澳-1

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

Issued to:

ABN: 61 010 675 439

Manufacturing Site Address:

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a Licence with number MI-11032005-LI-000470-1 to manufacture therapeutic goods under Section 38 of the *Therapeutic Goods Act, 1989* and is included in the national inspection program following section 40(4)(b) of the *Therapeutic Goods Act 1989*.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 10/09/2012 to 12/09/2012, 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 inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. This certificate should also not be relied upon where the status of the Licence to manufacture therapeutic goods is not current. Where required, the Therapeutic Goods Administration as the issuing authority should be consulted.

I hereby certify that this is
a true copy of the original.

EXPIRY DATE: 12 September 2015

ISSUE DATE: 23 July 2013

Notary Public

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

Signed:

.....

Delegate of the Secretary
Office of Manufacturing Quality

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible.
This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MANUFACTURING OPERATIONS

The manufacturer above is authorised under Section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Active Pharmaceutical Ingredient manufacture	Non Sterile	Not Applicable	Not Applicable	Active material manufacture

Under the *Therapeutic Goods Act 1989* the following conditions have been imposed on the Licence:

Conditions - Refer to:

Section 40, Sub-section 4 of the Therapeutic Goods Act 1989.

Regulation 20 of the Therapeutic Goods Regulations 1990.

This licence authorises only the manufacture of hyoscine alkaloid and derivatives.

I hereby certify that this is
a true copy of the original

Notary Public

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

Signed:

.....

Delegate of the Secretary
Office of Manufacturing Quality

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible.
This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation