



This form, when completed, will be classified as 'For official use only'.
 For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<http://www.tga.gov.au/about/tga-information-to.htm>.

Module 1.7 Good manufacturing practice

Details form

The *Therapeutic Goods Act 1989* requires GMP clearances/licences for sites involved in production of the medicine. See [CTD Module 1](#), for legislative requirements.

Note: Requirements for GMP clearances, certifications, and manufacturing licence applications are available from the [GMP section](#) of the TGA website.

| Details of overseas manufacturers | | | | | |
|-----------------------------------|--------------------------|--|-------------------|---------|--------------------------|
| Currently cleared | Clearance required | GMP clearance or certification tracking number # | Manufacturer name | Country | Expiry date (if current) |
| <input type="checkbox"/> | <input type="checkbox"/> | (MI-YYYY-CL-NNNNN-N) | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | | | | |

Applications must have been submitted (draft status is not acceptable).

| Details of Australian manufacturers | | | |
|-------------------------------------|--------------------------|---|-------------------|
| Currently approved | Approval required | Licence or tracking number [#] | Manufacturer name |
| <input type="checkbox"/> | <input type="checkbox"/> | (MI-YYYY-LI-NNNNN-N) | |
| <input type="checkbox"/> | <input type="checkbox"/> | | |
| <input type="checkbox"/> | <input type="checkbox"/> | | |
| <input type="checkbox"/> | <input type="checkbox"/> | | |
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| <input type="checkbox"/> | <input type="checkbox"/> | | |
| <input type="checkbox"/> | <input type="checkbox"/> | | |

[#]Applications must have been submitted (draft status is not acceptable).