

Australian Government

Department of Health Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods - Part 1

Licence Number:

MI-2012-LI-05038-3

Granted to:

Syrinx Pharmaceuticals Pty Ltd ABN: 20 149 728 825

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
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Tablet, orally disintegrating	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Liquids	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Liquids	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Tablet, orally disintegrating	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Cream	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Wafer	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Wafer	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Paste	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Cream	Registered Therapeutic Good	Full Product Manufacture - excluding Testing

Signed:

Jenny Hantzinikolas, Delegate of the Secretary

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This licence is subject to the requirements of the *Therapeutic Goods Act1989*, 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: 05 July 2013

Date Revised: 12 March 2015

Signed:

Jenny Hantzinikolas, Delegate of the Secretary

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