Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2014-LI-10862-1

Issued to:

Comvita Australia Pty Ltd
ACN: 088 909 648

Manufacturing Site Address:

767 Bischoffs Rd
COOMINYA QLD 4311 Australia

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a Licence with number **MI-26102004-LI-000070-1** 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 26 to 27 October 2015, 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 after the expiry date. 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.

EXPIRY DATE: 27 October 2018

ISSUE DATE: 3 August 2016

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

Signed:

Robert Prestridge, Senior Inspector
Manufacturing Quality Branch

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.
The status of an Australian Licence may be viewed at https://www.ebs.tga.gov.au/

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

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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
Medicine manufacture	Non Sterile	Oral Liquid Group	Listed Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Capsule, soft	Listed Therapeutic Good	Release for supply

In addition to the statutory conditions that apply to all Licences granted under Section 38 of the *Therapeutic Goods Act, 1989,* the following specific conditions have been imposed on this Licence under Sections 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989* :

Manufacture is restricted to herbal therapeutic goods

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

Signed:

Robert Prestridge, Senior Inspector
Manufacturing Quality Branch

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