MANUFACTURER'S AUTHORISATION [1] , [2]

1. Authorisation Number	DE_SH_01_MIA_2022_0006
2. Name of authorisation holder	Lichtenheldt GmbH Pharmazeutische Fabrik (LOC-100020595)
3. Address(es) of manufacturing site(s)	Lichtenheldt GmbH Pharmazeutische Fabrik (LOC-100020595), Industriestrasse 7 - 11, Wahlstedt, Schleswig-Holstein, 23812, Germany Lichtenheldt GmbH Pharmazeutische Fabrik (LOC-100020699), Justus-Liebig-Weg 1, Wahlstedt, Schleswig-Holstein, 23812, Germany
4. Legally registered address of authorisation holder	Industriestrasse 7 - 11, Wahlstedt, Schleswig-Holstein, 23812, Germany
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. 88 of Regulation (EU) 2019/6 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	2022-06-30
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 and 44(1) of Directive 2001/82/EC, as amended, 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 Help menu of EudraGMDP database.*

[3] *The 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: Lichtenheldt GmbH Pharmazeutische Fabrik, Industriestrasse 7 - 11, Wahlstedt, Schleswig-Holstein, 23812, Germany

Human Medicinal Products Veterinary Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.2.1.6 Liquids for internal use Special Requirements 7 Other: Hormones or substances with hormonal activity(en) 1.2.1.11 Semi-solids Special Requirements 7 Other: Hormones or substances with hormonal activity(en)
	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: Human Medicinal Products with heparin or bee venom(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
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use

	1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids
	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)

To 1.2.1.5 Also Veterinary Investigational Medicinal Products in the dosage forms liquids for external use. Also Veterinary Investigational Products as placebos in the dosage forms liquids for external use.

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Lichtenheldt GmbH Pharmazeutische Fabrik, Industriestrasse 7 - 11, Wahlstedt, Schleswig-Holstein, 23812, Germany

Human Investigational Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
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 1.2.1.11 Semi-solids
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids
	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)

Manufacturing does NOT cover the release (according to para 16 AMWHV). To 1.5.1.6 and 1.5.1.11 The manufacturing steps blinding and randomization are excluded from the scope of production.

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Lichtenheldt GmbH Pharmazeutische Fabrik, Justus-Liebig-Weg 1, Wahlstedt, Schleswig-Holstein, 23812, Germany

Human Medicinal Products Veterinary Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Lichtenheldt GmbH Pharmazeutische Fabrik, Justus-Liebig-Weg 1, Wahlstedt, Schleswig-Holstein, 23812, Germany

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

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

Manufacturing does NOT cover the release (according to para 16 AMWHV). To 1.5.1.5 The manufacturing steps blinding and randomization are excluded from the scope of production.