

# MANUFACTURER'S AUTHORISATION<sup>1, 2</sup>

1. Authorisation Number M 20/214
2. Name of authorisation holder ELAIAPHARM
3. Address(es) of manufacturing site(s) ELAIAPHARM, 2881 route des Crêtes, ZI Les Bouillides, VALBONNE, 06560, France
4. Legally registered address of authorisation holder 2881 route des Crêtes, ZI Les Bouillides, VALBONNE, 06560, France
5. Scope of authorisation and dosage forms<sup>2</sup> 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 2020-12-21
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)<sup>3</sup>

<sup>1</sup> 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.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> 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 : ELAIAPHARM, 2881 route des Crêtes, ZI Les Bouillides,  
VALBONNE, 06560, France

Human Medicinal Products
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<b>Authorised Operations</b> MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids
	<i>1.1.3 Batch certification</i>
<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.8 Other solid dosage forms: granules(en) 1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.8 Other solid dosage forms: granules(en) 1.5.1.13 Tablets
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</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).

<b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	<i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i>
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1 Sterile products</i> <i>2.2.1.1 Aseptically prepared</i> <i>2.2.1.2 Terminally sterilised</i>
	<i>2.2.2 Non-sterile products</i>
<b>2.3</b>	<b>Other importation activities</b>
	<i>2.3.1 Site of physical importation</i> <i>2.3.2 Importation of intermediate which undergoes further processing</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: Mr Said Ioughlissen, deputy head of the 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 : ELAIAPHARM, 2881 route des Crêtes, ZI Les Bouillides,  
VALBONNE, 06560, France

Human Investigational Medicinal Products

### Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

### Part 1 - MANUFACTURING OPERATIONS

<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.3 Batch certification</i>
<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.2 Batch certification</i>
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.8 Other solid dosage forms: granules(en) 1.5.1.13 Tablets

### 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). --- This site is not authorised for blinding operations.

### Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	2.1.2 Microbiological: non-sterility 2.1.3 Chemical/Physical
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.2 Non-sterile products</i>
<b>2.3</b>	<b>Other importation activities</b>
	2.3.1 Site of physical importation 2.3.2 Importation of intermediate which undergoes further processing

### 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: Mr Said

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