MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	M 18/219
2. Name of authorisation holder	ELAIAPHARM
3. Address(es) of manufacturing site(s)	ELAIAPHARM, 2881 route des Crêtes, ZI les Bouillides Sophia Antipolis, VALBONNE, 06560, France
4. Legally registered address of authorisation holder	2881 route des Crêtes, ZI les Bouillides Sophia Antipolis, VALBONNE, 06560, 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	2018-12-21
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) [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 : ELAIAPHARM, 2881 route des Crêtes, ZI les Bouillides Sophia Antipolis, VALBONNE, 06560, France

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.8 Other solid dosage forms: granules(en) 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.8 Other solid dosage forms: granules(en) 1.5.1.13 Tablets
	1.5.2 Secondary packing
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: Mrs Dominique Debourges, deputy head of pharmaceutical product inspection and counterfeiting fight department. The ANSM does not issue hard copy of this authorisation.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.2 Importation of intermediate which undergoes further processing

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : ELAIAPHARM, 2881 route des Crêtes, ZI les Bouillides Sophia Antipolis, 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	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.8 Other solid dosage forms: granules(en) 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.8 Other solid dosage forms: granules(en) 1.5.1.13 Tablets
	1.5.2 Secondary packing
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). --- This site is not authorised for blinding operations. --- Signatory: Mrs Dominique Debourges, deputy head of pharmaceutical product inspection and counterfeiting fight department. The ANSM does not issue hard copy of this authorisation.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.2 Importation of intermediate which undergoes further processing