



G & M Procter Ltd. Certificate of Analysis

PRODUCT **BO0479Z**
T.S.B + 0.3% LECITHIN + 2%TWEEN
10X90ML IN 125ML SIROP

LOT NUMBER 1206034
EXPIRY DATE 2012.08.18
PRODUCTION DATE 2012.02.17
TEST DATE 2012.02.17
REPORTING DATE 2012.03.02

Physical Characteristics	Results	Specification	Accredited Method Reference
Appearance	Straw 2-3	Straw 2, straw 2-3 or straw 3	Appearance and colour
pH (25°C)	7.3	7.1 - 7.5	pH
Fill Volume/Weight	91.5g	90.0 - 91.5g	Fill volume weight check
Sterility @ 22°C & 32°C ± 2°C for 14days	No growth	No growth	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	49	Turbid growth	Turbid growth	Fertility of Specified Target Organism(s) (Liquid Media)
Pseudomonas aeruginosa ATCC®9027	70	Turbid growth	Turbid growth	Fertility of Specified Target Organism(s) (Liquid Media)
Escherichia coli ATCC®8739	53	Turbid growth	Turbid growth	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.



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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Bacillus subtilis ATCC®6633	28	Flocculent / surface growth	Flocculent / surface growth	Fertility of Specified Target Organism(s) (Liquid Media)
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Target Organism	Control(cfu)	Test	Specification	Accredited Method Reference
Candida albicans ATCC®10231	43	Flocculent / surface growth	Flocculent / surface growth	Fertility of Specified Target Organism(s) (Liquid Media)
Aspergillus brasiliensis ATCC®16404	65	White mycelia, no spores	White mycelia with/without black spores	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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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