

Bezirksregierung Detmold

CERTIFICATE NUMBER: **DE_NW_02_GMP_2020_0006**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

^{1, 2}

Part 1

Issued following an inspection in accordance with :

The competent authority of Germany confirms the following:

The manufacturer: **Baxter Oncology GmbH**

Site address: **Kantstrasse 2, Halle/Westfalen, Nordrhein-Westfalen, 33790, Germany**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **DE_NW_02_MIA_2019_0012** 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 **2020-01-29**, it is considered that it complies with:

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

1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<p><i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i></p> <p>1.1.1.2 Lyophilisates Special Requirements 7 Other: hormones, cytotoxics, immuno-suppressives(en)</p> <p>1.1.1.4 Small volume liquids Special Requirements 7 Other: hormones, cytotoxics, immuno-suppressives(en)</p> <p>1.1.1.5 Solids and implants Special Requirements 7 Other: hormones, cytotoxics, immuno-suppressives(en)</p> <p>1.1.1.6 Other: sterile active pharmaceutical ingredients(en)</p>
	<p><i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i></p> <p>1.1.2.3 Small volume liquids Special Requirements 7 Other: hormones, cytotoxics, immuno-suppressives(en)</p>
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products (list of product types)
	<p><i>1.3.1 Biological medicinal products (list of product types)</i></p> <p>1.3.1.5 Biotechnology products</p> <p>1.3.1.6 Human or animal extracted products Special Requirements 7 Other: hormones isolated from human urine; manufacturing of dosage form only(en)</p>
	<p><i>1.3.2 Batch Certification (list of product types)</i></p> <p>1.3.2.5 Biotechnology products</p> <p>1.3.2.6 Human or animal extracted products</p>
1.4	Other products or manufacturing activity
	<p><i>1.4.2 Sterilisation of active substance/ excipients/ finished product</i></p> <p>1.4.2.1 Filtration</p>

1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.13 Tablets Special Requirements 7 Other: cytotoxics(en)
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.1 Microbiological: sterility</i> <i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i> <i>2.1.4 Biological</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	<i>2.2.2 Non-sterile products</i>
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>
	<i>2.3.2 Importation of intermediate which undergoes further processing</i>
	<i>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(en)</i>

Clarifying remarks (for public users)

Any restrictions or clarifying related to the scope of These Manufacturing operations to 1.2.2: sugar coated tablets only to 1.3.1.5: manufacturing of dosage form only to 1.5.1.13: sugat coated tablets only

2020-02-11

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

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Bezirksregierung Detmold
Tel: **Confidential**
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