

## G & M Procter Ltd. Certificate of Analysis

PRODUCT BO0510M

THIOGLYCOLLATE MEDIUM (acc. to EP/USP)

**10X100ML IN 100ML DIN** 

 LOT NUMBER
 4511204

 EXPIRY DATE
 2026.06.19

 PACKING DATE
 2025.06.18

 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	SOP 183
	with red layer	or without red layer	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	62	Turbid growth	Turbid growth or single colonies	SOP 151 Fertility of Specified Target Organism(s) (Liquid Media)
Pseudomonas aeruginosa ATCC®9027	27	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.





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Ian Snowball Quality Manager G & M Procter Ltd.



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subtilis ATCC®6633	98	Turbia growth	single colonies	Target Organism(s) (Liquid Media)
Candida albicans ATCC®10231	73	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	68	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	91	Turbid growth	Turbid growth or single colonies	SOP 151 Fertility of Specified Target Organism(s) (Liquid Media)
Clostridium sporogenes ATCC®11437	97	Single colonies	Turbid growth or single colonies	SOP 151 Fertility of Specified Target Organism(s) (Liquid Media)
Clostridium perfringens ATCC®13124	85	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.

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<sup>\*</sup>Due to process restriction the packing date may be after the test date.



## 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.

Ian Snowball

Quality Manager, G&M Procter Ltd

Jan Snawboll