



## **Schedule of Conditions Applicable to the Manufacture of Therapeutic Goods**

The following conditions form part of Licence No. **77027** issued in respect of:

**Orielton Laboratories Pty Limited**  
ACN: 079 062 454  
8 Orielton Road  
SMEATON GRANGE NSW 2567  
Australia

*Under the Therapeutic Goods Act, 1989*

**This licence authorises only:**

- a) the manufacture of medicinal products in liquid dosage forms containing propolis, royal jelly, honey, vitamins, minerals, benzalkonium chloride and chemical substances included in Part 5 of Schedule 4 of the Therapeutic Goods Regulations;
- b) the packaging, labelling and release for supply of listed medicines in solid dosage forms.

Persons currently nominated as having control under Section 37 of the *Therapeutic Goods Act, 1989*:

Production: **Anita Kowalski**

Quality Control: **Kasper Kowalski**

Originally Issued: **12/08/1996**      Date Revised: **02/07/2008**

Signed:

  
.....  
Delegato of the Secretary





## **CERTIFICATE OF GMP COMPLIANCE**

Orielton Laboratories Pty Limited of 8 Orielton Road, Smeaton Grange NSW 2567, Australia has been subject to regular Good Manufacturing Practice (GMP) audits by officers of the Office of Manufacturing Quality, Therapeutic Goods Administration (TGA).

From the knowledge gained during the last audit conducted on 1-2 April 2008, it is considered that the company has maintained an overall acceptable level of compliance with the current Australian Code of Good Manufacturing Practice for Medicinal Products.

The company is holder of Licence No. 77027, issued under the Therapeutic Goods Act 1989. The company is the manufacturer of listed oral liquids, and the packaging and release for sale of listed therapeutic goods in the following dosage forms; tablets and capsules.

This certificate remains the property of the TGA and must be returned upon written demand. The validity of this certificate may be checked by contacting the undersigned.

This certificate remains valid for 3 years from the date of last inspection, provided that re-audits are conducted when scheduled by the TGA.

Signed:

  
.....Ca/07/2008

Dr Andrzej Wozniak  
A/g Chief Inspector  
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