Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2020/074***

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

Part 1

Issued following an inspection in accordance with :

The competent authority of Belgium confirms the following:
The manufacturer: ***Wyeth BioPharma Division of Wyeth Pharmaceuticals, Inc. a Subsidiary of Pfizer,Inc.***
Site address: ***1 Burtt Road Andover, Andover, Massachusetts, 01810, United States***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2) of Regulation (EC) 726/2004.

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

Other
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-12-02***, it is considered that it complies with:

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC.

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

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

Manufacture of active substance. Names of substances subject to inspection:
BNT162B2 DRUG SUBSTANCE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance:BNT162B2 DRUG SUBSTANCE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other: In vitro transcription, Purification by Ultrafiltration/Diafiltration, Final filtration and dispens
3.5	**General Finishing Steps**
	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)

4. Other Activities - Active Substances:
Limited to the DS manufacturing of the Covid-19 mRNA Vaccine BioNTech in the Andover Clinical Manufacturing Facility (Building E)

Clarifying remarks (for public users)

Inspection restricted to the Covid-19 mRNA Vaccine BioNTech activities

2020-12-15

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

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