



MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_SN_01_MIA_2020_0029/ L26-51177
2. Name of authorisation holder	L-A-W Services GmbH - Leipziger Arzneimittelwerk
3. Address(es) of manufacturing site(s)	L-A-W Services GmbH - Leipziger Arzneimittelwerk Elisabeth-Schumacher-Straße 54/56 04328 Leipzig
4. Legally registered address of authorisation holder	Elisabeth-Schumacher-Straße 54/56 04328 Leipzig
5. Scope of authorisation and dosage forms	ANNEX 1 and ANNEX 2
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dr. Brit Kalatz
8. Signature	
9. Date	10/09/2020
10. Annexes attached	Annex 1 and Annex 2 Annex 4 (Addresses of Contract Laboratories) Annex 5 (Name of Qualified Person) Annex 8 (Manufactured products authorised)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

L-A-W Services GmbH - Leipziger Arzneimittelwerk, Elisabeth-Schumacher-Straße 54/56, 04328 Leipzig

Human Medicinal Products Veterinary Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

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>
	1.2.1.5 Liquids for external use Special requirements 7. Others Hormones or substances with hormonal activity
	1.2.1.6 Liquids for internal use
	1.2.1.11 Semi-solids Special requirements 6. Ectoparasiticides 7. Others Hormones or substances with hormon. activity; Med. prod. contain. prions, genotoxics or teratogenes
	1.2.1.14 Transdermal patches
	<i>1.2.2 Batch certification</i>
1.4	Other products or manufacturing activity
	<i>1.4.1 Manufacture of:</i>
	1.4.1.1 Herbal 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
	1.5.1.8 Other solid dosage forms
	1.5.1.13 Tablets Special requirements 7. Others Hormones or substances with hormonal activity
	1.5.2 Secondary packing
1.6	Quality control testing
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

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

This manufacturing authorisation is valid for premises in accordance with Site Master File in a current version registered and approved by the authority.

This manufacturing authorisation is valid for warehouses and warehouse/forklift garage specified in accordance to the site and ground plans of the Site Master File in a current version registered and approved by the authority.

to 1.2.1.11

Ectoparasiticides as mentioned in (6) are primary and secondary packed only.

to 1.2.1.14

This authorisation is valid for batch certification and batch release only.

to 1.5.1.8

This authorisation is valid for primary and secondary packaging of granules.

to 1.6.4

This authorisation is valid for Heparin Testing only.

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

L-A-W Services GmbH - Leipziger Arzneimittelwerk, Elisabeth-Schumacher-Straße 54/56, 04328 Leipzig

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

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>
	1.2.1.5 Liquids for external use Special requirements 7. Others Hormones or substances with hormonal activity
	1.2.1.6 Liquids for internal use
	1.2.1.11 Semi-solids Special requirements 7. Others Hormones or substances with hormonal activity
	1.2.1.14 Transdermal patches
	<i>1.2.2 Batch certification</i>
1.4	Other products or manufacturing activity
	<i>1.4.1 Manufacture of:</i>
	1.4.1.1 Herbal 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

	1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	Quality control testing
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

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

Same restrictions as mentioned in Annex 1 - Part 1 regarding the limitation of this authorisation for specific premises apply.

to 1.2.1.14

This authorisation is valid for batch certification and batch release only.

to 1.6.4

This authorisation is valid for Heparin Testing only.

Address(es) of Contract Laboratories

SYNLAB Analytics & Services Germany GmbH
Hauptstraße 105
04416 Markkleeberg

- microbiological Assay of Nystatin

Annex 5

Name(s) of Qualified Person(s)

Mrs. Dr. Steffi Westphal

Mr. Ivan Makhnusha