

MANUFACTURER'S AUTHORISATION

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

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|--|---|
| 1. Authorisation number/file number | DE_SL_01_MIA_2025_0027/5000-120#002 |
| 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) |
| 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 |  |
| 8. Signature | On behalf |
| 9. Date | 06/11/2025 |
| 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

Veterinary Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS**1.6 Quality control testing***1.6.3 Chemical/Physical**1.6.4 Biological*

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)

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 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 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 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 Biopharma Product Testing Biologics, Zone
Industrielle Du Charpenay
12 Rue du Parc d'Activités
69210 Lentilly
Frankreich
Stability storage of raw materials
Analytical testing (e.g. release testing of raw materials)

Henkel AG & Co. KGaA, Department Corporate Scientific
Solutions
Henkelstraße 67

40589 Düsseldorf
Analytical testing for nitrosamines and residues of cleaning agents

Microcoat Biotechnologie GmbH
Am Neuland 3
82347 Bernried am Starnberger See
Microbiological tests (e.g. endotoxins)

Eurofins Biolab S. r. l.
Via Bruno Buozzi 2
20055 Vimodrone
Italien
Testing for mycoplasma
Qualification of reference standard substances using chromatographic and mass spectrometric methods
Microbiological testing (e.g. sterility, CCIT, endotoxins)
Analytical testing (e.g. titration, GC, nitrosamines, lubricity)

Eurofins Pharma Quality Control, ZI de Courtaboeuf
9 avenue de Laponie
91940 Les Ulis
Frankreich
Physical and chemical testing
Stability storage and testing

Eurofins BioPharma Product Testing Munich GmbH
Robert-Koch-Str. 3a
82152 Planegg
Sterility testing
Endotoxin testing
Analytical testing (e.g. bioassay, chromatographic methods)

Eurofins BioPharma Product Testing Czech Republic s.r.o
Videnska 204/125, Prizrenice
61900 Brno
Tschechische Republik
Analytical tests (e.g. chromatographic analyses)

Annex 5

Name(s) of Qualified Person(s)

Mrs. Dr. Franziska Krebs

Mr. Patrick Klein

Deputy

Annex 7

Date of Inspection on which
authorisation was granted

13/12/2023