



Baden-Württemberg
REGIERUNGSPRÄSIDIUM TÜBINGEN
LEITSTELLE ARZNEIMITTELÜBERWACHUNG

MANUFACTURER'S AUTHORISATION

(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number	DE_BW_01_MIA_2019_0027/DE_BW_01_Catalent Germany Schorndorf
2. Name of authorisation holder	Catalent Germany Schorndorf GmbH
3. Address(es) of manufacturing site(s)	Catalent Germany Schorndorf GmbH Steinbeisstr. 1 und 2 73614 Schorndorf
4. Legally registered address of authorisation holder	Steinbeisstr. 1 und 2 73614 Schorndorf
5. Scope of authorisation and dosage forms	ANNEX 1 and ANNEX 2
6. Legal basis of authorisation	Sect 13 para 1 and sect 72 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Reinhard Kerker
8. Signature	
9. Date	15/04/2019
10. Annexes attached	Annex 1 and Annex 2 Annex 4 (Addresses of Contract Laboratories)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Catalent Germany Schorndorf GmbH, Steinbeisstr. 1 und 2, 73614 Schorndorf

Human Medicinal Products
Veterinary 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>
1.5	Packaging
	<i>1.5.1 Primary Packing</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
	1.5.1.11 Semi-solids
	1.5.1.13 Tablets
	1.5.1.17 Other non-sterile medicinal products solid dosage forms and inhalants.
	<i>1.5.2 Secondary packing</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

1.2.1.8: 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 manufacturing covers batch certification.

Authorised batch certification does NOT cover blood products, immunological products (conventional sera, conventional vaccines, allergens, testsera and testantigenes) gene therapy medicinal products, somatic cell therapy medicinal products, tissue engineered products, xenogeneic products, tissue and cell products, medicinal products for use in in-vivo diagnosis by means of marker genes, radiopharmaceuticals and human or animal extracted products.

Manufacturing authorisation is granted on the basis of the technical drawings in the Site Master File, dated 20.10.2016.

The storage of pharmaceutical products take place partially in an external warehouse, Gueglingstrasse 85, 73529 Schwaebisch Gmuend.

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>
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>

Any restrictions or clarifying remarks related to the scope of these Importation operations

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, Steinbeisstr. 1 und 2, 73614 Schorndorf

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Importation of Investigational 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
	<i>1.3.2 Batch certification</i>
	1.3.2.5 Biotechnology products
1.5	Packaging
	<i>1.5.1 Primary Packing</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
	1.5.1.11 Semi-solids
	1.5.1.13 Tablets
	1.5.1.15 Other non-sterile medicinal products Solid dosage forma and inhalants.

	<i>1.5.2 Secondary packing</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

1.2.1.8: 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 manufacturing covers batch certification.

Authorised batch certification does NOT cover blood products, immunological products (conventional sera, conventional vaccines, allergens, testsera and testantigenes) gene therapy medicinal products, somatic cell therapy medicinal products, tissue engineered products, xenogeneic products, tissue and cell products, medicinal products for use in in-vivo diagnosis by means of marker genes, radiopharmaceuticals and human or animal extracted products.

Manufacturing authorisation is granted on the basis of the technical drawings in the Site Master File, dated 20.10.2016.

Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.1	Quality control testing of imported investigational medicinal products
	<i>2.1.3 Chemical/Physical</i>
2.2	Batch certification of imported investigational 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>
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>

Any restrictions or clarifying remarks related to the scope of these Importation operations

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

Address(es) of Contract Laboratories

Techpharm GmbH
Draisstr. 14
76646 Bruchsal
Physico-chemical methods (Ph.Eur. 2.2)
Limit tests (Ph.Eur. 2.4)
Assays (Ph.Eur. 2.5)
Pharmaceutical technical procedures (Ph.Eur. 2.9)

BAV Institut für Hygiene und Qualitätssicherung GmbH
Hanns-Martin-Schleyer-Str. 25
77656 Offenburg
Biological methods (Ph.Eur. 2.6)

Dr. Graner & Partner GmbH
Lochhausener Str. 205
81249 München
Physico-chemical methods (Ph.Eur. 2.2)
Limit tests (Ph.Eur. 2.4)
Assays (Ph.Eur. 2.5)
Methods in Pharmacognosy (Ph.Eur. 2.8)
Pharmaceutical technical procedures (Ph.Eur. 2.9)
Biological methods (Ph.Eur. 2.6.12 and 2.6.13)

Mikrobiologie Krämer GmbH
Odilienplatz 3
66763 Dillingen
Biological methods (Ph.Eur. 2.6)

BLS-Analytik GmbH & Co. KG
Columbiastraße 14
97688 Bad Kissingen
Physico-chemical methods (Ph.Eur. 2.2)
Limit tests (Ph.Eur. 2.4)
Assays (Ph.Eur. 2.5)
Methods in Pharmacognosy (Ph. 2.8)
Pharmaceutical technical procedures (Ph.Eur. 2.9)

BioChem Labor für biologische und chemische Analytik
GmbH
Daimlerstr. 5b
76185 Karlsruhe
Physico-chemical methods (Ph.Eur. 2.2)
Limit tests (Ph.Eur. 2.4)
Assays (Ph.Eur. 2.5)
Pharmaceutical technical procedures (Ph.Eur. 2.9)
Biological methods (Ph.Eur. 2.6)