

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number DE_BW_01_MIA_2022_0034
2. Name of authorisation holder Catalent Germany Schorndorf GmbH (LOC-100018835)
3. Address(es) of manufacturing site(s) Catalent Germany Schorndorf GmbH (LOC-100018835),
Steinbeisstrasse 1-2, Schorndorf, Baden-Wuerttemberg, 73614,
Germany
4. Legally registered address of authorisation holder Steinbeisstrasse 1-2, Schorndorf, Baden-Wuerttemberg, 73614,
Germany
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 2022-04-06
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

¹The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.

²Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).

SCOPE OF AUTHORISATION

ANNEX 1

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

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 |
| | <i>1.1.3 Batch certification</i> |
| 1.2 | Non-sterile 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>1.3.2 Batch Certification (list of product types)</i> 1.3.2.5 Biotechnology 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 1.5.1.17 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. Authorised manufacturing covers herbal products in the dosage forms mentioned in 1.2 and 1.5. Authorised manufacturing covers products substances with hormonal activity or other potentially hazardous active ingredients in a segregated manufacturing area, whereas the production of sex hormones, betalactam antibiotics, cephalosporins or cytotoxic drugs is NOT covered for bulk manufacturing (1.2) and primary packaging (1.5.1). Authorised manufacturing covers products containing Anagrelide as active ingredient (bulk manufacture and primary packaging) in defined manufacturing areas. Primary packaging of Anagrelide-containing film tablets is covered too. Authorised batch certification does NOT cover blood products, immunological products (conventional sera, conventional vaccines, allergens, testsera and testantigenes), somatic cell therapy (text missing)

| 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 2.2.1.2 Terminally sterilised |
| | <i>2.2.2 Non-sterile products</i> |
| | <i>2.2.3 Biological medicinal products</i> 2.2.3.5 Biotechnology products |
| 2.3 | Other importation activities |
| | <i>2.3.1 Site of physical importation</i> <i>2.3.2 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.

SCOPE OF AUTHORISATION

ANNEX 2

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

Human Investigational 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 |
| | <i>1.1.3 Batch certification</i> |
| 1.2 | Non-sterile 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 <i>Secondary packaging</i> |
| 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 indicated and authorised by the competent authority. 1.3.2.6 Authorised batch certification covers human or animal extracted products as indicated and authorised by the competent authority. Authorised manufacturing covers herbal products in the dosage forms mentioned in 1.2 and 1.5. Authorised manufacturing covers products substances with hormonal activity or other potentially hazardous active ingredients in a segregated manufacturing area, whereas the production of sex hormones, betalactam antibiotics, cephalosporins or cytotoxic drugs is NOT covered for bulk manufacturing (1.2) and primary packaging (1.5.1). Authorised manufacturing covers products containing Anagrelide as active ingredient (bulk manufacture and primary packaging) in defined manufacturing areas. Pr (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 <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> |
| | 2.2.3.2 Immunological products |
| | 2.2.3.4 Gene therapy products |
| | 2.2.3.5 Biotechnology 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)

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

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