

G & M Procter Ltd. Certificate of Analysis

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

LOT NUMBER 4507845
EXPIRY DATE 2026.03.18
PACKING DATE 2025.05.20
TEST DATE 2025.05.30
REPORTING DATE 2025.06.05

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) | 7.2 | 7.1 - 7.5 | SOP 53 pH |
| Fill Volume/Weight | 30.1g | 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 | 79 | 81 | 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 | 72 | 79 | 3-8 mm, green-yellow colonies. | 3-8 mm, green-yellow colonies. | SOP 151 Fertility of Specified Target Organism(s)(Agar) |

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Ian Snowball

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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

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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 | 42 | 42 | 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 | 84 | 78 | 1 mm, cream colonies. | 1 mm, cream colonies. | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| Escherichia coli ATCC®8739 | 68 | 74 | 2-10 mm, cream colonies. | 2-10 mm, cream colonies. | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| Bacillus subtilis ATCC®6633 | 86 | 91 | 4-8 mm, cream colonies. | 4-8 mm, cream colonies. | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| Candida albicans ATCC®10231 | 88 | 86 | 2 mm, cream colonies. | 2 mm, cream colonies. | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| Aspergillus brasiliensis ATCC®16404 | 84 | 88 | 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 | 84 | 90 | 1-2 mm, cream colonies. | 1-2 mm, cream colonies. | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| 20-25°C Incubation Bacillus subtilis ATCC®6633 | 85 | 88 | 2-8mm irregular straw colonies | 2-8mm irregular straw colonies | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| Candida albicans ATCC®10231 | 88 | 89 | 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 Incubation Aspergillus brasiliensis ATCC®16404 | 85 | 81 | 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 2183-11765A | N/A |

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