

Manufacturer/Importer Authorisation^{1, 2}

1. Authorisation Number DE_BW_01_MIA_2024_0081
2. Name of authorisation holder Catalent Germany Schorndorf GmbH (ORG-100011845 / LOC-100018835)
3. Address(es) of manufacturing site(s) Catalent Germany Schorndorf GmbH (ORG-100011845 / LOC-100018835), Steinbeisstrasse 1-2, Schorndorf, Baden-Wuerttemberg, 73614, Germany
- 3.a Additional details on units inspected of manufacturing site(s) address(es)
4. Legally registered address of authorisation holder Steinbeisstrasse 1-2, Schorndorf, Baden-Wuerttemberg, 73614, Germany
- 4.a Additional details on units inspected of legally registered address
5. Scope of authorisation and dosage forms² 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 2024-09-05
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

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: Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1-2,
Schorndorf, Baden-Wuerttemberg, 73614, Germany

Additional Details:

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
	1.1.3 Batch certification
1.2	Non-sterile products
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets
	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
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products
1.5	Packaging
	1.5.1 Primary Packaging 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 1.5.1.11 Semi-solids 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products: inhalants.(en)
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

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

1.2.1.8 and 1.5.1.8: covers powder, granules, globuli, pellets, coated dosage forms. 1.3.1.6: restricted to manufacture of medicinal product Creon. Authorised manufacturing covers herbal products in the dosage forms mentioned in 1.2 and 1.5. Authorised manufacturing and packaging covers dosage forms with potentially highly potent substances or substances with anti-androgenic hormonal activity in premises with special requirements for airlocks and exhaust air based on the risk of the dosage form if notified to the competent authority. The authorisation covers storage of pharmaceutical products at the following site: Gueglingstrasse 85, 73529 Schwaebisch Gmuend. This authorisation is based on facility lay-outs acc. to Appendix 6 of the SMF in the currently valid version.

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
	2.2.1 <i>Sterile products</i> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 <i>Non-sterile products</i>
	2.2.3 <i>Biological medicinal products</i> 2.2.3.5 Biotechnology products
2.3	Other importation activities
	2.3.1 <i>Site of physical importation</i> 2.3.2 <i>Importation of intermediate which undergoes further processing</i>

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

ad 2.2: covers sterile and non-sterile products as solid, liquid and semi-liquid dosage forms as well

as inhalants.

EudraGMP

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SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1-2,
Schorndorf, Baden-Wuerttemberg, 73614, Germany

Additional Details:

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.1	Sterile products
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile investigational medicinal products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.5 Biotechnology products
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.2 Immunological products 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products 1.3.2.6 Human or animal extracted products
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 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 1.5.1.11 Semi-solids 1.5.1.13 Tablets 1.5.1.15 Other non-sterile medicinal products: inhalants.(en)

	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)

1.2.1.8 and 1.5.1.8: covers powder, granules, globuli, pellets, coated dosage forms. 1.3.1: authorised manufacturing covers biological medicinal products, as far as indicated to the competent authority. 1.3.2.2: vaccines only. 1.3.2.6: authorised batch certification covers human or animal extracted products, as far as indicated to the competent authority. Authorised manufacturing covers herbal products in the dosage forms mentioned in 1.2 and 1.5. Authorised manufacturing and packaging covers dosage forms with potentially highly potent substances or substances with anti-androgenic hormonal activity in premises with special requirements for airlocks and exhaust air based on the risk of the dosage form if notified to the competent authority. The authorisation covers storage of investigational medicinal products for human use at the following site: Gueglingstrasse 85, 73529 Schwaebisch Gmuend. The authorisation covers the usage (text missing)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	2.1.3 Chemical/Physical
2.2	Batch certification of imported medicinal products
	2.2.1 Sterile products <ul style="list-style-type: none"> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products <ul style="list-style-type: none"> 2.2.3.2 Immunological products 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products 2.2.3.6 Human or animal extracted products
2.3	Other importation activities
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

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

2.2: covers sterile and non-sterile products as solid, liquid and semi-liquid dosage forms as well as

inhalants. 2.2.3.2: vaccines only. 2.2.3.6: authorised batch certification covers human or animal extracted investigational medicinal products, as far as indicated to the competent authority.

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