Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-25112004-LI-000211-1

Granted to:

Baxter Laboratories Pty Ltd
ACN: 093 625 435

Primary Manufacturing Site Address:

1019 Mountain Highway
BORONIA VIC 3155

Secondary Manufacturing Site Addresses:

12-14 Prospect Place
BORONIA VIC 3155

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 addresses specified above.

Primary site:

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Liquids	Registered Therapeutic Good	Full product manufacture - excluding microbiological testing
Medicine manufacture	Non Sterile	Semi solids	Registered Therapeutic Good	Full product manufacture - excluding microbiological testing
Medicine manufacture	Non Sterile	Powder, dusting	Registered Therapeutic Good	Full product manufacture - excluding microbiological testing
Sunscreen manufacture	Non Sterile	Cream	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing
Sunscreen manufacture	Non Sterile	Gel	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing
Sunscreen manufacture	Non Sterile	Lotion	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing

Signed: .....

Robert Prestridge, Delegate of the Secretary

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This Licence is the property of the Therapeutic Goods Administration and must be returned or destroyed upon demand.
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The status of an Australian Licence may be viewed at https://www.ebs.tga.gov.au/

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

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Sunscreen manufacture	Non Sterile	Ointment	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing
Sunscreen manufacture	Non Sterile	Spray	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing
Sunscreen manufacture	Non Sterile	Spray, solution	Listed Therapeutic Good	Full product manufacture - excluding microbiological testing
Medicine manufacture	Non Sterile	Inhalation	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing

Secondary site:

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	All Dosage Forms	Registered Therapeutic Good	Storage

This licence is subject to the requirements of the *Therapeutic Goods Act1989,* and its Regulations. For the secondary manufacturing site/s, refer to Section 38A of the *Therapeutic Goods Act 1989.*

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: **29 July 2003** Date Revised: **16 November 2016**

Signed: .....

Robert Prestridge, Delegate of the Secretary

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Licence to Manufacture Therapeutic Goods – Part 2:

Schedule of Conditions

Licence Number:

MI-25112004-LI-000211-1

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

Production: Ian Tilley

Quality Control: Devlin Gardner

Originally imposed: **29 July 2003** Date Revised: **16 November 2016**

Signed:

Robert Prestridge , Delegate of the Secretary

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BORONIA VIC 3155

Secondary Manufacturing Site Addresses:

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BORONIA VIC 3155

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 - The licence does not authorise the manufacture of preparations containing biological medicines, penicillins, cephalosporins, hormones, steroids or antineoplastic drugs.

The manufacture of liquid is restricted to preparations for topical use and for use in a vaporiser. The manufacture of semi solid and powder is restricted to preparations for topical use only.

The manufacture of inhalations is restricted to the manufacture of nasal sticks only.

Signed: .....

Robert Prestridge , Delegate of the Secretary

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