MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	F 20 /107
2. Name of authorisation holder	CENTRE D'ETUDES BIOLOGIQUES ET PHARMACEUTIQUES - CEBIPHAR
3. Address(es) of manufacturing site(s)	CENTRE D'ÉTUDES BIOLOGIQUES ET PHARMACEUTIQUES – CEBIPHAR, CANAL BIOTECH 2, 3 rue des Satellites, TOULOUSE, 31400, France
4. Legally registered address of authorisation holder	1 rue de la Bodinière, FONDETTES, 37230, 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	2020-07-30
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 : CENTRE D'ÉTUDES BIOLOGIQUES ET PHARMACEUTIQUES – CEBIPHAR, CANAL BIOTECH 2, 3 rue des Satellites, TOULOUSE, 31400, France

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**
	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)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical

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 Mélanie Cachet, deputy director - Inspection division. The ANSM does not issue hard copy of this authorisation.

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : CENTRE D'ÉTUDES BIOLOGIQUES ET PHARMACEUTIQUES – CEBIPHAR, CANAL BIOTECH 2, 3 rue des Satellites, TOULOUSE, 31400, France

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	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: Mrs Mélanie Cachet, deputy director - Inspection division. The ANSM does not issue hard copy of this authorisation.