



**APPLICATION FOR A MANUFACTURER'S
LICENCE FOR MEDICINAL PRODUCTS FOR HUMAN USE**

DEFINITIONS

Medicinal Product

“Medicinal product” means any substance or combination of substances presented for treating or preventing disease in human beings, as well as any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings

Qualified Person

The Qualified Person is that person responsible that each batch of medicinal products has been manufactured and checked in compliance with the laws in force and in accordance with the requirements of the marketing authorisation.

SECTION A:	GENERAL INFORMATION
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1a NAME OF PROPOSED LICENCE HOLDER

NOTE: Manufacturer's Licences are granted to persons who, in the course of a business, manufacture and/or assemble medicinal products. This can include :

- (i) A limited company
- (ii) An individual
- (iii) A group of individuals (i.e. a partnership)
- (iv) A body corporate
- (v) Any of the above with a trading style

1b LICENCE NUMBER (if known) _____

2a ADDRESS OF PROPOSED LICENCE HOLDER

2b ADDRESS FOR COMMUNICATIONS (if different from above)

3 LICENCE HOLDER CONTACT

Surname _____

Name _____

Telephone Number _____

Fax Number _____

4 PERIOD OF VALIDITY IF A LICENCE OF LESS THAN FIVE YEARS IS REQUIRED

SECTION B:	SITE INFORMATION
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PLEASE COMPLETE SEPARATE PAGES 5-21 FOR EACH SITE WHERE MANUFACTURING AND/OR ASSEMBLY ACTIVITIES TAKE PLACE

5a **SITE NAME** (if different from name of the licence applicant)

5b **SITE ADDRESS**

Has this site previously held any licence?

YES NO

If **YES** please attach details in Annex 1

6 **SITE CONTACT**

Surname _____

Name _____

Telephone Number _____

Fax Number _____



7 SITE USAGE

Describe below any other activities on this site which are not connected with licensed medicinal products.

8 ACTIVITIES AT SITE

Filling of sterile products is classified as manufacture not as assembly. Please tick as appropriate.

8.1 Sterile medicinal products8.1.1 *Aseptically prepared (list of dosage forms)*

8.1.1.1 Large volume liquids

8.1.1.2 Lyophilisates

8.1.1.3 Semi-solids

8.1.1.4 Small volume liquids

8.1.1.5 Solids and implants

8.1.1.6 Other aseptically prepared products

8.1.2 *Terminally sterilised (list of dosage forms)*

8.1.2.1 Large volume liquids

8.1.2.2 Semi-solids

8.1.2.3 Small volume liquids

8.1.2.4 Solids and implants

8.1.2.5 Other terminally sterilised prepared products

8.1.3 *Batch certification only***8.2 Non-sterile medicinal products**8.2.1 *Non-sterile products (list of dosage forms)*

8.2.1.1 Capsules, hard shell

8.2.1.2 Capsules, soft shell

- 8.2.1.3 Chewing gums
- 8.2.1.4 Impregnated matrices
- 8.2.1.5 Liquids for external use
- 8.2.1.6 Liquids for internal use
- 8.2.1.7 Medicinal gases
- 8.2.1.8 Other solid dosage forms
- 8.2.1.9 Pressurised preparations
- 8.2.1.10 Radionuclide generators
- 8.2.1.11 Semi-solids
- 8.2.1.12 Suppositories
- 8.2.1.13 Tablets
- 8.2.1.14 Transdermal patches
- 8.2.1.15 Other non-sterile medicinal product

8.2.2 *Batch certification only*

8.3 Biological medicinal products

8.3.1 *Biological medicinal products*

- 8.3.1.1 Blood products
- 8.3.1.2 Immunological products
- 8.3.1.3 Cell therapy products
- 8.3.1.4 Gene therapy products
- 8.3.1.5 Biotechnology products
- 8.3.1.6 Human or animal extracted products
- 8.3.1.7 Other biological medicinal products

8.3.2 Batch certification only (list of product types)

- 8.3.2.1 Blood products
- 8.3.2.2 Immunological products
- 8.3.2.3 Cell therapy products
- 8.3.2.4 Gene therapy products
- 8.3.2.5 Biotechnology products
- 8.3.2.6 Human or animal extracted products
- 8.3.2.7 Other biological medicinal products

8.4 Other products or manufacturing activity (*any other relevant manufacturing activity/ product type that is not covered above e.g. sterilisation of active substance, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing, etc.*)

8.4.1 *Manufacture of:*

8.4.1.1 Herbal products

8.4.1.2 Homeopathic products

8.4.1.3 Biological active starting materials

8.4.1.4 Other e.g intermediate products – please specify _____

8.4.2 *Sterilisation of active substances/excipients/finished product:*

8.4.2.1 Filtration

8.4.2.2 Dry heat

8.4.2.3 Moist heat

8.4.2.4 Chemical

8.4.2.5 Gamma irradiation

8.4.2.6 Electron beam

8.4.3 *Others*

8.5 Packaging only

8.5.1 *Primary packing*

8.5.1.1 Capsules, hard shell

8.5.1.2 Capsules, soft shell

8.5.1.3 Chewing gums

8.5.1.4 Impregnated matrices

8.5.1.5 Liquids for external use

8.5.1.6 Liquids for internal use

8.5.1.7 Medicinal gases

8.5.1.8 Other solid dosage forms

- 8.5.1.9 Pressurised preparations
- 8.5.1.10 Radionuclide generators
- 8.5.1.11 Semi-solids
- 8.5.1.12 Suppositories
- 8.5.1.13 Tablets
- 8.5.1.14 Transdermal patches
- 8.5.1.15 Other non-sterile medicinal products

8.5.2 *Secondary packing*

8.6 Quality control testing

- 1.6.1 Microbiological: sterility
- 1.6.2 Microbiological: non-sterility
- 1.6.3 Chemical/Physical
- 1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

Please tick **MA** (Manufacture and Assembly) or **MO** (Manufacture only) as appropriate for each category of production.

9 OTHER ACTIVE INGREDIENTS produced or handled and appearing in the finished product

[A] Potentially hazardous

- Penicillins
- Cephalosporins
- Hormones
- Cytostatics/cytotoxics
- Others, please specify below :

MA	MO

[B] Miscellaneous

- Radioactive materials
- Homoeopathics

MA	MO

10 OVERPRINTING AND OVERLABELLING ONLY

Filling of sterile products is classified as manufacture, not as assembly.

Please tick the boxes as appropriate.

- Overprinting of primary packaging
- Overprinting of secondary packaging
- Overlabelling of primary packaging
- Overlabelling of secondary packaging

11.1 ASSEMBLY ACTIVITIES

- Replacement of secondary packaging
- Replacement of secondary packaging with change in blister quantity in each box
- Removal of leaflet
- Insertion of leaflet
- Removal/Insertion of other items. Please specify _____

11.2 Dosage forms assembled

Liquid dosage forms	<input type="checkbox"/>
Semi-solid dosage forms (including creams and ointments)	<input type="checkbox"/>
Solid dosage forms including tablets and powders)	<input type="checkbox"/>
Medical gases	<input type="checkbox"/>

Other dosage forms (please specify below)

12 CONTRACT MANUFACTURE AND/OR ASSEMBLY
Relating to this site

Licence holder/applicant is contract acceptor (i.e. manufactures partially/wholly for others)	<input type="checkbox"/>
Licence holder/applicant is contract giver (i.e. uses external manufacturers for some products)	<input type="checkbox"/>

13 CONTRACT QUALITY CONTROL TESTING relating to this site

Licence holder/applicant is contract acceptor (i.e. carries out testing partially/wholly for others)	<input type="checkbox"/>
Licence holder/applicant is contract giver (i.e. uses external test houses for some/all testing)	<input type="checkbox"/>

14 OTHER DOSAGE FORMS MANUFACTURED AND/OR ASSEMBLED

Any other medicinal products not listed elsewhere in this application
Please specify:

MA	MO

15 OTHER SPECIFIC PROCESSES/ACTIVITIES

- Form/fill/seal processes
- Strip and/or blister packing
- Assembly of parallel-imported products
- Manufacture and/or assembly for export
- Sterilisation processes used (for products or components):
 - Steam or steam/air
 - Dry heat
 - Irradiation/electron beam
 - Biocidal gas/chemical

16 EQUIPMENT ON SITE

On a separate sheet of paper (attached to Annex 1) please describe the major items of equipment (approximately 1000 words) available for carrying out each stage of the manufacturing or assembly operations.

18 THE QUALIFIED PERSON

Please give the following details of the person/s who is to carry out the functions of the qualified person (QP). Please complete a separate page for each person.

Surname _____

Name _____

a Address for communications, if not permanently based at this site

b Qualifications

c Experience

d Professional Association

Please submit the candidate's curriculum vitae with this application (attached to Annex 1).

e If the QP is not a permanent employee of the company please give details of the time spent on this site

19 PERSON/S RESPONSIBLE FOR PRODUCTION

Please give the following details for the person/s with overall responsibility for production. Where this responsibility is split between more than one person, please complete a separate page for each person, and give details of each person's area of responsibility.

Surname _____

Name _____

a Qualifications

b Experience

c Address for communications, if not permanently based at this site

d Name and function of the person(s) to whom he reports

e Area of responsibility

20 PERSON/S RESPONSIBLE FOR QUALITY CONTROL

Please give the following details of the person/s with overall responsibility for quality control. Where this responsibility is split between more than one person, please complete a separate page for each person, and give details of each person's area of responsibility.

Surname _____

Name _____

a Qualifications

b Experience

c Address for communications, if not permanently based at this site

d Name and function of the person(s) to whom he reports

e Area of responsibility

21 PERSON/S IN CHARGE OF ANIMALS

Please give the following details of the person/s in charge of animals. Please complete a separate page for each person.

Surname _____

Name _____

a Address for communications, if not permanently based at this site

b Name and function of the person to whom he reports

22 PERSON/S RESPONSIBLE FOR LIVING TISSUE CULTURES

Please give the following details of the person/s responsible for living tissue cultures.
Please complete a separate page for each person.

Surname _____

Name _____

a Address for communications, if not permanently based at this site

b Qualifications

c Name and function of the person to whom he reports

23 ANALYTICAL TESTING SITES - please complete a separate sheet

For each site

This refers to the site/s at which analysis or testing of starting materials, packaging materials, intermediate, bulk and finished products takes place. This may also include one or more of the sites where manufacture and/or assembly also takes place.

SITE NAME

SITE ADDRESS

Testing activities at this site:

Chemical/physical

Microbiological/sterility/environmental/LAL

Pyrogens (rabbit method)

Bioassay

Other (please specify):

24 STORAGE AND HANDLING OF MATERIALS

PLEASE COMPLETE SEPARATE PAGES 22-24 FOR EACH SITE FROM WHICH STORAGE, DISTRIBUTION OR OTHER ACTIVITIES TAKE PLACE

25.1 SITE NAME (if different from name of the licence applicant)

25.2 SITE ADDRESS

25.3 SITE CONTACT

Surname _____

Name _____

Telephone Number _____

Fax Number _____



25.4 SITE USAGE

Is this site used for distribution only
(i.e. onward dispatch of ready packed orders)

Yes

No

Or is this site used for other purposes

Yes

No

Please specify these other purposes (e.g. order receipt, invoicing,
Assembly/picking of orders, handling of goods returned from customers).

25.5 Facilities on site

On a separate sheet of paper please provide a brief description (approximately 500 words) of the facilities available for the storage and distribution of medicinal products.

25.6 Equipment on site

On a separate sheet of paper (attached to Annex 1), please describe the major items of equipment (approximately 500 words), other than transport available for the storage and distribution of medicinal products.

In particular please provide details of any refrigeration equipment available.

SECTION C:**DECLARATION**

I/We apply for the grant of a Manufacturer's Licence to the proposed holder named in this application form in respect of the activities to which the application refers.

1. The licence to be subject to all the Standard Provisions applicable to Manufacturer's Licences under regulations for the time being in force under
2. The manufacturing operations are to be only in accordance with the information set out in the application or furnished in connection with it.
3. I/We declare that we hold the relevant product licences or are named on the relevant product licences as manufacturers and/or assemblers relating to the medicinal products we wish to manufacture and/or assemble pursuant to this application.
4. To the best of my knowledge and belief the particulars I have given in this form are correct and complete.

Signed :

Name :
CAPITALS)

_____ (BLOCK

Date :

State capacity in which signed :

ANNEX 1: DOCUMENTS TO BE ATTACHED WITH APPLICATION

A) Site Licence	<input type="checkbox"/>
B) Description of the major items of equipment (Storage and handling of materials)	<input type="checkbox"/>
C) Curriculum vitae of Qualified Person	<input type="checkbox"/>
D) Description of the major items of equipment (Storage and handling of materials)	<input type="checkbox"/>