

G & M Procter Ltd. Certificate of Analysis

PRODUCT PO0821B

TRYPTONE SOYA AGAR (X3 WRP IRR DEEP FL)

1 PACK OF 10 PLATES

 LOT NUMBER
 4528597

 EXPIRY DATE
 2026.02.24

 PACKING DATE
 2025.11.04

 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/	Straw 1, straw 1/2	SOP 178
	2	or straw 2	Appearance and colour
pH (25°C)	7.2	7.1 - 7.5	SOP 53 pH
Fill Volume/Weight	22.9g	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	72	Straw cols	Straw cols	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Escherichia coli ATCC®8739	96	92	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	61	Straw colonies	Straw colonies	SOP 151 Fertility of Specified Target Organism(s)(Agar)
Candida albicans ATCC®10231 @30-35°C	72	77	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	84	>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	92	97	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	77	1-2mm cream colonies	1-2mm cream colonies	SOP 151 Fertility of Specified Target Organism(s)(Agar)
A. brasiliensis ATCC®16404 20-25°C	45	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 R	un ID 2183-14732A	N/A
Packaging and Presentation	Conforms	Conforms to sp	ecification
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.





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Ian Snowball Quality Manager G & M Procter Ltd.