Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-09022005-LI-000428-1

Previously granted under Licence number: 77007

Granted to:

Silliker Australia Pty Ltd

ABN: 94 006 462 335

Manufacturing Site Address:

18-20 King Street BLACKBURN VIC 3130

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	Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing microbial
Testing Laboratory	Sterile	All Dosage Forms	Registered Therapeutic Good	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 of the *Therapeutic Goods Act 1989.*

Originally Granted: **22 August 1996** Date Revised: **9 December 2014**

Signed: .....

Hongxia Jin, Delegate of the Secretary

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TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

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

Licence Number:

MI-09022005-LI-000428-1

Previously issued under Licence 77007

Issued to:

Silliker Australia Pty Ltd

ABN: 94 006 462 335

Manufacturing Site Address:

18-20 King Street BLACKBURN VIC 3130

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 40 of the *Therapeutic Goods Act 1989*:

This licence authorises only: microbiological analysis and testing including sterility testing associated with the manufacture of therapeutic goods.

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

Production: Michelle Cope

Quality Control: Melinda Skipper

Originally imposed: **22 August 1996** Date Revised: **9 December 2014**

Signed: .....

Hongxia Jin, Delegate of the Secretary

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TGA Health Safety Regulation