Health and Youth Care Inspectorate – Pharmaceutical Products

CERTIFICATE NUMBER: ***NL/H 22/2041220***

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: ***Abbott Biologicals B.V.***
Site address: ***Veerweg 12, Olst, 8121 AA, Netherlands***
OMS Organisation Id. / OMS Location Id.: ***ORG-100000485*** / ***LOC-100007112***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***108926 F*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-04-20***, 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 Art. 111(5) of Directive 2001/83/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.*

Digitally signed by Dicusar Vladimir
Date: 2024.02.05 13:16:24 EET
Reason: MoldSign Signature
Location: Moldova

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use 1.2.1.13 Tablets Special Requirements 7 Other: hormones(en) 1.2.1.17 Other: granules in bulk for oral administration(en)
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products 1.3.1.6 Human or animal extracted products
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.6 Human or animal extracted products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use 1.5.1.13 Tablets Special Requirements 7 Other: hormones(en)
	1.5.2 Secondary packaging

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

2022-06-30

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

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Confidential
Health and Youth Care Inspectorate – Pharmaceutical Products
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