

G & M Procter Ltd. Certificate of Analysis

PRODUCT PO0410B

SAB. DEXTROSE AGAR IRRAD + X3 WRAP

1 PACK OF 10 PLATES

LOT NUMBER 1278558
EXPIRY DATE 2014.02.10
PRODUCTION DATE 2013.11.04
TEST DATE 2013.11.12
REPORTING DATE 2013.11.12

Physical Characteristics	Results	Specification	Accredited Method Reference
Appearance	Straw 1 /	Straw 1, straw 1/2 or straw 2	Appearance and colour
pH (25°C)	5.6	5.1 - 5.6	рН
Fill Volume/Weight Sterility @ 22°C & 32°C ± 2°Cfor 5 days	18.9g No growth	18.5 - 20.5g 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 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
Candida albicans ATCC®10231	56	53	Cream, domed cols	Cream, domed cols	Fertility of Specified Target Organism (s)(Agar)
Aspergillus brasiliensis ATCC®16404	28	23	White mycelia, black spores	White mycelia, black spores	Fertility of Specified Target Organism (s)(Agar)

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.



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



CERTIFICATE OF ANALYSIS

Delivery/Customer information

Date Printed 2013.11.08 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

Product Performance Manager, G&M Procter Ltd

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

PHYSICAL CHARACTERISTICS	Results	Specification	
Irradiation Dose	Conforms	8-20 kGy	
Irradiation Certificate No.	S11069977-2-1	N/A	
Packaging and Presentation	Conforms	Conforms to specification	

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.