

G & M Procter Ltd. Certificate of Analysis

PRODUCT BO0348Z MAXIMUM RECOVERY DILUENT 10 X 90 ML IN 125 ML SIROP

| LOT NUMBER | 1151003 |
|-----------------|------------|
| EXPIRY DATE | 2011.11.05 |
| PRODUCTION DATE | 2010.11.13 |
| TEST DATE | 2010.11.15 |
| REPORTING DATE | 2010.11.25 |

| Physical Characteristics | Results | Specification | Accredited Method Reference |
|---|------------|---------------|--------------------------------|
| Appearance | Colourless | Colourless | Appearance and colour |
| pH (25°C) | 7.1 | 6.8 - 7.2 | pH |
| Fill Volume/Weight | 90.0g | 90.0 - 91.5g | Fill volume weight check |
| Sterility @ $22^{\circ}C$ & $32^{\circ}C \pm 2^{\circ}C$ for 5 days | No growth | No growth | Ster.at 22,32,37 & 44°C |

MICROBIOLOGICAL PERFORMANCE

For the target organism both inocula must achieve a colony count of 50-150 cfu. Recovery after holding at 25 degrees C +/- 2 degrees C for 45 minutes shall be between 50% - 150% of the initial count.

| Target Organism | Initial cfu | Post holding period cfu | Specification | Accredited Method Reference |
|-------------------------------|-------------|-------------------------|--------------------|--------------------------------|
| Escherichia coli ATCC®8739 | 60 | 55 | As described above | Maintenance of viability |

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.



EMESIL

Moira McCallum Quality Manager, G & M Procter Ltd.

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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 2013.11.11 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.

M.E.Mesle.

MOIRA MCCALLUM Quality 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.

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