

Manufacturer/Importer Authorisation^{1, 2}

1. Authorisation Number 2025_236_1
2. Name of authorisation holder Pathoquest (ORG-100033674 / LOC-100052857)
3. Address(es) of manufacturing site(s) Pathoquest (ORG-100033674 / LOC-100052857), Batiment B, 11 Rue Watt, Paris, 75013, France
4. Legally registered address of authorisation holder Batiment B, 11 Rue Watt, Paris, 75013, France
5. Scope of authorisation and dosage forms² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 40 of Directive 2001/83/EC
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 2025-09-18
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 Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site: Pathoquest, Batiment B, 11 Rue Watt, Paris, 75013, France

Additional Details:

Human 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 (for Public users)

Manufacturer (Article R.5124-2 1° of the French Public Health Code) --- Signatory: Mrs Florence Descamps-Delesalle, head of pharmaceutical product inspection and counterfeiting fight department
--- The ANSM does not issue hard copy of this authorisation.

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : Pathoquest, Batiment B, 11 Rue Watt, Paris, 75013, France

Additional Details:

Human Investigational Medicinal Products
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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 (for Public users)

Manufacturer (Article R.5124-2 1° of the French Public Health Code) --- Signatory: Mrs Florence Descamps-Delesalle, head of pharmaceutical product inspection and counterfeiting fight department
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