Bezirksregierung Koeln

CERTIFICATE NUMBER: ***DE_NW_04_GMP_2024_0006***

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

Part 1

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

The competent authority of Germany confirms the following:
The manufacturer: ***Dyckerhoff Pharma GmbH & Co. KG***
Site address: ***Robert-Perthel-Straße 49, Longerich, Cologne, North Rhine-Westphalia, 50739, Germany***
OMS Organisation Id. / OMS Location Id.: ***ORG-100005807*** / ***LOC-100002160***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_NW_04_MIA_2024_0005*** in accordance with Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC.

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

Other
Ist auch Wirkstoffhersteller und wurde inspiziert gemaess - Art. 111 (1) Richtlinie 2001/83/EG umgesetzt in deutsches Recht durch: SECT. 64 Abs. 1 Arzneimittelgesetz

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-03-15***, 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]
- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/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. 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. 111(5) of Directive 2001/83/EC and 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 Medicinal Products Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	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) 1.2.1.6 Liquids for internal use
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.6 Human or animal extracted products Special Requirements 7 Other: Manufacturing of active pharmaceutical ingredients out of bovine, porcine and horse organs(en) 1.3.1.8 Other: Manufacturing of active pharmaceutical ingredients of microbial origin: yeast(en)
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products 1.4.1.2 Homoeopathic products
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.3 Moist heat
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Clarifying remarks (for public users)

The manufacturing authorisation as per item 1.3.1.6 regarding the bovine material does only include the manufacturing of active pharmaceutical ingredients out of extracts from bovine organs: only material of the category IB and IC according to Ph.Eur. 5.2.8 - Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products. The manufacturing authorisation also includes batch certification of all sterile and non-sterile products. The manufacturing authorisation does not include medicinal products specified in sect 15 para 3 and 3a German drug law. The manufacturing authorisation does not include medicinal products which require cold chain distribution with the exception of batch certification. The manufacturing authorisation as per item 1.1.2.3, 1.3.1.6, 1.3.1.8, 1.5.1.1, 1.5.1.2, 1.5.1.5, 1.5.1.6, 1.5.1.8 und 1.5.1.13 does not include medicinal products which contain substances with hormonelike, immunsuppres (text missing)

2024-02-05

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

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Confidential
Bezirksregierung Koeln
Tel:***Confidential***
Fax:***Confidential***