Staatliches Gewerbeaufsichtsamt Hannover

CERTIFICATE NUMBER : ***DE_NI_02_GMP_2021_0003***

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 :***Siegfried Hameln GmbH***
Site address :***Langes Feld 13, Hameln, Niedersachsen, 31789, Germany***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_NI_02_MIA_2021_0005*** in accordance with Art. 40 of Directive 2001/83/EC .

Other
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-12-03*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [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 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

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids 1.1.1.6 Other: suspensions(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products
1.5	**Packaging**
	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**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical* *2.1.4 Biological*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared

2.3	Other importation activities
	2.3.1 Site of physical importation
	2.3.4 Other: Active substances with microbiological origin(en)

Clarifying remarks (for public users)

Due to the COVID-10 pandemic the inspection was performed by videoconference without on-site visit. To no. 1.1.3 and 1.5.2 Dosage forms according no. Nr. 1.1.1.1, 1.1.1.4, 1.1.1.6 (suspensions only), 1.1.2.1 or 1.1.2.3 or lyophilisates only To no. 1.3.1.2: No manufacturing of drug substance Recombinant proteins/DNA: vaccines based on recombinant proteins only To no. 2.2.1.1 Manufacturer: PHARMASCIENCE INC. 100 de l'Industrie blvd. Candiac, Quebec, CANADA J5R 1J1 To. no. 2.3.4 manufacturer of active substances: Xinyu Pharmaceutical Co., Ltd. 158, Jintai 5th Road, Economic Development Zone, SuZho Anhui, PR China Manufacturing of Lincomycin HCl List of products To no. 2.2.1: For the manufacturer PHARMASCIENCE INC. Methotrexat 7,5 mg Fertigspritze MTX 7,5 mg PFS Methotrexat 10 mg Fertigspritze MTX 10 mg PFS Methotrexat 15 mg Fertigspritze MTX 15 mg PFS Methotrexat 20 mg Fertigspritze MTX 20 mg PFS Methotrexat 25 mg Fertigspritze MTX 25 mg PFS only. Release for pac (text missing)

2021-01-27

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

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Confidential
Staatliches Gewerbeaufsichtsamt Hannover
Tel:***Confidential***
Fax:***Confidential***