

G & M Procter Ltd. Certificate of Analysis

PRODUCT BO0510M

THIOGLYCOLLATE MEDIUM (acc. to EP/USP)

10X100ML IN 100ML DIN

 LOT NUMBER
 1086712

 EXPIRY DATE
 2010.04.23

 PRODUCTION DATE
 2009.04.23

 TEST DATE
 2009.04.24

 REPORTING DATE
 2009.05.08

Physical Characteristics	Results	Specification	Accredited Method Reference
Appearance	•	Straw/yellow with or without red layer	Appearance and colour
pH (25°C)	7.1	6.9 - 7.3	pН
Fill Volume/Weight Sterility @ 22°C & 32°C ± 2°Cfor 14days	100.9g No growth	100.0 - 101.5g No growth	Fill volume weight check Ster.at 22,32,37 & 44°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	47	Turbid growth and / or single	Turbid growth and / or single	Fertility of Specified Target Organism(s) (Liquid Media)
Pseudomonas aeruginosa ATCC®9027	32	Turbid growth and / or single	Turbid growth and / or single	Fertility of Specified Target Organism(s) (Liquid Media)
Bacillus subtilis ATCC®6633	19	Turbid growth and / or single	Turbid growth and / or single	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. 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. Values are not reported on the Certificate of Analysis but details can be provided on request.



Moira McCallum

Quality Manager, G & M Procter Ltd.



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Candida albicans ATCC®10231 Flocculent growth

Flocculent growth

Fertility of Specified Target Organism(s) (Liquid

Media)

Target Organism	Control(cfu)	Test	Specification	Accredited Method Reference
Aspergillus brasiliensis ATCC®16404	39	White mycelia withou black spores	at White mycelia with/ without black spores	Fertility of Specified Target Organism(s) (Liquid Media)
Clostridium sporogenes ATCC®19404	28	Turbid growth and / or single	Turbid growth and / or single	Fertility of Specified Target Organism(s) (Liquid Media)
Clostridium sporogenes ATCC®11437	22	Turbid growth and / or single	Turbid growth and / or single	Fertility of Specified Target Organism(s) (Liquid Media)

EXTRA INFORMATION

The product was tested in accordance with the current versions of the European Pharmacopoeia, the British Pharmacopoeia, the US Pharmacopoeia and the Japanese Pharmacopoeia. Clearly visible growth was observed within 3 days for bacteria and within 5 days for fungi

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Moira McCallum

Quality Manager, G & M Procter Ltd.



CERTIFICATE OF ANALYSIS

Delivery/Customer information

Date Printed 2013.11.11 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.

MOIRA MCCALLUM

Quality Manager G & M Procter Ltd

M. E. Mcslc.