



Australian Government
Department of Health
 Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-15112007-LI-002191-11

Granted to:

Eurofins ams Laboratories Pty Limited
 ABN: 47 075 467 757

Manufacturing Site Address:

8 Rachael Close
 SILVERWATER NSW 2128

The manufacturer above is hereby 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


This licence is subject to the requirements of the *Therapeutic Goods Act 1989*, and its Regulations.

Section 40(4) of the *Therapeutic Goods Act 1989* and Regulation 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 impose various statutory conditions on all licences to manufacture therapeutic goods.

In addition to that, the specific conditions mentioned in Part 2 of this licence have been imposed under Section 40 of the *Therapeutic Goods Act 1989*.

Originally Granted: **20 December 2007** Date Revised: **01 June 2016**

Signed:

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Hongxia Jin, Delegate of the Secretary

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