G & M Procter Ltd. Certificate of Analysis

PRODUCT

PO4001B TRIPLE WRAP STERILE TSA + NEUTRALIZERS 1BOX=10PCKS=100PLTS

LOT NUMBER	4505109
EXPIRY DATE	2026.02.25
PACKING DATE	2025.04.29
TEST DATE	2025.05.12
REPORTING DATE	2025.05.19

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)	7.4	7.1 - 7.5	SOP 53 pH
Fill Volume/Weight	30.3g	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	97	101	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	82	76	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.



Jan Snonbell

Ian Snowball Quality Manager G & M Procter Ltd.

Performance tested by the Quality Control Laboratory, G & M Procter Ltd, 4 Auld Bond Road, Perth, PH1 3FX, a UKAS accredited testing laboratory NO. 2727

G & M Procter Ltd. Certificate of Analysis

Target Organism	Control c.f.u	Test c.f.u	Colonial Appearance	Colonial Appearance Specification	Accredited Method Reference
Kocuria rhizophila ATCC®9341	62	67	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	64	1 mm, cream colonies.	1 mm, cream colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Escherichia coli ATCC®8739	99	108	2-10 mm, cream colonies.	2-10 mm, cream colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Bacillus subtilis ATCC®6633	98	98	4-8 mm, cream colonies.	4-8 mm, cream colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Candida albicans ATCC®10231	67	61	2 mm, cream colonies.	2 mm, cream colonies.	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Aspergillus brasiliensis ATCC®16404	85	82	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	69	61	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 95	91	2-8mm irregular straw colonies	2-8mm irregular straw colonies	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Candida albicans ATCC®10231	98	96	2 mm, cream colonies.	2 mm, cream 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.



Jan Snonbell

Ian Snowball Quality Manager G & M Procter Ltd.

G & M Procter Ltd. Certificate of Analysis					
Target Organism	Control c.f.u	Test c.f.u	Colonial Appearance	Colonial Appearance Specification	Accredited Method Reference
20-25°C Incubat	tion				
Aspergillus	99	94	10-30 mm, white	10-30 mm, white	SOP 151 Fertility
brasiliensis			mycelium, black	mycelium, black	of Specified Target
ATCC®16404			spores.	spores.	Organism(s)(Agar)
PHYSICAL CI	HARACTERIST	TICS		Results	Specification
* Irradiation Do	ose			Conforms	14.5 - 22.0 kGy
* Irradiation Ce	rtificate No.			Gamma Process Run I	D 2183-11394A N/A

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.



Jan Snonbell

Ian Snowball Quality Manager G & M Procter Ltd.