

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_2023_0009/54.3/GMP/Popack/20230324
2. Name of authorisation holder	Popack Logistik GmbH (LOC-100021394)
3. Address(es) of manufacturing site(s)	Popack Logistik GmbH Achardstraße 1 55127 Mainz (LOC-100021394)
4. Legally registered address of authorisation holder	Achardstraße 1 55127 Mainz
5. Scope of authorisation and dosage forms	ANNEX 1 and ANNEX 2
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law) Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 13 para 5 AMG
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dr. Ilka Petry
8. Signature	On behalf
9. Date	24/03/2023
10. Annexes attached	Annex 1 and Annex 2 Annex 5 (Name of Qualified Person) Annex 7 (Date of inspection on which authorisation granted, scope of

last inspection)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Popack Logistik GmbH, Achardstraße 1, 55127 Mainz

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.5	Packaging
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	<i>1.5.2 Secondary packing</i>
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SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

Popack Logistik GmbH, Achardstraße 1, 55127 Mainz

Investigational Medicinal Products for Human Use
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AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.5	Packaging
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	<i>1.5.2 Secondary packing</i>
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Name(s) of Qualified Person(s)

Mrs. Dr. Christel Schmelzer

Mrs. Dr. Cathrin Pauly

deputy qualified person

Date of Inspection on which
authorisation was granted

10/05/2022

Scope of last Inspection

General GMP-Inspection (details see inspection report)