



MANUFACTURER'S AUTHORISATION

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

- | | |
|--|---|
| 1. Authorisation number/file number | DE_SL_01_MIA_2024_0016 |
| 2. Name of authorisation holder | Eurofins PHAST GmbH
(LOC-100022643) |
| 3. Address(es) of manufacturing site(s) | Eurofins PHAST GmbH
Kardinal-Wendel-Straße 16
66424 Homburg
(LOC-100022643)
Eurofins PHAST GmbH
Entenmühlstraße 48
66424 Homburg
(LOC-100067022) |
| 4. Legally registered address of authorisation holder | Kardinal-Wendel-Straße 16
66424 Homburg |
| 5. Scope of authorisation and dosage forms | ANNEX 1 |
| 6. Legal basis of authorisation | Art. 88 of Regulation (EU) 2019/6 and Sect 28
para 1 German Veterinary Medicinal Products Law |
| 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Dr. Thomas Rohn
 |
| 8. Signature | On behalf  |
| 9. Date | 01/03/2024 |
| 10. Annexes attached | Annex 1
Annex 3 (Addresses of Contract Manufacturing Site(s)) |

Annex 4 (Addresses of Contract Laboratories)

Annex 5 (Name of Qualified Person)

Annex 7 (Date of inspection on which authorisation
granted, scope of last inspection)

SCOPE OF AUTHORISATION

Name and address of the site:

Eurofins PHAST GmbH, Kardinal-Wendel-Straße 16, 66424 Homburg

Annex 1

Veterinary Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>
	<i>1.6.4 Biological</i>

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

The GMP certificate also covers the implementation of the listed methods on imported veterinary medicinal products.
However, batch certification of imported veterinary medicinal products is not covered by the GMP certificate - the manufacturing authorisation.

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Eurofins PHAST GmbH, Entenmühlstraße 48, 66424 Homburg

Veterinary Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>
	<i>1.6.4 Biological</i>

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

The GMP certificate also covers the implementation of the listed methods on imported veterinary medicinal products.

However, batch certification of imported veterinary medicinal products is not covered by the GMP certificate - the manufacturing authorisation.

Annex 3

Address(es) of Contract
Manufacturing Sites

Rhenus Archiv Services GmbH
Schmickstraße 14
60314 Frankfurt am Main
Storage of documents

Movianto Deutschland GmbH
In der Vogelsbach 1
66540 Neunkirchen
Storage of back-up samples

Address(es) of Contract Laboratories

Biochem Labor Für Biologische Und Chemische Analytik
GmbH

Daimlerstraße 5b

76185 Karlsruhe

Microbiological tests:

Test for sterility and adequate preservation of sterile
products and test according to

Ph. Eur. 5. 1. 4 for non-sterile products

Physico-chemical tests (e. g. loss of drying, sulphate ash,
Melting point determination)

Eurofins BioPharma Product Testing Munich GmbH

Robert-Koch-Str. 3a

82152 Planegg

Test for sterility

Test for endotoxins

MikroBiologie Krämer GmbH

Primsaue 7

66809 Nalbach

Microbiological tests:

testing for sterility and adequate preservation of sterile
products; and

Examination according to Ph. Eur. 5. 1. 4 for non-sterile
products

Labor LS SE & Co. KG

Mangelsfeld 4, 5, 6

97708 Bad Bocklet-Großenbrach

Microbiological tests:

testing for sterility and adequate preservation of sterile
products; and

Examination according to Ph. Eur. 5. 1. 4 for non-sterile
products

Eurofins Biolab S.r.l. Milan

Via Bruno Buozzi 2

20090 Vimodrone

Italien

Test for mycoplasma

Qualification of reference standard substances by means of
chromatographic and
mass spectrometric methods

Eurofins PROXY Laboratories B.V.

Darwinweg 24

2333CR LEIDEN

Test for mycoplasma

Eurofins Spinnovation Analytical B.V.

Kloosterstraat 9 PP, RK, OSS

5349AB Netherlands

Qualification of reference standard substances by means of
DSC, DVS, XRD and NMR

Eurofins IDmyk SAS

1 Rue des Vergers Batiment 4 Hall B

69760 Limonest, Frankreich

Frankreich

Testing of starting material, method development and
validation, release analysis

Eurofins PHAST Development GmbH & Co. KG

Byk-Gulden-Strasse 2

78467 Konstanz

Physico-chemical investigations:

e. g. determination of content, purity and/or identity by
means of HPLC and GC

by mass spectroscopy,

water determination by Karl Fischer titrations,

Content determination by titration and ion chromatography

Particle determination using Helos, Sprayview and micro
flow imaging

biological tests

determination of HCP by sprayblot,

Identity determination by means of SDS-Page,

Protein activity by means of Elisa

Storage of stability samples

Eurofins Amatsi Analytics SAS

Parc de Génibrat

31470 Fontenilles

Frankreich

Stability storage and testing

Eurofins Analytics & Services Austria GmbH

Sankt-Peter-Straße 25

A-4020 Linz

Österreich

Purity tests and raw material testing

Eurofins BioPharma Product Testing Hamburg GmbH

Am Neuländer Gewerbepark 2

21079 Hamburg

Raw material testing and microbiological examinations

Eurofins BioPharma Product Testing Switzerland AG

Parkstraße 10
5012 Schönenwerd
Schweiz
microbiological examinations

Eurofins Biopharma Product Testing Spain S.L.U.
Calle de Josep Argemi 13-15
08950 Esplugues de Llobregat, Barcelona
Spanien
Testing for nitrosamines

Eurofins Pharma Quality Control (EPQC)
Rue Clément Ader 16
68127 Sainte Croix en Plaine
Frankreich
Stability storage and testing

Eurofins Pharma Quality Control
9 Avenue de Laponie
91978 Les Ulis
Frankreich
Stability storage and testing

Name(s) of Qualified Person(s)

Mr. Dr. Denis Theobald

Mr. Dr. Achim Caspar

Deputy

Date of Inspection on which
authorisation was granted

13/12/2023