Bezirksregierung Detmold

CERTIFICATE NUMBER: ***DE_NW_02_GMP_2023_0006***

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

Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Germany confirms the following:
The manufacturer: ***Baxter Oncology GmbH***
Site address: ***Kantstrasse 2, Kuensebeck, Halle (Westf), 33790***
OMS Organisation Id. / OMS Location Id.: ***ORG-100004031*** / ***LOC-100007567***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_NW_02_MIA_2020_0023*** in accordance with Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-11-10***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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.

[1] *The certificate referred to in paragraph Art. 15 of Directive 2001/20/EC and 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.*

Part 2

Human Investigational Medicinal Products Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates Special Requirements 7 Other: hormones / substances with hormonal activity, cytotoxics, immuno-suppressives(en) 1.1.1.4 Small volume liquids Special Requirements 7 Other: hormones / substances with hormonal activity, cytotoxics, immuno-suppressives(en) 1.1.1.5 Solids and implants Special Requirements 7 Other: hormones / substances with hormonal activity, cytotoxics, immuno-suppressives(en) 1.1.1.6 Other: sterile active pharmaceutical ingredients(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids Special Requirements 7 Other: hormones / substances with hormonal activity, cytotoxics, immuno-suppressives(en)
	1.1.3 Batch certification
1.2	**Non-sterile products**
	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 1.3.1.5 Biotechnology products 1.3.1.6 Human or animal extracted products Special Requirements 7 Other: hormones isolated from human urine;(en)
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products 1.3.2.6 Human or animal extracted products
1.4	**Other products or manufacturing activity**

	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.1 Filtration
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.13 Tablets Special Requirements 7 Other: cytotoxics(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*

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
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing
	2.3.4 Other: 2.3.3: Biological Active Substance 2.3.4: active pharmaceutical ingredients (API)/ API-Solutions: biotechnology products, hormon of human origin to be used as excipient: Albumin (human) U:S:P:20%, Grofols(en)

Clarifying remarks (for public users)

Any restrictions or clarifying related to the scope of These Manufactering operations 1.3.1.2 This number is limited to the manufacturing steps for a vaccine with recombinant antigen and for a vaccine with mRNA following the manufacturing of the active ingredient (antigen or mRNA respectively) without batch certification of the vaccines. 1.2.2: sugar coated tablets only 1.3.1.5 and 1.3.1.6: manufactering of dosage form only 1.5.1.13: sugat coated tablets only 1.1.1.6 and 1.4: do not apply to investigational medicinal products

2023-01-19

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

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Tel:***Confidential***
Fax:***Confidential***