e-form

Application for a GMP Certificate

SECTION A: GENERAL INFORMATION

1 DETAILS OF APPLICANT

1.1 If Individual:

Name:	
Surname:	
National ID or passport number:	

1.2 If Company:

Name:	
Company registration number:	

Legal and judicial representative of company:

Name:	
Surname:	
National ID or passport number:	

This document is not valid without all the number of pages specified.

2 LEGAL ADDRESS OF APPLICANT

Building Name/No.:	
Street:	
Locality:	
Postcode:	
Country:	

If individual – address on national ID card.
If company – address registered with national competent authority.

SECTION B: SITE INFORMATION

3 SITE DETAILS:

3.1 Name of proposed manufacturer:	

3.2 Site Address of proposed manufacturer:

Building Name/No.:	
Street:	
Locality:	
Postcode:	
Country:	

3.3 Site contact (if different from 3):

Name:	
Surname:	
Telephone number:	
Mobile number:	
Email-address:	

3.4 Site Usage [tick as appropriate]:

Indicate any other activities on this site which are not associated with medicinal products or investigational medicinal products:

- ☐ Manufacture/importation/distribution/holding of medical devices.
- ☐ Manufacture/importation/distribution/holding of food supplements.
- ☐ Manufacture/importation/distribution/holding of veterinary medicinal products.
- ☐ Manufacture/importation/distribution/holding of cosmetic products.

4 ACTIVITIES AT SITE

Tick activities to be held at the site:

A. Manufacturing of Medicinal Products:

1.1 Sterile products:

1.1.1 Aseptically prepared (list of dosage forms):

- [ ] **1.1.1.1 Large volume liquids.**
- [ ] **1.1.1.2 Lyophilisates.**
- [ ] **1.1.1.3 Semi-solids.**
- [ ] **1.1.1.4 Small volume liquids.**
- [ ] **1.1.1.5 Solids and implants.**
- [ ] **1.1.1.6 Other aseptically prepared products.**

Please specify

1.1.2 Terminally sterilized (list of dosage forms):

- [ ] **1.1.2.1 Large volume liquids.**
- [ ] **1.1.2.2 Semi-solids.**
- [ ] **1.1.2.3 Small volume liquids.**
- [ ] **1.1.2.4 Solids and implants.**
- [ ] **1.1.2.5 Other aseptically prepared products:**

Please specify

1.2 Non-sterile products

1.2.1 Non-sterile products (list of dosage forms):

1.2.1.1 Capsules, hard shell.

1.2.1.2 Capsules, soft shell.

1.2.1.3 Chewing gums.

1.2.1.4 Impregnated matrices.

1.2.1.5 Liquids for external use.

1.2.1.6 Liquids for internal use.

1.2.1.7 Medicinal gases.

1.2.1.8 Other solid dosage forms:

Please specify

1.2.1.9 Pressurised preparations.

1.2.1.10 Radionuclide generators.

1.2.1.11 Semi-solids.

1.2.1.12 Suppositories.

1.2.1.13 Tablets.

1.2.1.14 Transdermal patches.

1.2.1.15 Intraruminal devices.

1.2.1.16 Veterinary premixes.

1.2.1.17 Other non-sterile medicinal product:

Please specify

1.3 Biological medicinal products

1.3.1 Biological medicinal products:

1.3.1.1 Immunological products.

1.3.1.2 Cell therapy products.

1.3.1.3 Gene therapy products.

1.3.1.4 Biotechnology products.

1.3.1.5 Human or animal extracted products.

1.3.1.6 Other biological medicinal products excluding blood products:

Please specify

1.4 Other products or manufacturing activity

1.4.1 Manufacture of:

- [ ] **1.4.1.1 Herbal products.**
- [ ] **1.4.1.2 Homeopathic products.**
- [ ] **1.4.1.3 Biological active starting materials.**
- [ ] **1.4.1.4 Other:**

Please specify

1.4.2 Sterilisation of active substances/excipients/finished product:

- [ ] **1.4.2.1 Filtration.**
- [ ] **1.4.2.2 Dry heat.**
- [ ] **1.4.2.3 Moist heat.**
- [ ] **1.4.2.4 Chemical.**
- [ ] **1.4.2.5 Gamma irradiation.**
- [ ] **1.4.2.6 Electron beam.**
- [ ] **1.4.3 Others:**

Please specify

1.5 Packaging only

1.5.1 Primary packing:

- [ ] **1.5.1.1 Capsules, hard shell.**
- [ ] **1.5.1.2 Capsules, soft shell.**
- [ ] **1.5.1.3 Chewing gums.**
- [ ] **1.5.1.4 Impregnated matrices.**
- [ ] **1.5.1.5 Liquids for external use.**
- [ ] **1.5.1.6 Liquids for internal use.**
- [ ] **1.5.1.7 Medicinal gases.**
- [ ] **1.5.1.8 Other solid dosage forms:**

Please specify

- [ ] **1.5.1.9 Pressurised preparations.**
- [ ] **1.5.1.10 Radionuclide generators.**
- [ ] **1.5.1.11 Semi-solids.**
- [ ] **1.5.1.12 Suppositories.**
- [ ] **1.5.1.13 Tablets.**

1.5.1.14 Transdermal patches.

1.5.1.15 Intraluminal devices.

1.5.1.17 Other non-sterile medicinal products:

Please specify

1.5.2 Secondary packing.

1.6 Quality control testing:

1.6.1 Microbiological: sterility.

1.6.2 Microbiological: non-sterility.

1.6.3 Chemical/Physical.

1.6.4 Biological.

Any clarifying remarks related to the scope of these manufacturing operations:
(e.g. name of product in case of product-specific inspections):

B. Manufacturing of Active Pharmaceutical Products

2.1 Manufacture of Active Substance by Chemical Synthesis:

2.1.1 Manufacture of active substance intermediates.

2.1.2 Manufacture of crude active substance.

2.1.3 Salt formation/Purification steps (e.g. crystallisation):

Please specify

2.1.4 Other:

Please specify

2.2 Extraction of Active Substance from Natural Sources:

2.2.1 Extraction of substance from plant source.

2.2.2 Extraction of substance from animal source.

2.2.3 Extraction of substance from human source.

2.2.4 Extraction of substance from mineral source.

2.2.5 Modification of extracted substance (specify source 1, 2, 3, 4):

Source 1 Source 2 Source 3 Source 4

2.2.6 Purification of extracted substance (specify source 1,2,3,4):

Source 1 Source 2 Source 3 Source 4

2.2.7 Other:

Please specify

2.3 Manufacture of Active Substance using Biological Processes:

2.3.1 Fermentation.

2.3.2 Cell Culture (e.g. mammalian/bacterial):

Please specify cell type

2.3.3 Isolation/Purification.

2.3.4 Modification.

2.3.5 Other:

Please specify

2.4 Manufacture of sterile active substance (sections 3.1, 3.2, 3.3 to be completed as applicable):

2.4.1 Aseptically prepared.

2.4.2 Terminally sterilised.

2.5 General Finishing Steps:

2.5.1 Physical processing steps (e.g. drying, milling / micronisation, sieving):

Please specify

2.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance).

2.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container). (This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance).

2.5.4 Other (for operations not described above):

Please specify

2.6 Quality Control Testing:

2.6.1 Physical/Chemical testing.

2.6.2 Microbiological testing (excluding sterility testing).

2.6.3 Microbiological testing (including sterility testing).

2.6.4 Biological Testing.

2.7 OTHER ACTIVITIES – ACTIVE SUBSTANCES:

Please specify

Any clarifying remarks related to the scope of these manufacturing operations:

C. Manufacturing of Investigational Medicinal Products

1 .1 Sterile investigational medicinal products:

1.1.1 Aseptically prepared (list of dosage forms):

1.1.1.1 Large volume liquids.

1.1.1.2 Lyophilisates.

1.1.1.3 Semi-solids.

1.1.1.4 Small volume liquids.

1.1.1.5 Solids and implants.

1.1.1.6 Other aseptically prepared products (please specify):

Please specify

1.1.2 Terminally sterilised (list of dosage forms):

1.1.2.1 Large volume liquids.

1.1.2.2 Semi-solids.

1.1.2.3 Small volume liquids.

1.1.2.4 Solids and implants.

1.1.2.5 Other terminally sterilised prepared products:

Please specify

1.2 Non-sterile investigational medicinal products:

1.2.1 Non-sterile products (list of dosage forms):

1.2.1.1 Capsules, hard shell.

1.2.1.2 Capsules, soft shell.

1.2.1.3 Chewing gums.

1.2.1.4 Impregnated matrices.

1.2.1.5 Liquids for external use.

1.2.1.6 Liquids for internal use.

1.2.1.7 Medicinal gases.

1.2.1.8 Other solid dosage forms:

Please specify

1.2.1.9 Pressurised preparations.

1.2.1.10 Radionuclide generators.

1.2.1.11 Semi-solids.

1.2.1.12 Suppositories.

1.2.1.13 Tablets.

1.2.1.14 Transdermal patches.

1.2.1.15 Other non-sterile medicinal product:

Please specify

1.3 Biological investigational medicinal products:

1.3.1 Biological medicinal products (list of product types):

1.3.1.1 Immunological products.

1.3.1.2 Cell therapy products.

1.3.1.3 Gene therapy products.

1.3.1.4 Biotechnology products.

1.3.1.5 Human or animal extracted products.

1.3.1.6 Other biological medicinal products excluding blood products:

Please specify

1.4 Other investigational medicinal products or manufacturing activity:

1.4.1 Manufacture of:

1.4.1.1 Herbal products.

1.4.1.2 Homeopathic products.

1.4.1.3 Biological active starting materials.

1.4.1.4 Other (please specify):

1.4.2 Sterilisation of active substances/excipients/finished product:

1.4.2.1 Filtration.

1.4.2.2 Dry heat.

1.4.2.3 Moist heat.

1.4.2.4 Chemical.

1.4.2.5 Gamma irradiation.

1.4.2.6 Electron beam.

1.4.3 Others (please specify):

1.5 Packaging only:

1.5.1 Primary packing:

1.5.1.1 Capsules, hard shell.

1.5.1.2 Capsules, soft shell.

1.5.1.3 Chewing gums.

1.5.1.4 Impregnated matrices.

1.5.1.5 Liquids for external use.

1.5.1.6 Liquids for internal use.

1.5.1.7 Medicinal gases.

1.5.1.8 Other solid dosage forms (please specify):

1.5.1.9 Pressurised preparations.

1.5.1.10 Radionuclide generators.

1.5.1.11 Semi-solids.

1.5.1.12 Suppositories.

1.5.1.13 Tablets.

1.5.1.14 Transdermal patches.

1.5.1.15 Other non-sterile medicinal products (please specify):

1.5.2 Secondary packing.

1.6 Quality control testing:

1.6.1 Microbiological: sterility.

1.6.2 Microbiological: non-sterility.

1.6.3 Chemical/Physical.

1.6.4 Biological.

Any clarifying remarks related to the scope of these manufacturing operations:

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

[A] Potentially hazardous:

Penicillins

Manufacture Assembly

Cephalosporins

Manufacture Assembly

Hormones

Manufacture Assembly

Cytostatics/cytotoxics

Manufacture Assembly

Others (please specify):

[B] Miscellaneous:

Radioactive materials

Manufacture Assembly

Homoeopathics

Manufacture Assembly

6 INVESTIGATIONAL MEDICINAL PRODUCTS ONLY

If you propose to manufacture investigational medicinal products, indicate which of the following activities you intend to conduct (tick as appropriate):

- ☐ **Bulk products will be purchased or otherwise sourced.**
- ☐ **Intermediate products will be purchased or otherwise sourced.**
- ☐ **Finished products will be purchased or otherwise sourced.**
- ☐ **Blinding of investigational medicinal product.**

If none of the above have been ticked, please state who will be responsible for purchasing/sourcing (eg. Company Name/Sponsor):

7 CONTRACT MANUFACTURE AND/OR ASSEMBLY [tick if applicable]

☐ Licence holder/applicant is contract giver (i.e. uses external manufacturers for some products).

List contract manufacturers/assemblers (as on contractor's GMP certificate):

Name of proposed contractor:

Site of proposed manufacturer:

Building Name/No.:

Street:

Locality:

Postcode:

Country:

Print this section and fill in additional copies if necessary.

Number of copies attached:

8 CONTRACT QUALITY CONTROL TESTING (including testing for stability studies) [tick if applicable]

☐ Licence holder/applicant is contract giver (i.e. uses external test houses for some/all testing).

List contract laboratories (as on contractor's GMP certificate):

Name of proposed laboratory:

Site of proposed manufacturer:

Building Name/No.:

Street:

Locality:

Postcode:

Country:

Testing activities at this site:

☐ Chemical/physical.

☐ Microbiological/sterility/environmental/LAL.

☐ Pyrogens (rabbit method).

☐ Bioassay.

☐ Other (please specify):

Print this section and fill in additional copies if necessary.

Number of copies attached:

This document is not valid without all the number of pages specified.

9 OTHER SPECIFIC PROCESSES/ACTIVITIES (tick as applicable)

- [ ] Form/fill/seal processes.
- [ ] Strip and/or blister packing.
- [ ] Sterilisation processes used (for products or components):
- [ ] Steam or air.
- [ ] Dry heat.
- [ ] Irradiation/electron beam.
- [ ] Biocidal gas/chemical.

I confirm that the above particulars are to the best of my knowledge and belief accurate and true.

Signed (applicant):

Date:

This document is not valid without all the number of pages specified.

10 PERSON/S RESPONSIBLE FOR PRODUCTION

Please give the following details for the person with overall responsibility for production.

Name:

Surname:

Qualifications:

Experience:

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

11 PERSON/S RESPONSIBLE FOR QUALITY CONTROL

Please give the following details of the person/s with overall responsibility for quality control.

Name:

Surname:

Qualifications:

Experience:

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

SECTION C: APPLICANT'S DECLARATION

I/We apply for the issue of a GMP certificate to the site named in this application form in respect of the activities to which the application refers.

1. The GMP certificate to be subject to all the Standard Provisions applicable to GMP certificates under regulations for the time being in force.

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. To the best of my/our knowledge and belief the particulars I/we have given in this form are correct and complete.

Signed:

Name:

Surname:

Date:

This document is not valid without all the number of pages specified.

ANNEX 1: DOCUMENTS TO BE ATTACHED TO APPLICATION

A) Site Master File.

B) Curriculum vitae of Production Manager.

C) Curriculum vitae of Quality Control Manager.

D) Certificate of Registration issued by the competent authority (for private & public companies only).

This document is not valid without all the number of pages specified.