MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	M 19/082
2. Name of authorisation holder	ACM PHARMA
3. Address(es) of manufacturing site(s)	ACM PHARMA, 34 avenue du 21 août 1944, BELLEGARDE, 45270, France Annexe de stockage ACM PHARMA, 16 rue orléanaise, BELLEGARDE, 45270, France
4. Legally registered address of authorisation holder	34 avenue du 21 Août 1944, BELLEGARDE, 45270, France
5. Scope of authorisation and dosage forms [2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 40 of Directive 2001/83/EC Art. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2019-06-04
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 and 44(1) of Directive 2001/82/EC, as amended, 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 Help menu of EudraGMDP database.*

[3] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site : ACM PHARMA, 34 avenue du 21 août 1944, BELLEGARDE, 45270, France

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

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

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: Mr Said Ioughlissen, deputy 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 août 1944, BELLEGARDE, 45270, France

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

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

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: Mr Said Ioughlissen, deputy 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 : Annexe de stockage ACM PHARMA, 16 rue orléanaise, BELLEGARDE, 45270, France

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

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

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