

MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_RP_01_MIA_2022_0018
2. Name of authorisation holder	Midas Pharma GmbH (LOC-100004656)
3. Address(es) of manufacturing site(s)	Midas Pharma GmbH (LOC-100004656) Rheinstraße 49 55218 Ingelheim am Rhein
4. Legally registered address of authorisation holder	Rheinstraße 49 55218 Ingelheim am Rhein
5. Scope of authorisation and dosage forms	ANNEX 1
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law) Sect 72 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dr. Burkhard Trapp
8. Signature	On behalf
9. Date	12/05/2022
10. Annexes attached	Annex 1 Annex 3 (Addresses of Contract Manufacturing Site(s)) Annex 4 (Addresses of Contract Laboratories) Annex 5 (Name of Qualified Person)

Annex 7 (Date of inspection on which authorisation granted, scope of last inspection)

Annex 8 (Manufactured/ imported products authorised)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Midas Pharma GmbH, Rheinstraße 49, 55218 Ingelheim am Rhein

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Importation of Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.1	Sterile Products
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	<i>1.1.3 Batch certification</i>
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1.2	Non-sterile products
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	<i>1.2.2 Batch certification</i>
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Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

1.1.3 Batch Certification Sterile Products

The Authorisation is granted only for the application for a registration.

1.2.2 Batch Certification Non-sterile Products

The Authorisation is granted only for the application for a registration.

The manufacturing authorisation is also valid for the permitted activities in the buildings with the addresses Rheinstraße 63 und Dietrich-Bonhoeffer-Straße 2-4.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.3 Chemical/Physical</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.1 Sterile products</i>
	2.2.1.1 Aseptically prepared
	<i>2.2.2 Non-sterile products</i>
	<i>2.2.3 Biological products</i>
	2.2.3.5 Biotechnology products
2.3	Other importation activities
	<i>2.3.4 Other</i> Active pharmaceutical ingredients

Any restrictions or clarifying remarks related to the scope of these Importation operations

The importation authorisation is also valid for the permitted activities in the buildings with the addresses Rheinstraße 63 and Dietrich-Bonhoeffer-Straße 2-4.

Amendment 2.2.1.1: Meropenem vial

Amendment 2.2.2: Paracetamol DC blend

Amendment 2.2.3.5: Ranibizumab vial

Amendment 2.3.4: Acetylcystein Ph.Eur., Heparin Sodium Ph.Eur./non steril, Spironolacton Ph.Eur.

The imported products Meropenem vial, Paracetamol DC blend, Acetylcystein Ph.Eur., Heparin Sodium Ph.Eur./non steril and Spironolacton Ph.Eur. are further processed and for this purpose certified according EU GMP Guideline Annex 16 only (CoC).

There is no final certification according german drug law for the imported products in place.

The product Ranibizumab vial (trade name Ongavia) is imported as the finished medicinal product.

The final certification and release for the market supply is performed according the german drug law.

Medicinal products, Active pharmaceutical ingredients and manufacturing sites see Annex 8

Address(es) of Contract
Manufacturing Sites

Popack Logistik GmbH
Achardstraße 1
55127 Mainz

The company Popack is a service provider.

Scope of the service: Storage of drug products and active
pharmaceutical ingredients.

Address(es) of Contract Laboratories

BioChem Labor für biologische und chemische Analytik
GmbH
Daimlerstr. 5b
76185 Karlsruhe
1.6.1 Microbiological Testing: Sterility
1.6.2 Microbiological Testing: non steril Products
1.6.3 Chemical/Physical Testing
1.6.4 Biological Testing

Haupt Pharma Wolfratshausen GmbH
Pfaffenrieder Straße 5
82515 Wolfratshausen
1.6.2 Microbiological Testing: non steril Products
1.6.3 Chemical/Physical Testing

WESSLING Laboratorien GmbH
Johann-Krane-Weg 42
48149 Münster
1.6.1 Microbiological Testing: Sterility
1.6.2 Microbiological Testing: non steril Products
1.6.3 Chemical/Physical Testing
1.6.4 Biological Testing

Famar Italia S.p.A.
Via Zambelletti 25
20021 Baranzate (MI)
Italien
1.6.2 Microbiological Testing: non steril Products
1.6.3 Chemical/Physical Testing

Name(s) of Qualified Person(s)

Mr. Hendrick Habermann

Pharmaceutical bulk drugs: Meropenem vial and Paracetamol DC blend

Active pharmaceutical ingredients: Acetylcystein Ph.Eur., Heparin Sodium Ph.Eur./non steril, Spironolacton Ph.Eur.

Mr. Dr. Frank Sievert

Pharmaceutical Bulk drugs: Meropenem vial, Paracetamol DC blend

Active pharmaceutical ingredients: Acetylcystein Ph.Eur., Heparin Sodium Ph.Eur./non steril, Spironolacton Ph.Eur.

Mr. Dr. Michael Lambert

Active pharmaceutical ingredients: Acetylcystein Ph.Eur., Heparin Sodium Ph.Eur./non steril, Spironolacton Ph.Eur.

Mr. Dr. Andreas Brutsche

Biological medicinal products: Ranibizumab vial

Pharmaceutical bulk drugs: Meropenem vial, Paracetamol DC blend

Active pharmaceutical ingredients: Acetylcystein Ph.Eur., Heparin Sodium Ph.Eur./non steril, Spironolacton Ph.Eur.

Date of Inspection on which
authorisation was granted

28/10/2021

Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 89 and 90 of Regulation (EU) 2019/6, as amended).

Ranibizumab vial
Vial Abfüllung/vial filling:

Ajinomoto Biopharma Services
11040 Roselle Street
San Diego CA 92121, US

Verpackung/packaging:

PCI Pharma Services
3001 Red Lion Rd.
Philadelphia PA 19114, US

Acetylcystein Ph.Eur.
Wuhan Grand Hoyo Co., Ltd
Gedian Economy Development Zone, No. 1
Industrial Park
436030 Ezhou City, Hubei Provinz
China

Heparin Natrium/sodium Ph.Eur./nicht steril/non steril
Shenzhen Hepalink Pharmaceutical Group Co., Ltd.
21 Langshan Road, Songpingshan, Nanshan District,
Shenzhen 518057, China

Spirolacton Ph.Eur.
Zhejiang Shenzhou Pharmaceutical Co., Ltd.
No 9 Hongyun Road, Xiandai Industrial Zone
Fuying Subdistrict, Xianju, 317300 Taizhou
Zhejiang, China

Paracetamol DC Mischung/blend
Atabay Kimya Sanayi ve Ticaret A.S.
Acibadem, Köftünci Sodak No. 1
34718 Kadiköy, Istanbul
Türkei

Meropenem Trihydrat E.P./Natriumcarbonat
(1,141 g à 30 ml vial 0,57 g à 20 ml vial)/
Shenzhen Haibin Pharmaceutical Co., Ltd.
Shenyan Road Yantian District No. 2003
518081 Shenzhen City Guangdong Province

China