



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

## Licence to Manufacture Therapeutic Goods – Part 1

**Licence Number:**

MI-2011-LI-03353-3

**Granted to:**

Chemical Analysis Pty Ltd

ACN: 114 804 572

**Manufacturing Site Address:**

110 Merrindale Drive

CROYDON SOUTH VIC 3136

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

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(1) or 40(2) of the *Therapeutic Goods Act 1989*.

Originally Granted: **15 March 2012** Date Revised: **8 March 2017**

Signed:

Matthew Davis, Delegate of the Secretary

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## **Licence to Manufacture Therapeutic Goods – Part 2: Schedule of Conditions**

**Licence Number:**

MI-2011-LI-03353-3

**Issued to:**

Chemical Analysis Pty Ltd

ACN: 114 804 572

**Manufacturing Site Address:**

110 Merrindale Drive  
CROYDON SOUTH VIC 3136

In addition to the statutory conditions that have been imposed on all licences to manufacture therapeutic goods under Section 40(4) of the *Therapeutic Goods Act 1989* and Regulations 19, 20 and 21 of the Therapeutic Goods Regulations 1990, the conditions specified below have been imposed on this licence under Section/s 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

Conditions - Refer to: Section 40, Sub-section 4 of the Therapeutic Goods Act 1989.

Regulation 19, 20 and 21 of the Therapeutic Goods Regulations 1990.

No further conditions are applicable.

Persons currently nominated under Section 37(1)(e) of the Act as having control:

Production: Jason Hall

Quality Control: Elizabeth Ooi

Originally imposed: **15 March 2012** Date Revised: **8 March 2017**

Signed:

Matthew Davis, Delegate of the Secretary

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