Health and Youth Care Inspectorate – Pharmaceutical Affairs

CERTIFICATE NUMBER: ***NL/H 18/2008094***

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 as amended

The competent authority of Netherlands confirms the following:
The manufacturer: ***Astellas Pharma Europe B.V.***
Site address: ***Hogemaat 2, MEPPEL, 7942JG, Netherlands***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***108513 F*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-09-20*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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 EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	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 1.2.1.5 Liquids for external use 1.2.1.13 Tablets Special Requirements 1 B-lactam Antibiotics 1.2.1.17 Other: powders and granulates(en)
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.13 Tablets Special Requirements 1 B-lactam Antibiotics 1.5.1.17 Other non-sterile medicinal products: powders(en)
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical*

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
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Any restrictions related to the scope of this certificate :

Building	Room	Line/equipment	QC testing	Products
PEN Plant	***All rooms in PEN plant***	***All equipment in PEN-plant***	***All QC tests performed in PEN plant***	***All beta-lactam antibiotics (tablets)***
NON-PEN plant	***All rooms in NON-PEN plant***	***All equipment in NON-PEN plant***	***All QC tests performed in NON-PEN plant***	***All products listed in part 2 except for beta-lactam products***

2018-11-22

Name and signature of the authorised person of the Competent Authority of Netherlands

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: THE NETHERLANDS
   This public document
2. has been signed by **ing. M. van Berlo**
3. acting in the capacity of Inspector for Medical Technology of the Ministry of Public Health, Welfare and Sports
4. bears the seal/stamp of aforesaid Ministery

Certified

5. in Den Haag
6. on 14-12-2018
7. by the registrar of the district court of Den Haag
8. no. 2018-13330

9. Seal/stamp:

10. Signature:

C.D. van de Ree