Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	DE_NW_04_MIA_2024_0005
2. Name of authorisation holder	Dyckerhoff Pharma GmbH & Co. KG (ORG-100005807 / LOC-100002160)
3. Address(es) of manufacturing site(s)	Dyckerhoff Pharma GmbH & Co. KG (ORG-100005807 / LOC-100002160), Robert-Perthel-Straße 49, Longerich, Cologne, North Rhine-Westphalia, 50739, Germany
3.a Additional details on units inspected of manufacturing site(s) address(es)	
4. Legally registered address of authorisation holder	Robert-Perthel-Straße 49, Longerich, Cologne, North Rhine-Westphalia, 50739, Germany
4.a Additional details on units inspected of legally registered address	
5. Scope of authorisation and dosage forms [2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 40 of Directive 2001/83/EC Art. 61 of Regulation (EU) No 536/2014
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2024-02-05
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3(Addresses of Contract Manufacturing Site(s)) Annex 4(Addresses of Contract laboratories) Annex 5(Name of Qualified Person) Annex 6(Name of responsible persons) Annex 7(Date of inspection on which authorisation granted, scope of last inspection) Annex 8(Manufactured/ imported products authorised) [3]

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[1]*The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC as amended and Article 88(1) of Regulation (EU) 2019/6, shall also be required for imports coming from third countries into a Member State.*

[2]*Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.*

[3]*The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).*

SCOPE OF AUTHORISATION — ANNEX 1

Name and address of the site: Dyckerhoff Pharma GmbH & Co. KG, Robert-Perthel-Straße 49, Longerich, Cologne, North Rhine-Westphalia, 50739, Germany

Additional Details:

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS(according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.6 Human or animal extracted products Special Requirements 7 Other: Manufacturing of active pharmaceutical ingredients out of bovine, porcine and horse organs(en) 1.3.1.8 Other: Manufacturing of active pharmaceutical ingredients of microbial origin: yeast(en)
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products

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	1.4.1.2 Homoeopathic products
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.3 Moist heat
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

The manufacturing authorisation as per item 1.3.1.6 regarding the bovine material does only include the manufacturing of active pharmaceutical ingredients out of extracts from bovine organs: only material of the category IB and IC according to Ph.Eur. 5.2.8 - Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products. The manufacturing authorisation also includes batch certification of all sterile and non-sterile products. The manufacturing authorisation does not include medicinal products specified in sect 15 para 3 and 3a German drug law. The manufacturing authorisation does not include medicinal products which require cold chain distribution with the exception of batch certification. The manufacturing authorisation as per item 1.1.2.3, 1.3.1.6, 1.3.1.8, 1.5.1.1, 1.5.1.2, 1.5.1.5, 1.5.1.6, 1.5.1.8 und 1.5.1.13 does not include medicinal products which contain substances with hormonelike, immunsuppr (text missing)

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SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Dyckerhoff Pharma GmbH & Co. KG, Robert-Perthel-Straße 49, Longerich, Cologne, North Rhine-Westphalia, 50739, Germany

Additional Details:

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.6 Human or animal extracted products Special Requirements 7 Other: Manufacturing of active pharmaceutical ingredients out of bovine, porcine and horse organs(en) 1.3.1.8 Other: Manufacturing of active pharmaceutical ingredients of microbial origin: yeast(en)
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products 1.4.1.2 Homoeopathic products
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.3 Moist heat
1.5	**Packaging**
	1.5.1 Primary Packaging

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	1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

The manufacturing authorisation as per item 1.3.1.6 regarding the bovine material does only include the manufacturing of active pharmaceutical ingredients out of extracts from bovine organs: only material of the category IB and IC according to Ph.Eur. 5.2.8 - Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products. The manufacturing authorisation also includes batch certification of all sterile and non-sterile products. The manufacturing authorisation does not include medicinal products specified in sect 15 para 3 and 3a German drug law. The manufacturing authorisation does not include medicinal products which require cold chain distribution with the exception of batch certification. The manufacturing authorisation as per item 1.1.2.3, 1.3.1.6, 1.3.1.8, 1.5.1.1, 1.5.1.2, 1.5.1.5, 1.5.1.6, 1.5.1.8 und 1.5.1.13 does not include medicinal products which contain substances with hormonelike, immunsupp (text missing)

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