Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Certificate No: MI-2011-LI-065383

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an audit in accordance with Section 37(2) of the *Therapeutic Goods Act 1989.*

The competent authority of Australia confirms the following:

The manufacturer Sphere Healthcare Pty Ltd
10-12 Church Road
MOOREBANK NSW 2170
Australia

has been audited under the national audit program in connection with Manufacturing Licence No. MI-08122004-LI-000289-1 in accordance with Section 38, *Therapeutic Goods Act, 1989.*

From the knowledge gained during audit of this manufacturer, the latest of which was conducted on 11-12 May 2010 , it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 15 January 2009.

This certificate reflects the status of the manufacturing site at the time of the audit noted above. It should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that audit or where the Australian Licence to Manufacture Therapeutic Goods is not current[1]. After this time, or if the Licence is not current, the issuing authority should be consulted. The authenticity of this certificate may be verified with the issuing authority.

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[1] The status of an Australian Licence may be viewed at https:/ww.ebs.tga.gov.au/

Office of Manufacturing Quality
Therapeutic Goods Administration
GMP@tga.gov.au

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Part 2

MANUFACTURING OPERATIONS

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Powders and Granules	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Capsule, soft	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Semi Solids - Creams, Gels and Ointments	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Oral Liquid	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Liquids	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Essential Oils and Herbal Extract	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing

Conditions - Refer to: Section 40, Sub-section 4 of the Therapeutic Goods Act 1989. Regulation 20 of the Therapeutic Goods Regulations 1990.

The manufacture of registered medicines is restricted to complimentary medicines and solutions for topical application only.

This licence does not include microbiological testing.

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Expiry Date: 12/05/2013

Name and signature of the authorised person of the Competent Authority of Australia

Dragana Milic
Audit Manager
Office of Manufacturing Quality
Therapeutic Goods Administration

10 August 2011