

G & M Procter Ltd. Certificate of Analysis

PRODUCT **BO0510M**
THIOGLYCOLLATE MEDIUM (acc. to EP/USP)
10X100ML IN 100ML DIN

LOT NUMBER 4511203
EXPIRY DATE 2026.06.19
PACKING DATE 2025.06.17
TEST DATE 2025.06.18
REPORTING DATE 2025.07.02

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

| Physical Characteristics | Results | Specification | Accredited Method Reference |
|---|-------------------------------|--|--|
| Appearance | Straw / yellow with red layer | Straw/yellow with or without red layer | SOP 183 Appearance and colour |
| pH (25°C) | 7.1 | 6.9 - 7.3 | SOP 53 pH |
| Fill Volume/Weight | 100.5g | 100.0 - 101.5g | SOP 154 Fill volume weight check |
| Sterility @ 22°C & 32°C ± 2°C for 14 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 show clearly visible growth as stated in the specification.

| Target Organism | Control(cfu) | Test | Specification | Accredited Method Reference |
|-------------------------------------|--------------|---------------|----------------------------------|--|
| Staphylococcus aureus ATCC®6538 | 68 | Turbid growth | Turbid growth or single colonies | SOP 151 Fertility of Specified Target Organism(s) (Liquid Media) |
| Pseudomonas aeruginosa ATCC®9027 | 21 | Turbid growth | Turbid growth or single colonies | SOP 151 Fertility of Specified Target Organism(s) (Liquid Media) |

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.

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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|--------------------------------|----|-------------------|-------------------------------------|---|
| Bacillus subtilis ATCC®6633 | 94 | Turbid growth | Turbid growth or single colonies | SOP 151 Fertility of Specified Target Organism(s) (Liquid Media) |
| Candida albicans ATCC®10231 | 86 | Flocculent growth | Flocculent growth | SOP 151 Fertility of Specified Target Organism(s) (Liquid Media) |

| Target Organism | Control(cfu) | Test | Specification | Accredited Method Reference |
|--|--------------|------------------------------------|---|---|
| Aspergillus brasiliensis ATCC®16404 | 71 | White mycelia without black spores | White mycelia with/ without black spores | SOP 151 Fertility of Specified Target Organism(s) (Liquid Media) |
| Clostridium sporogenes ATCC®19404 | 92 | Turbid growth | Turbid growth or single colonies | SOP 151 Fertility of Specified Target Organism(s) (Liquid Media) |
| Clostridium sporogenes ATCC®11437 | 98 | Single colonies | Turbid growth or single colonies | SOP 151 Fertility of Specified Target Organism(s) (Liquid Media) |
| Clostridium perfringens ATCC®13124 | 87 | Single colonies | Turbid growth or single colonies | SOP 151 Fertility of Specified Target Organism(s) (Liquid Media) |

EXTRA INFORMATION

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

Tested in accordance with the harmonized methods described in the current European, United States and Japanese pharmacopoeias for sterility tests.

*Due to process restriction the packing date may be after the test date.

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CERTIFICATE OF ANALYSIS

Delivery/Customer information

Date Printed

2025.07.02

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.



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Quality Manager, G&M Procter Ltd

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.

G & M Procter Ltd, Thermo Fisher Scientific, Microbiology,
4 Auld Bond Road, Perth, PH1 3FX