

G & M Procter Ltd.
Certificate of Analysis

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| PRODUCT | PO0821B TRYPTONE SOYA AGAR (X3 WRP IRR DEEP FL) 1 PACK OF 10 PLATES |
| LOT NUMBER | 4528659 |
| EXPIRY DATE | 2026.02.25 |
| PACKING DATE | 2025.11.05 |
| TEST DATE | 2025.11.12 |
| REPORTING DATE | 2025.11.17 |

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

*Indicates the result provided is out-with the ISO 17025 scope of accreditation

| Physical Characteristics | Results | Specification | Accredited Method Reference |
|-------------------------------------|----------------|----------------------------------|---|
| Appearance | Straw 1 / 2 | Straw 1, straw 1/2 or straw 2 | SOP 178 |
| pH (25°C) | 7.2 | 7.1 - 7.5 | Appearance and colour SOP 53 pH |
| Fill Volume/Weight | 22.7g | 22.0 - 23.5g | SOP 74 Fill volume weight check |
| 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 70%-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 | 85 | Straw cols | Straw cols | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| Escherichia coli ATCC®8739 | 96 | 97 | Cream cols | Cream cols | SOP 151 Fertility of Specified Target Organism(s)(Agar) |

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|--------------------------------------|----|----|-----------------------------------|-----------------------------------|---|
| Bacillus subtilis ATCC®6633 30-35°C | 99 | 96 | 2-8mm irregular straw colonies | 2-8mm irregular straw colonies | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| Pseudomonas aeruginosa ATCC®9027 | 55 | 58 | Straw colonies | Straw colonies | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| Candida albicans ATCC®10231 @30-35°C | 58 | 73 | 1-2mm cream colonies | 1-2mm cream colonies | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| A. brasiliensis ATCC®16404 30-35°C | 78 | 81 | >10mm white mycelia, black spores | >10mm white mycelia, black spores | SOP 151 Fertility of Specified Target Organism(s)(Agar) |

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 |
|-------------------------------------|---------------|------------|-----------------------------------|-----------------------------------|---|
| Bacillus subtilis ATCC®6633 20-25°C | 97 | 93 | 2-8mm irregular straw colonies | 2-8mm irregular straw colonies | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| Candida albicans ATCC®10231 20-25°C | 92 | 81 | 1-2mm cream colonies | 1-2mm cream colonies | SOP 151 Fertility of Specified Target Organism(s)(Agar) |
| A. brasiliensis ATCC®16404 20-25°C | 44 | 55 | >10mm white mycelia, black spores | >10mm white mycelia, black spores | SOP 151 Fertility of Specified Target Organism(s)(Agar) |

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| PHYSICAL CHARACTERISTICS | Results | Specification |
|---------------------------------|----------------------------------|---------------------------|
| * Irradiation Dose | Conforms | 8-20 kGy |
| * Irradiation Certificate No. | Gamma Process Run ID 2183-14758A | N/A |
| Packaging and Presentation | Conforms | Conforms to specification |

EXTRA INFORMATION

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

Tested in accordance with the methods described in the current United States pharmacopoeia for the microbiological control and monitoring of aseptic processing environments.

* Due to process restrictions the packaging date may be after the test date.

CERTIFICATE OF ANALYSIS

Delivery/Customer information

Date Printed

2025.11.17

Delivery No.

Customer

Customer Order number

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.



Ian Snowball

Ian Snowball
Quality Manager
G & M Procter Ltd.

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