Regierungspräsidium Darmstadt

CERTIFICATE NUMBER: ***DE_HE_01_GMP_2022_0222***

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

The competent authority of Germany confirms the following:
The manufacturer: ***Pharmazeutische Fabrik Dr. Reckeweg & Co. GmbH***
Site address: ***Berliner Ring 32, Bensheim, 64625***
OMS Organisation Id. / OMS Location Id.: ***ORG-100000921*** / ***LOC-100004724***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_HE_01_MIA_2022_0108*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-05-17***, 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.

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[1] *The certificate referred to in paragraph 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 Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms 1.2.1.11 Semi-solids 1.2.1.17 Other: Intermediates (solutions, oil, drugs) for the production of prescription medicinal products(en)
	1.2.2 Batch certification
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products 1.4.1.2 Homoeopathic products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms 1.5.1.11 Semi-solids 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical*

2.3	Other importation activities
	2.3.4 Other: Mother tinctures and dilutions(en)

Clarifying remarks (for public users)

The site include the addresses Berliner Ring 22, 24 and 32, 64625 Bensheim. Only manufacturing and import of homoeopathic and herbal products. Ref. to 1.2.1.8: globules and powder (trituration for manufacturing of tablets) Ref. to 1.2.1.11 and 1.5.1.11: ointment Ref. to 1.2.1.17: Cannabis extracts, Dronabinol preparations, CBD oil, Cannabis flowers Ref. to 1.5.1.8: globules Storage of retain and reference samples: Berliner Ring 22 und 32, 64625 Bensheim

2022-12-07

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

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Regierungspräsidium Darmstadt
Tel:***Confidential***
Fax:***Confidential***