

G & M Procter Ltd. Certificate of Analysis

PRODUCT PO4001B

TRIPLE WRAP STERILE TSA + NEUTRALIZERS

1BOX=10PCKS=100PLTS

 LOT NUMBER
 4499025

 EXPIRY DATE
 2026.01.14

 PACKING DATE
 2025.03.18

 TEST DATE
 2025.03.26

 REPORTING DATE
 2025.04.04

All testing in accordance with internally derived specifications, unless otherwise stated.

Physical Characteristics	Results	Specification	Accredited Method Reference
Appearance	Ivory	Ivory	SOP 178 Appearance and colour
pH (25°C)	7.3	7.1 - 7.5	SOP 53 pH
Fill Volume/Weight	30.4g	29.0 - 31.0g	SOP 74 Fill volume weight
Sterility@ 22 & 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	78	79	1-2 mm, cream, shiny colonies.	1-2 mm, cream, shiny colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Pseudomonas aeruginosa ATCC®9027	48	44	3-8 mm, green-yellow colonies.	3-8 mm, green-yellow colonies.	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. The testing laboratory is not responsible or accredited for the sampling process. 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, but not reported on the Certificate.





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Ian Snowball Quality Manager G & M Procter Ltd.



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Target Organism	Control c.f.u	Test c.f.u	Colonial Appearance	Colonial Appearance Specification	Accredited Method Reference
Kocuria rhizophila ATCC®9341	90	87	0,5-0,75 mm, yellow colonies.	0,5-0,75 mm, yellow colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Staph epidermidis ATCC®12228	64	61	1 mm, cream colonies.	1 mm, cream colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Escherichia coli ATCC®8739	90	82	2-10 mm, cream colonies.	2-10 mm, cream colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Bacillus subtilis ATCC®6633	86	80	4-8 mm, cream colonies.	4-8 mm, cream colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Candida albicans ATCC®10231	84	78	2 mm, cream colonies.	2 mm, cream colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Aspergillus brasiliensis ATCC®16404	90	83	10-30 mm, white mycelium, black spores.	10-30 mm, white mycelium, black spores.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Clostridium sporogenes ATCC®19404	88	91	1-2 mm, cream colonies.	1-2 mm, cream colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
20-25°C Incuba Bacillus subtilis ATCC®6633	tion 77	75	2-8mm irregular straw colonies	2-8mm irregular straw colonies	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Candida albicans ATCC®10231	88	76	2 mm, cream colonies.	2 mm, cream colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)

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Target Organism	Control c.f.u	Test c.f.u	Colonial Appearance	Colonial Appearance Specification	Accredited Method Reference
20-25°C Incuba Aspergillus brasiliensis ATCC®16404	tion 65	74	10-30 mm, white mycelium, black spores.	10-30 mm, white mycelium, black spores.	SOP 151 Fertility of Specified Target Organism(s)(Agar)

PHYSICAL CHARACTERISTICS	Results	Specification	
* Irradiation Dose	Conforms	14.5 - 22.0 kGy	
* Irradiation Certificate No.	Gamma Process Run	ID 2183-10686A	N/A

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