

**Regierungspraesidium Tuebingen Leitstelle Arzneimittelueberwachung
Baden-Wuerttemberg**

CERTIFICATE NUMBER: **DE_BW_01_GMP_2024_0090**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1,2}

Part 1

Issued following an inspection in accordance with
Art. 63 of Regulation (EU) 536/2014
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Germany confirms the following:

The manufacturer: **Roche Pharma AG**

Site address: **Emil-Barell-Strasse 1, Grenzach, Grenzach-Wyhlen, Baden-Wuerttemberg, 79639, Germany, GPS: 47.549485, 7.668084**

OMS Organisation Id. / OMS Location Id.: **ORG-100001131 / LOC-100004781**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **DE_BW_01_MIA_2020_0096** in accordance with Art. 61 of Regulation (EU) No 536/2014 and Art. 40 of Directive 2001/83/EC transposed in the following national legislation: **The Human Medicines Regulations 2012 (SI 2012/1916)**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2024-03-21**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.³

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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>). 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 is also applicable to importers.

² Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³ These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products
Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<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)
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products

2 IMPORTATION OF MEDICINAL PRODUCTS	
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>
	<i>2.2.3 Biological medicinal products</i> 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>

Clarifying remarks (for public users)

Includes storage of medicinal products at the address Warmbacher Str. 80, D-79618 Rheinfelden (also relates to physical importation).

Competent Authority of

Confidential
Regierungspraesidium Tuebingen Leitstelle
Arzneimittelueberwachung Baden-Wuerttemberg
Tel: **Confidential**
Fax: **Confidential**

EudraGMP