Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

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>.

Instructions for completing a Certificate for subsection 40(6) of the *Therapeutic Goods Act 1989*

Amendments to the *Therapeutic Goods Act 1989* (the Act) that commenced on 1 December 2009, included powers for the Secretary, or delegate, under subsection 40(6) of the Act, to require, by notice in writing to the holder of a manufacturing Licence, the Licence holder to give the Secretary, or delegate, within the period, and in the specified manner, information to be used by the Secretary, or delegate, in deciding whether to revoke or suspend the manufacturing Licence under section 41 of the Act in the circumstances referred to in paragraph 41(1)(a) of the Act.

The provisions of the Act may be viewed through the TGA website at <http://www.tga.gov.au> or at <http://www.comlaw.gov.au>.

Holders of a manufacturing Licence who are required by the Secretary, or delegate, to complete this Certificate, are expected to self-assess whether they, or certain other persons associated with the holder, including a body corporate, meet the criteria in paragraphs 38(1)(g)(i) – (x) of the Act, and to certify the outcome by submitting this Certificate to the Therapeutic Goods Administration (the TGA).

Steps to submitting this certificate

1. Carefully read the relevant provisions, ensuring you understand this Certificate. Make enquiries necessary in order to answer any matters required for certification;

2. Complete the required details and sign and attach any additional information. The signatory must mark the relevant box to either certify (i.e. "þ hereby certify that"), or signal their inability to certify (i.e. "þ I am unable to certify"), when completing the document. Marking both boxes invalidates the certification.

3. To reduce processing times, please send the completed Certificate by email to gmp@tga.gov.au. Please ensure that your email identifies the number of the associated manufacturing Licence. If email delivery is not an available option, then the completed Certification may be submitted by fax to 02 6232 8426, or by post to the following address:

   The Licensing and Certification Section
   Office of Manufacturing Quality
   PO Box 100
   Therapeutic Goods Administration
   Woden ACT 2606

Note the signatory must:

· if the holder of a manufacturing Licence is an individual, be that individual; or

- if the holder of a manufacturing Licence is a body corporate, hold a senior position in that body corporate (e.g. Chief Executive Officer or Managing Director) and be authorised to make the certification on behalf of the body corporate.

Further information

Under paragraph 40(6) of the Act the Secretary, or delegate, may, by written notice and within a reasonable period of time, require a Licence holder to give the Secretary, or delegate, further information about their compliance or non compliance with the criteria set out in this Certificate.

Special circumstances

This Certificate allows for the submission of additional information by a holder of a manufacturing Licence who is unable to certify that they or persons mentioned in (i)-(iii) below meet the new criteria. The Secretary, or delegate, will consider this information and may decide to suspend or revoke, or not suspend or revoke, a manufacturing Licence depending upon the circumstances.

Avoiding an invalid certificate

Your Certificate will **not** be considered valid if this form:

- is not used;
- is incomplete;
- is unclear or ambiguous;
- has not been signed by the appropriate person (refer to the Note above); or
- has been submitted more than a month since the date of its signing.

Privacy Information

- For general privacy information, go to <http://www.tga.gov.au/about/website-privacy.htm>.

Personal information in applications relating to manufacturing licences:

- The TGA collects personal information in applications for Australian manufacturing licences, and associated applications such as to vary existing manufacturing licences.
- The personal information is used to maintain a record of manufacturing licence applications, to consider applications, and to contact applicants about their application.
- Personal information provided in applications may also be used to contact sponsors or manufacturers of goods in the Register where there is a need to do so – for example, in the event of a safety, quality or efficacy issue concerning the manufacture of certain goods, or to administer fees and payments relating to the licence.
- Personal information relating to holders of licences to manufacture therapeutic goods may be disclosed where authorised or required by an Australian law, Court or Tribunal order; or with the consent of the person the information is about.

Note: A “major interest holder” of a body corporate means a person who:
(a) is in a position to cast, or control the casting of, more than one-fifth of the maximum number of votes that might be cast at a general meeting of the body corporate; or
(b) holds more than one-fifth of the issued share capital of the body corporate (excluding any part of that issued share capital that carries no right to participate beyond a specified amount in a distribution of either profits or capital.

Certificate for subsection 40(6) of the *Therapeutic Goods Act 1989*

I, [1]

hold the position of [2]

in [3]

at [4]

EITHER

☐ **hereby certify that, in relation to the application for a manufacturing licence,**

[5] **dated**

none of the following people:

i. the holder of the Licence to manufacture therapeutic goods (the Holder);

ii. a person who makes, or participates in making, decisions that affect the whole, or a substantial part, of the Holder's affairs;

iii. if the Holder is a body corporate, a person who is a major interest holder of the body corporate;

has, within the 10 years immediately before this application:

iv. been convicted of an offence against the Therapeutic Goods Act 1989 (the Act) or a corresponding State law; or

v. been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

vi. been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of the Act or a corresponding State law; or

vii. been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

viii. breached a condition of a manufacturing Licence; or

ix. had a manufacturing Licence suspended or revoked; or

x. been a manager, or major interest holder, of a body corporate in respect of which paragraphs (iv), (v), (vi), (vii), (viii) or (ix), noted above, applied in that 10 year period, if the conduct resulting in that paragraph applying occurred when the person was a manager or major interest holder of the body corporate.

OR

☐ I am **unable** to certify that paragraphs (iv) - (x) can be met as set out above.

AND

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[1] Insert full name of CEO / Managing Director / or equivalent.
[2] Insert position title (Relevant position holders as defined in Section 38(1)(g) of the Act
[3] Insert Manufacturer name
[4] Insert Manufacturer street address
[5] Insert MIS application tracking number

I **wish** the Secretary, or delegate, or his or her delegate to consider special circumstances in this case.

Special Circumstances: I have attached the following information about the holder or other relevant persons to assist the Secretary, or delegate, in determining whether to grant, or refuse to grant, a Licence to manufacture therapeutic goods.

Please enter details of claimed special circumstances for consideration. Leave blank if there is no relevant information.

Attachment No.	No. of Pages	Title of document

I hereby declare that the above information is true and correct:

Full name (printed)			
Signature		Date	

Witness full name			
Witnessed by (Signature)		Date	

Note: Giving false or misleading information is a criminal offence under the Criminal Code.