EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medical products: quality, safety, innovation

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Union format for a GMP certificate

Title	**Union format for a GMP certificate**
Date of adoption	May 2023
Date of entry into force	1 January 2024
Supersedes	Version published in April 2022
Reason for revision	Modifications were introduced as a result of the entry into application of Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC and Regulation (EU) 2019/5 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
Notes	Not applicable
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Document version	1

Union format for a GMP certificate

(LETTERHEAD OF COMPETENT AUTHORITY)

Certificate No: _ _ _/_ _ _/_ _ _

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER[1],[2]

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC or Art. 94(1) of Regulation (EU) 2019/6 or Article 63(4) of Regulation (EU) No 536/2014*

or

Issued under the provisions of the Mutual Recognition Agreement between the European Union and *[MRA Partner].**

The competent authority of .....*[Member State]* confirms the following:

The manufacturer .....

Manufacturer's alternative name .....

Site address.....

Additional details on units inspected.....

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ..... in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

....., or Art. 88 of Regulation (EU) 2019/6 or Art. 61(1) of Regulation (EU) No 536/2014*

or

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2)/19(3) of Regulation (EC) 726/2004*, or Art. 94(4)/123 of Regulation (EU) 2019/6 or Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation:

..... *

*and/or**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:

.....* and/or Art. 123 (1) to (6) of Regulation (EU) 2019/6*

*and/or**

Is an excipient manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC* transposed in the following national legislation:

..... *

*and/or**

Is an investigational medicinal product manufacturer that has been inspected in accordance with Art. 63 of Regulation (EU) No 536/2014 and/or GMP for investigational medicinal products for veterinary use in accordance with the following national legislation:

..... *

or

Other (please specify)..... *

[1] The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 94(1) of Regulation (EU) 2019/6 is also applicable to importers.

[2] Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on …../……/.....*[date]*, it is considered that it complies with the Good Manufacturing Practice requirements[1] referred to in the Agreement of Mutual Recognition between the European Union and *[MRA partner]/* The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569, as appropriate / The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC[3]/ The principles of GMP for active substances[3] referred to in Article 47 of Directive 2001/83/EC / Article 93(2) of Regulation 2019/6.* an appropriate level of GMP as referred to in Article 46(f) of Directive 2001/83/EC and Art. 93(1)(j) of Regulation (EU) 2019/6.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/).

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

Part 2

☐ Human Medicinal Products*
☐ Veterinary Medicinal Products*
☐ Human Investigational Medicinal Products*

1 MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS*	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following 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 <free text>
	1.1.2 Terminally sterilised (processing operations for the following 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 <free text>
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following 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 <free text>
	1.2.2 Batch certification

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 products 1.3.1.7 Tissue engineered products 1.3.1.8 Other <free text>
	1.3.2 Batch certification (list of product types) 1.3.2.1 Blood products 1.3.2.2 Immunological products 1.3.2.3 Cell therapy products 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products 1.3.2.6 Human or animal extracted products 1.3.2.7 Tissue engineered products 1.3.2.8 Other <free text>
1.4	**Other products or processing activity**
	1.4.1 Manufacture of: 1.4.1.1 Herbal products 1.4.1.2 Homoeopathic products 1.4.1.3 Other <free text >
	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 <free text>
1.5	**Packaging**
	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 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 <free text>
	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

2 IMPORTATION OF MEDICINAL PRODUCTS*	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
	2.1.4 Biological
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile Products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.1 Blood products 2.2.3.2 Immunological products 2.2.3.3 Cell therapy products 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products 2.2.3.6 Human or animal extracted products 2.2.3.7 Tissue engineered products 2.2.3.8 Other <free text>
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing
	2.3.3. Biological active substance
	2.3.4 Other <free text>

Any restrictions or clarifying remarks related to the scope of this certificate*:

.....

.....

3 MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance(s):	
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 text> (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*

4. OTHER ACTIVITIES - ACTIVE SUBSTANCES

<free text>

Any restrictions or clarifying remarks related to the scope of this certificate*:

.....

.....

……./……./……. *[date]* .....

Name and signature of the authorised person of the Competent

Authority of *[country]*[3]

.....

.....

[name, title, national authority, phone number and e-mail]

(*): delete that which does not apply

[3] The signature, date and contact details should appear on each page of the certificate.