

Manufacturer/Importer Authorisation^{1, 2}

1. Authorisation Number V 369328/25
2. Name of authorisation holder Eurofins Pharma Quality Control (ORG-100011502 / LOC-100019504)
3. Address(es) of manufacturing site(s) Eurofins Pharma Quality Control (ORG-100011502 / LOC-100020938), Zone Industrielle De Courtaboeuf, 9 Avenue De Laponie, Les Ulis, 91940, France
4. Legally registered address of authorisation holder Site De La Geraudiere, Rue Pierre Adolphe Bobierre, Nantes, 44300, France
- 4.a Additional details on units inspected of legally registered address
5. Scope of authorisation and dosage forms² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 88 of Regulation (EU) 2019/6
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2025-01-09
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 as amended and Article 88(1) of Regulation (EU) 2019/6, 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 Interpretation of the Union format for Manufacturer/Importer Authorisation.

³ The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site: Eurofins Pharma Quality Control, Zone Industrielle De
Courtaboeuf, 9 Avenue De Laponie, Les Ulis, 91940, France

Additional Details:

Veterinary Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS(according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS(according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.4 Other products or manufacturing activity

1.4.1 Manufacture of

1.4.1.3 Other: holding of samples for on-going stability studies(en)

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 (for Public users)

This site is also authorised to manufacture veterinary investigational medicinal products, for the same operations.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.2 Microbiological: non-sterility

2.1.3 Chemical/Physical

2.1.4 Biological

2.3 Other importation activities

2.3.1 Site of physical importation

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

This site is also authorised to import veterinary investigational medicinal products for the same operations.

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