MANUFACTURER’S AUTHORISATION

(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number
DE_NI_01_MIA_2023_0005/41401.01.09

2. Name of authorisation holder
Fraunhofer Institut für Toxikologie und Experimentelle Medizin (LOC-100022118)

3. Address(es) of manufacturing site(s)
Fraunhofer Institut für Toxikologie und Experimentelle Medizin, Bereich Pharmazeutische Biotechnologie
Inhoffenstr. 7
38124 Braunschweig
(LOC-100021660)

4. Legally registered address of authorisation holder
Nikolai-Fuchs-Str. 1
30625 Hannover

5. Scope of authorisation and dosage forms
ANNEX 2

6. Legal basis of authorisation
Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 13 para 5 AMG
Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 72 para 2a AMG

7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation
Dr. Lena Schurer

8. Signature
On behalf

9. Date
21/03/2023

10. Annexes attached
DE_NI_01_MIA_2023_0005
Annex 2
Annex 4 (Addresses of Contract Laboratories)
Investigational Medicinal Products for Human Use

**AUTHORISED OPERATIONS**

Manufacturing Operations (according to part 1)
Importation of Investigational Medicinal Products (according to part 2)

### Part 1 - MANUFACTURING OPERATIONS

#### 1.1 Sterile Products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)

- 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

#### 1.3 Biological medicinal products

1.3.1 Biological medicinal products

- 1.3.1.5 Biotechnology products

1.3.2 Batch certification

- 1.3.2.5 Biotechnology products

#### 1.4 Other products or manufacturing activity

1.4.1 Manufacture of:

- 1.4.1.3 Other
  - active pharmaceutical ingredients of genetically modified microbial and animal cells
  - aliquotation and primary packaging of provocation substances
  - Bacteriophages - API

#### 1.5 Packaging

1.5.2 Secondary packing

#### 1.6 Quality control testing

1.6.2 Microbiological: non-sterility
Any restrictions or clarifying remarks related to the scope of these Manufacturing operations
ad 1.3.1.5 und 1.3.2.5: valid for
- recombinant, monoclonal antibody/antibody fragments produced in CHO cell lines
- following bacteriophages for inhaled use: JG005-IMP acc. to current process description PBF-004;
  JG024-IMP acc. to current process description PBF-005; Bhz17-IMP acc. to current process description PBF-006

ad 1.4.1.3: valid for
- 
- 
-
### Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

#### 2.1 Quality control testing of imported investigational medicinal products

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#### 2.2 Batch certification of imported investigational medicinal products

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</table>

Any restrictions or clarifying remarks related to the scope of these importation operations
Address(es) of Contract Laboratories

Protagen Protein Services GmbH
Inselwiesenstr. 10
74076 Heilbronn
RP-HPLC of proteins

BioChem Labor für biologische und chemische Analytik GmbH
Daimlerstr. 5b
76185 Karlsruhe
- chemical-physical testing
- molecular biological analytic

Menal GmbH
Im Hausgrün 15
79312 Emmendingen

Bayer AG, Werksteil Elberfeld
Friedrich-Ebert-Straße 217-333
42117 Wuppertal

DSMZ - Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH
Inhoffenstr. 7b
38124 Braunschweig
- Sequencing for identity test in the context of phage projects

Labor LS SE & Co. KG
Mangelsfeld 4, 5, 6
97708 Bad Bocklet-Großenbrach
- chemical/physical testing
- microbiological testing: sterility
- biological testing
- testing of pharmaceutical Technology
- leakage test (according Ph.Eur. 3.2.9)
- efficacy of antimicrobial preservation (Ph.Eur. 5.1.3)

AvenCell Europe GmbH
Tatzberg 47
01307 Dresden
Microcoat Biotechnologie GmbH
Am Neuland 3
82347 Bernried am Starnberger See
- testing of Bacterial Endotoxins