



Certificate No: MI-2010-LI-01063-3

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 AMS Laboratories Pty Limited
 8 Rachael Close
 SILVERWATER NSW 2128
 Australia

has been audited under the national audit program in connection with Manufacturing Licence No. MI-15112007-LI-002191-11 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 20 May 2011, 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 current¹. 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.



¹ The status of an Australian Licence may be viewed at <https://www.ebs.tga.gov.au/>



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Part 2

MANUFACTURING OPERATIONS

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Testing Laboratory	Sterile	All Dosage Forms	Not Applicable	Testing microbial
Testing Laboratory	Non Sterile	Not elsewhere classified	Not Applicable	Testing chemical and physical

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:

- Microbiological analysis and testing, including sterility testing, bacterial endotoxin testing and antibiotic bioassay.
- Sub visible particle count testing.
- Ethylene oxide residue testing by gas liquid chromatography.



Expiry Date: 20 April 2014

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

Doug Fenwick
Audit Manager

Office of Manufacturing Quality
Therapeutic Goods Administration

7 September 2011