Certificate of Analysis

PRODUCT PO0746B

PRO-TECT MEDIUM 90MM D FILL (x3 WR+ IRR)

1 PACK OF 10 PLATES

 LOT NUMBER
 2598088

 EXPIRY DATE
 2019.04.24

 PACKING DATE
 2019.01.15

 TEST DATE
 2019.01.23

 REPORTING DATE
 2019.01.28

Physical Characteristics	Results	Specification	Accredited Method Reference
Appearance	Straw 1-2	Straw 1-2	SOP 178 Appearance and colour
pH (25°C)	7.3	7.1 - 7.5	SOP 53 pH
Fill Volume/Weight	23.0g	22.0 - 23.5g	SOP 74 Fill volume weight check
Sterility @ 22°C & 32°C ± 2°C for 5 days	no growth	no growth	SOP 167 Contamination Check at 22°C & 32°C

#### MICROBIOLOGICAL PERFORMANCE

For target organisms the control media must achieve a colony count of 10-100 cfu. The test medium must achieve between 50%-150% of the control medium and show the colonial appearance stated in the specification.

Target Organism	Control c.f.u	Test c.f.u	Colonial Appearance	Colonial Appearance Specification	Accredited Method Reference
Staphylococcus aureus ATCC®6538	96	85	Straw cols	Straw cols	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Escherichia coli ATCC®8739	53	54	Cream cols	Cream cols	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Bacillus subtilis ATCC®6633	61	58	Irregular, straw cols	Irregular, straw cols	SOP 151 Fertility of Specified Target Organism(s)(Agar)

All of the results reported within the G & M Procter Certificate of Analysis relate only to the sample tested. The results were derived from a representative sample of the batch and were obtained at the time of release. All test specifications are defined in the G&M Procter manufacturing and test procedures for this product, which are available on request. The uncertainty of measurement introduced during pH, fill weight and microbiological performance testing has been determined. Values are not reported on the Certificate of Analysis but details can be provided on request.





The test laboratory of Thermo Fisher Scientific is accredited by UK accreditation authority UKAS as registered test laboratory 2727 according to EN ISO/IEC 17025 for the performance testing of media for microbiology.



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Target Organism	Control c.f.u	Test c.f.u	Colonial Appearance	Colonial Appearance Specification	Accredited Method Reference
Pseudomonas aeruginosa ATCC®9027	17	11	Straw colonies	Straw colonies	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Candida albicans ATCC®10231	66	67	Cream colonies	Cream colonies	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Aspergillus brasiliensis ATCC®16404	52	56	White mycelia, black spores	White mycelia, black spores	SOP 151 Fertility of Specified Target Organism(s)(Agar)

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### CERTIFICATE OF ANALYSIS

Delivery/Customer information

Date Printed 2019.01.28 Delivery No.

Customer

Customer Order number

The information given is believed to be correct. However both the information and the product are offered without warranty for any specific application other than that specified. The results reported were derived from a representative sample of the batch and were obtained at the time of release.



Ian Snowball

Quality Manager, G&M Procter Ltd

**EXTRA INFORMATION** 

#### All results within this section are reported out with the UKAS ISO 17025 Scope of Accreditation.

The product was tested in accordance with the current versions of the European Pharmacopoeia, the British Pharmacopoeia, the US Pharmacopoeia and the Japanese Pharmacopoeia. Clearly visible growth was observed within 3 days for bacteria and within 5 days for fungi

\*Due to process restrictions the packing date may be after the test date

PHYSICAL CHARACTERISTICS	Results	Specification	
Irradiation Dose	Conforms	8-20 kGy	
Irradiation Certificate No.	UK31S12224687-1-1	N/A	
Packaging and Presentation	Conforms	Conforms to specification	

Our management system is certified by BSI as being in conformity with ISO 9001:2008, certificate number FM 27644 and ISO 13485:2003, certificate number MD 85850.