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>.

Report of the manufacture of exempt therapeutic goods

(as defined in item 5 of Schedule 5A of the Therapeutic Goods Regulations 1990)

1. Manufacturer's details:

a. Manufacturer's business name _____

b. Manufacturer's licence number _____

c. Declaration:

I declare that.

1. the Special Therapeutic Product(s) was/were manufactured during the _____ quarter of the calendar year _____;
2. each product was manufactured to a formulation specified by the sponsoring hospital or public institution which contracted the manufacture;
3. for each product, no substantially similar product was included in the Australian Register of Therapeutic Goods at the time of manufacture;
4. manufacture subcontracted for stages in the manufacture of each product (if any) held a valid manufacture's licence where required under the Therapeutic Goods Act 1989; and
5. the information provided in this notification is current and correct.

Name (capitals)			
Relationship to the manufacturer			
Signature		Date	

(This declaration must be signed by the manufacturer's representative as outlined in Schedule 5A, item 5 of the Therapeutic Goods Regulations)

2. Sponsor details

a. Name and Address of sponsoring hospital or public institution;

b. Sponsor representative responsible for placing contract with manufacturer;

Name (capitals) _____

Position in hospital or institution _____

Contact phone number _____

3. Special therapeutic product details

a. Product name _____

b. Code name _____

c. ***** Dosage form _____

d. ***** Route of Administration _____

e. ***** Type of Container _____

f. Is this product intended to be sterile? ☐ Yes ☐ No

g. Is this product radioactive? ☐ Yes ☐ No

h. Is this product of biological origin? ☐ Yes ☐ No

i. Is this product genetically engineered? ☐ Yes ☐ No

j. Date(s) of manufacture ☐ Yes ☐ No

k. Quantity manufactured _____

l. Indication/Condition _____

***** Refer to TGA approved Terminology

4. Special therapeutic products formulation details

Provide names and quantities of active and excipients.

Active ingredient(s) in special therapeutic product as detailed in section 3.

(Attach additional pages as required)

Active 1: Name _____

Strength: *Quantity _____ *Units _____

Active 2: Name _____

Strength: *Quantity _____ *Units _____

Active 3: Name _____

Strength: *Quantity _____ *Units _____

Active 4: Name _____

Strength: *Quantity _____ *Units _____

Excipient ingredient(s) in special therapeutic product as detailed in section 3.

(Attach additional pages as required)

Excipient 1: Name _____

Strength: *Quantity _____ *Units _____

Excipient 2: Name _____

Strength: *Quantity _____ *Units _____

Excipient 3: Name _____

Strength: *Quantity _____ *Units _____

Excipient 4: Name _____

Strength: *Quantity _____ *Units _____

Excipient 5: Name _____

Strength: *Quantity _____ *Units _____

Excipient 6: Name _____

Strength: *Quantity _____ *Units _____

* Refer to TGA approved Terminology

Please provide an estimate of the time taken to complete this form.

Include:

- The time actually spent reading the instructions, working on the question and obtaining the information.
- The time spent by all employees in collecting and providing this information.

_____ hrs _____ mins