




MANUFACTURING/IMPORT AUTHORISATION

- | | |
|--|---|
| 1. Authorisation number/reference number | DE_BY_04_MIA_2025_0081/ROB-53Ph-2677.Ph_2-467 |
| 2. Name of the holder of the authorisation | PharmaKorell GmbH
(LOC-100076822) |
| 3. Address(es) of the manufacturer's / importer's place(s) of operation | PharmaKorell GmbH
Schleißheimer Straße 373
80935 München
(LOC-100076822) |
| 4. Registered address of the holder of the authorisation | Schleißheimer Straße 373
80935 München |
| 5. Scope of the authorisation and dosage forms | ANNEX 1 and 2 |
| 6. Legal basis on which authorisation was granted | Section 13 para. 1 of the German Pharmaceuticals Act (AMG)
Section 72 para. 1 of the German Pharmaceuticals Act (AMG)
Article 61 paragraphs 1 to 3 of Regulation EU No. 536/2014 in connection with Section 13 para. 5 of the German Pharmaceuticals Act (AMG)
Article 61 paragraphs 1 to 3 of Regulation EU No. 536/2014 in connection with Section 72 para. 2a of the German Pharmaceuticals Act (AMG) |
| 7. Name of the responsible officer of the responsible authority of the Member State granting the authorisation |  |
| 8. Signature | [Signature: illegible] |
| 9. Date | 22 Oct. 2025 |
| 10. Annexes | Annex 1 and Annex 2
Annex 4 (address(es) of test centres commissioned)
Annex 5 (names of the expert persons)
Annex 8 (list of products covered by the |

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Eimeldingen, 13 November 2025

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manufacturing/ import authorisation)

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SCOPE OF THE AUTHORISATION

Name and address of the place of operation:

PharmaKorell GmbH, Schleißheimer Straße 373, 80935 München/Munich

Pharmaceutical products for human use

PERMITTED ACTIVITIES

Manufacturing activities (according to part 1)

Import of pharmaceutical products (according to part 2)

Part 1 – MANUFACTURING ACTIVITIES

1.1 Sterile products

1.1.3 Batch release

1.2 Non-sterile products

1.2.2 Batch release

1.3 Biological pharmaceutical products

1.3.2 Batch release

1.3.2.5 Biotechnological products

Restrictions or clarifications regarding the manufacturing activities

Batch release also includes the release of intermediate products

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Part 2 – IMPORT OF PHARMACEUTICAL PRODUCTS	
2.2	Batch release for imported pharmaceuticals
2.2.1	Sterile products
	2.2.1.1 Aseptically manufactured
	2.2.1.2 Sterilised in the final container
2.2.2	Non-sterile products
2.2.3	Biological pharmaceuticals
	2.2.3.1 Blood products
	Other preparations originating from foreign blood
	2.2.3.5 Biotechnological products

Restrictions or clarifications regarding the import activities

Place of operation for physical import is ParmaKorell GmbH, Georges-Köhler-Str. 2, 79539 Lörrach

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SCOPE OF THE AUTHORISATION

Name and address of the place of operation:

PharmaKorell GmbH, Schleißheimer Straße 373, 80935 München/Munich

Investigational medicinal products for human use

PERMITTED ACTIVITIES

Manufacturing activities (according to part 1)

Import of investigational medicinal products (according to part 2)

Part 1 – MANUFACTURING ACTIVITIES	
1.1	Sterile products
	1.1.3 Batch release
1.2	Non-sterile products
	1.2.2 Batch release
1.3	Biological pharmaceutical products
	1.3.2 Batch release
	1.3.2.5 Biotechnological products

Restrictions or clarifications regarding the manufacturing activities

Batch release also includes the release of intermediate products

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Part 2 – IMPORT OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.2	Batch release for imported investigational medicinal products
2.2.1	<i>Sterile products</i>
	2.2.1.1 Aseptically manufactured
	2.2.1.2 Sterilised in the final container
2.2.2	<i>Non-sterile products</i>
2.2.3	<i>Biological pharmaceuticals</i>
	2.2.3.5 Biotechnological products

Restrictions or clarifications regarding the import activities

Place of operation for physical import is ParmaKorell GmbH, Georges-Köhler-Str. 2, 79539 Lörrach

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Address(es) of test centres commissioned

Untersuchungsinstitut Heppeler
Marie-Curie-Strasse 7
79539 Lörrach
Chemical/physical /microbiological (non-sterile)

Labor LS SE & Co. KG
Mangelsfeld 4, 5, 6
97708 Bad Bocklet-Großenbrach
Microbiological (sterile and non-sterile)/
Endotoxin test

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