

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number 2021_114_1_2
2. Name of authorisation holder EUROFINS AMATSI ANALYTICS
3. Address(es) of manufacturing site(s) EUROFINS AMATSI ANALYTICS, Champ Paillard, SAINT AUGUSTIN, 19390, France
4. Legally registered address of authorisation holder Parc de Génibrat, FONTENILLES, 31470, France
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. 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 2021-07-06
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 : EUROFINS AMATSI ANALYTICS, Champ Paillard, SAINT AUGUSTIN, 19390, 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
	<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)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.3 Chemical/Physical</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 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 : EUROFINS AMATSI ANALYTICS, Champ Paillard, SAINT AUGUSTIN, 19390, France

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
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	1.6.3 Chemical/Physical
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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
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	2.1.3 Chemical/Physical
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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.