|  |  |
| --- | --- |
| 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:

|  |  |
| --- | --- |
| * 1. Manufacturer's business name
 |       |
| * 1. Manufacturer's licence number
 |       |

* 1. 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

* 1. Name and Address of sponsoring hospital or public institution;

|  |
| --- |
|       |

* 1. Sponsor representative responsible for placing contract with manufacturer;

|  |  |
| --- | --- |
| Name (capitals) |       |
| Position in hospital or institution |       |
| Contact phone number |       |

## 3. Special therapeutic product details

|  |  |
| --- | --- |
| * 1. Product name
 |       |
| * 1. Code name
 |       |
| * 1. **\*** Dosage form
 |       |
| * 1. **\*** Route of Administration
 |       |
| * 1. **\*** Type of Container
 |       |
| * 1. Is this product intended to be sterile?
 | [ ]  Yes [ ]  No |
| * 1. Is this product radioactive?
 | [ ]  Yes [ ]  No |
| * 1. Is this product of biological origin?
 | [ ]  Yes [ ]  No |
| * 1. Is this product genetically engineered?
 | [ ]  Yes [ ]  No |
| * 1. Date(s) of manufacture
 | [ ]  Yes [ ]  No |
| * 1. Quantity manufactured
 |       |
| * 1. 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 |