MALTA MEDICINES AUTHORITY

IN001-12 APPENDIX 3 VERSION 1

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 _____

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 _____

E-mail 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 the activities to be held at the site:

A. Manufacturing Operations 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 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 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
- ☐ 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 Blood Products
- ☐ 1.3.1.2 Immunological products
- ☐ 1.3.1.3 Cell therapy products
- ☐ 1.3.1.4 Gene therapy products
- ☐ 1.3.1.5 Biotechnology products
- ☐ 1.3.1.6 Human or animal extracted product
- ☐ 1.3.1.7 Tissue Engineered Products
- ☐ 1.3.1.8 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 Intraruminal devices
- ☐ 1.5.1.16 Veterinary premixes
- ☐ 1.5.1.17 Other non-sterile medicinal products (please specify):

☐ 1.5.2 *Secondary packing*

1.6 Quality control testing

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

Any additional comments related to the scope of the manufacturing operations *(e.g. name of product in case of product-specific inspections):*

_____

_____

B. Manufacturing of Investigational Medicinal Products

2 .1 Sterile investigational medicinal products

2.1.1 *Aseptically prepared (list of dosage forms)*

- □ 2.1.1.1 Large volume liquids
- □ 2.1.1.2 Lyophilisates
- □ 2.1.1.3 Semi-solids
- □ 2.1.1.4 Small volume liquids
- □ 2.1.1.5 Solids and implants
- □ 2.1.1.6 Other aseptically prepared products (please specify):

2.1.2 *Terminally sterilised (list of dosage forms)*

- □ 2.1.2.1 Large volume liquids
- □ 2.1.2.2 Semi-solids
- □ 2.1.2.3 Small volume liquids
- □ 2.1.2.4 Solids and implants
- □ 2.1.2.5 Other terminally sterilised prepared products (please specify):

2.2 Non-sterile investigational medicinal products

2.2.1 *Non-sterile products (list of dosage forms)*

- □ 2.2.1.1 Capsules, hard shell
- □ 2.2.1.2 Capsules, soft shell
- □ 2.2.1.3 Chewing gums
- □ 2.2.1.4 Impregnated matrices
- □ 2.2.1.5 Liquids for external use
- □ 2.2.1.6 Liquids for internal use
- □ 2.2.1.7 Medicinal gases
- □ 2.2.1.8 Other solid dosage forms
- □ 2.2.1.9 Pressurised preparations
- □ 2.2.1.10 Radionuclide generators
- □ 2.2.1.11 Semi-solids
- □ 2.2.1.12 Suppositories
- □ 2.2.1.13 Tablets
- □ 2.2.1.14 Transdermal patches
- □ 2.2.1.15 Other non-sterile medicinal product (please specify):

2.3 Biological investigational medicinal products

2.3.1 *Biological medicinal products (list of product types)*

- □ 2.3.1.2 Immunological products
- □ 2.3.1.3 Cell therapy products
- □ 2.3.1.4 Gene therapy products
- □ 2.3.1.5 Biotechnology products
- □ 2.3.1.6 Human or animal extracted products
- □ 2.3.1.7 Other biological medicinal products excluding blood products (please specify):

2.4 Other investigational medicinal products or manufacturing activity

2.4.1 *Manufacture of:*

- □ 2.4.1.1 Herbal products
- □ 2.4.1.2 Homeopathic products
- □ 2.4.1.3 Biological active starting materials
- □ 2.4.1.4 Other (please specify):

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

- □ 2.4.2.1 Filtration
- □ 2.4.2.2 Dry heat
- □ 2.4.2.3 Moist heat
- □ 2.4.2.4 Chemical
- □ 2.4.2.5 Gamma irradiation
- □ 2.4.2.6 Electron beam

□ 2.4.3 *Others* (please specify):

2.5 Packaging only

2.5.1 *Primary packing*

- □ 2.5.1.1 Capsules, hard shell
- □ 2.5.1.2 Capsules, soft shell
- □ 2.5.1.3 Chewing gums
- □ 2.5.1.4 Impregnated matrices
- □ 2.5.1.5 Liquids for external use
- □ 2.5.1.6 Liquids for internal use
- □ 2.5.1.7 Medicinal gases
- □ 2.5.1.8 Other solid dosage forms
- □ 2.5.1.9 Pressurised preparations
- □ 2.5.1.10 Radionuclide generators

- ☐ 2.5.1.11 Semi-solids
- ☐ 2.5.1.12 Suppositories
- ☐ 2.5.1.13 Tablets
- ☐ 2.5.1.14 Transdermal patches
- ☐ 2.5.1.15 Other non-sterile medicinal products (please specify):

☐ 2.5.2 *Secondary packing*

2.6 Quality control testing

- ☐ 2.6.1 Microbiological: sterility
- ☐ 2.6.2 Microbiological: non-sterility
- ☐ 2.6.3 Chemical/Physical
- ☐ 2.6.4 Biological

Any additional comments related to the scope of these manufacturing operations:

_____

_____

C. Manufacturing of Active Pharmaceutical Products

3.1 Manufacture of Active Substance by Chemical Synthesis

- ☐ 3.1.1 Manufacture of active substance intermediates
- ☐ 3.1.2 Manufacture of crude active substance
- ☐ 3.1.3 Salt formation/Purification steps : (free text) (e.g. crystallisation)
- ☐ 3.1.4 Other (free text)

3.2 Extraction of Active Substance from Natural Sources

- ☐ 3.2.1 Extraction of substance from plant source
- ☐ 3.2.2 Extraction of substance from animal source
- ☐ 3.2.3 Extraction of substance from human source
- ☐ 3.2.4 Extraction of substance from mineral source
- ☐ 3.2.5 Modification of extracted substance (specify source 1,2,3,4)
- ☐ 3.2.6 Purification of extracted substance (specify source 1,2,3,4)
- ☐ 3.2.7 Other (free text)

3.3 Manufacture of Active Substance using Biological Processes

- ☐ 3.3.1 Fermentation
- ☐ 3.3.2 Cell Culture (specify cell type) (e.g. mammalian/bacterial)
- ☐ 3.3.3 Isolation/Purification
- ☐ 3.3.4 Modification
- ☐ 3.3.5 Other (free text)

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

- ☐ 3.4.1 Aseptically prepared
- ☐ 3.4.2 Terminally sterilised

3.5 General Finishing Steps

- ☐ 3.5.1 Physical processing steps (specify) (e.g. drying, milling / micronisation, sieving)
- ☐ 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
- ☐ 3.5.3 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)
- ☐ 3.5.4 Other (free tex) (for operations not described above)

3.6 Quality Control Testing

- ☐ 3.6.1 Physical/Chemical testing
- ☐ 3.6.2 Microbiological testing (excluding sterility testing)
- ☐ 3.6.3 Microbiological testing (including sterility testing)
- ☐ 3.6.4 Biological Testing

3.7 OTHER ACTIVITIES – ACTIVE SUBSTANCES

(please specify) _____

Additional comments 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 (1):

_____

Site Address of proposed manufacturer:

Building Name/No. _____

Street _____

Locality _____

Postcode _____

Country _____

[Fill in additional copies of this sheet if necessary]

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 Address of proposed laboratory:

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: _____)

[Fill in additional copies of this sheet if necessary]

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 steam/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:

10 PERSON/S RESPONSIBLE FOR PRODUCTION

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

Surname _____

Name _____

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.

Surname _____

Name _____

Qualifications

Experience

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

12. INFORMATION RE PRODUCTS ON THE EUROPEAN UNION MARKET

(This section is applicable only to intermediate and finished dosage forms manufacturers located outside of the European Union)

Does the site have any medicinal products on the EU market? _YES / NO

If yes, list the name, marketing authorisation number/s and country/ies where marketed for each product. (Can use a separate page annexed to the application)

_____
_____
_____
_____

If yes, where are the products being imported and batch released in the EU? Name of country/ies:_____
_____

Does the site have any ongoing marketing authorisation application procedures for medicinal products to be placed on the EU market? YES / NO

If yes, list the name, marketing authorisation application number/s and country/ies where marketing authorisation applications were lodged for each product. (Can use a separate page annexed to the application)

_____
_____
_____
_____

If yes, in which EU member state is the importation and batch release site situated as applied for in the marketing authorisation application? Name of countries:

_____
_____

What is the total number of employees employed by the company (full time and part-time) and total number of employees engaged on contract for service basis?

_____

_____

Does the company have any specific restrictions for who can enter production areas, e.g., pregnant women, due to the nature of some products handled at the site? YES / NO

If yes, list categories of restrictions, why and due to which products/product category:

_____

_____

_____

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 : _____

Surname: _____

Name: _____

Date : _____

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)