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Regierungspraesidium Tuebingen, Leitstelle Arzneimittelueberwachung Baden-Wuerttemberg

CERTIFICATE NUMBER: ***DE_BW_01_GMP_2019_0123***

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

Part 1

Issued following an inspection in accordance with :
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Germany confirms the following:
The manufacturer: ***Boehringer Ingelheim Pharma GmbH & Co. KG***
Site address: ***Birkendorfer Str. 65, Biberach a.d.R., Baden-Wuerttemberg, 88397, Germany***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_BW_01_MIA_2017_1040*** in accordance with Art. 44 of Directive 2001/82/EC .

Is an active substance manufacturer that has been inspected in accordance with Art. 80(1) of Directive 2001/82/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-05-23*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC [3]
- The principles of GMP for active substances [3] referred to in Article 51 of Directive 2001/82/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.

[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

Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
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 1.1.1.4 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) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.4 Other: active pharmaceutical ingredients, biotechnologically manufactured : recombinant proteins monoclonal antibodies cytokines(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets
	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*

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 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.4 Other: active pharmaceutical ingredients, biotechnologically manufactured : recombinant proteins monoclonal antibodies cytokines(en)

Clarifying remarks (for public users)

ad 1.2.1.8: Other solid dosage forms are powder, granulates, pellets. ad 1.3.1.5: Recombinant proteins/DNA Others monoclonal antibodies cytokines ad 2.2.3.5: Drug Products, biotechnologically manufactured: recombinant proteins, monoclonal antibodies, cytokines. Authorised manufacturing or imprtation does NOT cover blood products, immunological products (conventional vaccines, conventional sera, conventional allergens, testsera & testantigenes) gene therapy medicinal products, somatic cell therapy medicinal products, tissue engineered products, xenogeneic products, tissue and cell products, medicinal products for use in in-vivo diagnosis by means of marker genes, radiopharmaceuticals and human or animal extracted products.

2019-09-19

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

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Confidential
Regierungspraesidium Tuebingen, Leitstelle Arzneimitteluebeberwachung Baden-Wuerttemberg
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