

Manufacturer/Importer Authorisation^{1, 2}

1. Authorisation Number 2024_277_1_2
2. Name of authorisation holder ACM Pharma (ORG-100004844 / LOC-100090521)
3. Address(es) of manufacturing site(s) ACM Pharma (ORG-100004844 / LOC-100090521), 34 Avenue Du 21 Aout 1944, Bellegarde, 45270, France, GPS: 47.993427, 2.475984
ACM Pharma (ORG-100004844 / LOC-100052779), 16 Rue Orleanaise, Bellegarde, 45270, France
4. Legally registered address of authorisation holder 34 Avenue Du 21 Aout 1944, Bellegarde, 45270, France, GPS: 47.993427, 2.475984
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 2024-09-13
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

¹The 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.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.

³The 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: ACM Pharma, 34 Avenue Du 21 Aout 1944, Bellegarde, 45270, France, GPS: 47.993427, 2.475984

Additional Details:

Human Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i>
	<i>1.6.2 Microbiological: non-sterility</i>
	<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 (for Public users)

Manufacturer (Article R.5124-2 1° of the French Public Health Code) ---

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.1 Microbiological: sterility</i>
	<i>2.1.2 Microbiological: non-sterility</i>
	<i>2.1.3 Chemical/Physical</i>
	<i>2.1.4 Biological</i>

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

Importer (Article R.5124-2 2° 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 : ACM Pharma, 34 Avenue Du 21 Aout 1944, Bellegarde, 45270, France, GPS: 47.993427, 2.475984

Additional Details:

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
	1.6.1 Microbiological: sterility
	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)

Manufacturer (Article R.5124-2 1° of the French Public Health Code) ---

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.1	Quality control testing of imported medicinal products
	2.1.4 Biological

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

Importer (Article R.5124-2 2° 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 1

Name and address of the site: ACM Pharma, 16 Rue Orleanaise, Bellegarde, 45270, France

Additional Details:

Human Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS(according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.4	Other products or manufacturing activity
	<i>1.4.3 Other: limited to the storage of documentation(en)</i>

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

1.4.3: storage facility according to article R.5124-7, I of the French Public Health Code