Landesamt Fuer Soziales Jugend Und Versorgung

CERTIFICATE NUMBER: ***DE_RP_01_GMP_2024_0027***

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 as amended

The competent authority of Germany confirms the following:
The manufacturer: ***AbbVie Deutschland GmbH & Co. KG***
Site address: ***Knollstrasse, Ludwigshafen Am Rhein, 67061, Germany***
OMS Organisation Id. / OMS Location Id.: ***ORG-100001365*** / ***LOC-100000825***
DUNS Number: ***34-273-0478***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_RP_01_MIA_2024_0007*** in accordance with Art. 61 of Regulation (EU) No 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-09-28***, 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]

Digitally signed by Moraru Grigore
Date: 2024.10.21 10:35:16 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANA

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/ECis 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 Investigational 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 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 Special Requirements 7 Other: Coated tablets, granules, powder in bottles(en) 1.2.1.13 Tablets 1.2.1.17 Other: a) Processing of Corticoid-containing drug products b) Overencapsulation c) Intermediates for further processing: Extrudates(en)
	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) 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products

1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.8 Other solid dosage forms Special Requirements 7 Other: Coated tablets, granules, powder in bottles(en) 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products: a) Processing of Corticoid-containing drug products b) Overencapsulation(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**
	2.1.3 Chemical/Physical
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 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing
	2.3.3 Biological active substance

Clarifying remarks (for public users)

Ad 1.3.2.4) Manufactured by TPM Ad 1.6.1) Testing in contract laboratories according to sect 14 para 4 German drug law (see annex 4) Ad 1.6.2, 1.6.3, 1.6.4) Partial testing in contract laboratories according to sect 14 para 4 German drug law (see annex 4) Ad 2.1.3: organoleptic tests and validation of analytical results

2024-09-03

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

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Confidential
Landesamt Fuer Soziales Jugend Und Versorgung
Tel:***Confidential***
Fax:***Confidential***