



Gewerbeaufsicht  
in Niedersachsen



**Staatliches Gewerbeaufsichtsamt  
Braunschweig**  
Behörde für Arbeits-, Umwelt- und  
Verbraucherschutz

Staatliches Gewerbeaufsichtsamt Braunschweig  
Ludwig-Winter-Str. 2, 38120 Braunschweig

## 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<br>Experimentelle Medizin<br>(LOC-100022118)  |
| 3. Address(es) of manufacturing site(s)  | Fraunhofer Institut für Toxikologie und<br>Experimentelle Medizin, Bereich Pharmazeutische<br>Biotechnologie<br>Inhoffenstr. 7<br>38124 Braunschweig<br>(LOC-100021660)                         |
| 4. Legally registered address of authorisation holder  | Nikolai-Fuchs-Str. 1<br>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.<br>536/2014 in conjunction with Sect 13 para 5 AMG<br>Art. 61 para 1 to 3 of Regulation (EU) No.<br>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   |   |

Annex 2  
Annex 4 (Addresses of Contract Laboratories)

**SCOPE OF AUTHORISATION**

Annex 2

Name and address of the site:

Fraunhofer Institut für Toxikologie und Experimentelle Medizin, Bereich Pharmazeutische Biotechnologie, Inhoffenstr. 7, 38124 Braunschweig

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*

1.6.3 Chemical/Physical

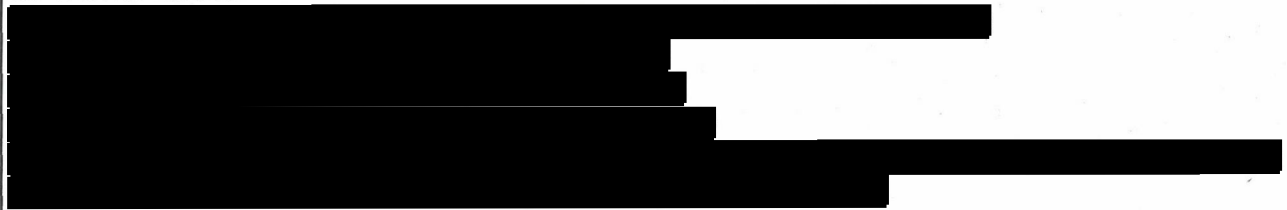
1.6.4 Biological

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



<b>Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported investigational medicinal products</b>
	2.1.4 <i>Biological</i>
<b>2.2</b>	<b>Batch certification of imported investigational medicinal products</b>
	2.2.1 <i>Sterile products</i>
	2.2.1.1 Aseptically prepared
	2.2.2 <i>Non-sterile products</i>
	2.2.3 <i>Biological products</i>
	2.2.3.5 Biotechnology products

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  
[REDACTED]

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

DSMZ - Deutsche Sammlung von Mikroorganismen und  
Zellkulturen GmbH  
Inhoffenstr. 7 b  
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  
[REDACTED]

Microcoat Biotechnologie GmbH  
Am Neuland 3  
82347 Bernried am Starnberger See  
- testing of Bacterial Endotoxins