



G & M Procter Ltd. Certificate of Analysis

PRODUCT PO0779A
ISO-SENSITEST AGAR (4MM DEPTH)
1 PACK OF 10 PLATES

LOT NUMBER 1266246
EXPIRY DATE 2013.09.19
PRODUCTION DATE 2013.07.18
TEST DATE 2013.07.18
REPORTING DATE 2013.07.23

| Physical Characteristics | Results | Specification | Accredited Method Reference |
|---|----------|--------------------------|-----------------------------|
| Appearance | Straw 2 | Straw 2 | Appearance and colour |
| pH (25°C) | 7.5 | 7.2 - 7.6 | pH |
| Fill Volume/Weight | 26.1g | 25.5 - 26.5g | Fill volume weight check |
| Sterility @ 22°C & 32°C ± 2°C for 5 days | Conforms | Within acceptable limits | Ster. at 22,32,37 & 44°C |
| The sterility test is performed in accordance with ISO 2859-1: 1999, AQL 1%, general inspection level =1. | | | |

MICROBIOLOGICAL PERFORMANCE

Each organism must achieve a zone size within the range stated in the range specification.

| Target Organism | Zone size (mm) | Zone size range (mm) | Accredited Method Reference |
|---|----------------|----------------------|-----------------------------|
| Zone diameter(mm) BSAC S.aureus ATCC®9144 Erythromycin 5 | 29 | 22 - 31 | Zone Diameter (mm) |
| S.aureus ATCC®9144 Gentamicin 10 | 25 | 24 - 30 | Zone Diameter (mm) |
| S.aureus ATCC®9144 Penicillin 1 | 37 | 32 - 40 | Zone Diameter (mm) |
| S.aureus ATCC®9144 Rifampicin 2 | 37 | 27 - 39 | Zone Diameter (mm) |

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



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| Target Organism | Zone size (mm) | Zone size range (mm) | Accredited Method Reference |
|---|----------------|----------------------|-----------------------------|
| Zone diameter(mm) BSAC S.aureus ATCC®9144 Teicoplanin 30 | 21 | 17 - 23 | Zone Diameter (mm) |
| S.aureus ATCC®9144 Vancomycin 5 | 19 | 14 - 20 | Zone Diameter (mm) |
| E.coli ATCC®10536 Ampicillin 10 | 23 | 21 - 26 | Zone Diameter (mm) |
| E.coli ATCC®10536 Ceftazidime 30 | 35 | 32 - 40 | Zone Diameter (mm) |
| E.coli ATCC®10536 Trimethoprim 2.5 | 35 | 30 - 37 | Zone Diameter (mm) |
| E.coli ATCC®10536 Cefuroxime 30 | 31 | 25 - 32 | Zone Diameter (mm) |
| E.coli ATCC®10536 Ciprofloxacin 1 | 36 | 31 - 40 | Zone Diameter (mm) |
| E.coli ATCC®10536 Gentamicin 10 | 27 | 21 - 27 | Zone Diameter (mm) |
| E.faecalis ATCC®29212 Ampicillin 10 | 28 | 26 - 35 | Zone Diameter (mm) |
| E.faecalis ATCC®29212 Gentamicin 200 | 27 | 22 - 27 | Zone Diameter (mm) |

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| Target Organism | Zone size (mm) | Zone size range (mm) | Accredited Method Reference |
|---|----------------|----------------------|-----------------------------|
| Zone diameter(mm) BSAC | | | |
| E.faecalis ATCC®29212 Teicoplanin 30 | 21 | 19 - 25 | Zone Diameter (mm) |
| E.faecalis ATCC®29212 Vancomycin 5 | 16 | 13 - 19 | Zone Diameter (mm) |
| P.aeruginosa ATCC®27853 Amikacin 30 | 31 | 26 - 32 | Zone Diameter (mm) |
| P.aeruginosa ATCC®27853 Ceftazidime 30 | 34 | 27 - 35 | Zone Diameter (mm) |
| P.aeruginosa ATCC®27853 Ciprofloxacin 1 | 29 | 24 - 30 | Zone Diameter (mm) |
| P.aeruginosa ATCC®27853 Colistin 25 | 19 | 16 - 20 | Zone Diameter (mm) |
| P.aeruginosa ATCC®27853 Gentamicin 10 | 27 | 22 - 28 | Zone Diameter (mm) |
| P.aeruginosa ATCC®27853 Imipenem 10 | 28 | 23 - 28 | Zone Diameter (mm) |

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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.

A handwritten signature in black ink that reads "Ian Snowball".

Ian Snowball
Product Performance 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