



Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2016-LI-10302-1

Issued to:

Eurofins ams Laboratories Pty Ltd
ABN: 47 075 467 757

Manufacturing Site Address:

8 Rachael Close
SILVERWATER NSW 2128

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a Licence with number **MI-15112007-LI-002191-11** 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 4 May 2016 to 6 May 2016, 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: 6 May 2019

ISSUE DATE: 28 September 2016

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

Signed:


Robert Prestidge, 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/>



Australian Government
Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2016-LI-10302-1

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
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Testing microbial
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Testing chemical and physical
Testing Laboratory	Sterile	All Dosage Forms	Not Applicable	Testing sterility
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Endotoxin Testing

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 the Licence under Sections 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

The licence also authorises antibiotic bioassay; Sub visible particle count testing; and Ethylene oxide residue testing by gas liquid chromatography.

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/>