(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. 80(5) of Directive 2001/82/EC or Art. 15 of Directive 2001/20/EC*

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 .....

Site address.....

.....

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ..... in accordance with Art. 40 of Directive 2001/83/EC/ Art. 44 of Directive 2001/82/EC/ Art. 13 of Directive 2001/20/EC* transposed in the following national legislation:

..... *

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)/33(2)/19(3)/44(3)* of Regulation (EC) 726/2004* or Art. 111(4) of Directive 2001/83/EC/Art. 80(4) of Directive 2001/82/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/ Art. 80(1) of Directive 2001/82/EC* transposed in the following national legislation:

..... *

*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:

..... *

or

Other (please specify): .....*

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 2003/94/EC[3]/Directive 91/412/EEC[3]/The principles of GMP for active substances[3] referred to in Article 47 of Directive 2001/83/EC / Article 51 of Directive 2001/82/EC.* an appropriate level of GMP as referred to in Article 46(f) of Directive 2001/83/EC

[1] The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, is also applicable to importers.
[2] Guidance on the interpretation of this template can be found in the Help menu of EudraGMP database.
[3] These requirements fulfil the GMP recommendations of WHO.

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.

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 EudraGMP. 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 Lyophillsates 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 <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 terminally sterilised prepared products <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 non-sterile medicinal product <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 biological medicinal products <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 biological medicinal products <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 non-sterile medicinal products <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 biological medicinal products <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 Other <free text>

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

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