

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number F007/001/2020
2. Name of authorisation holder Hovione FarmaCiência, S.A.
3. Address(es) of manufacturing site(s) Hovione FarmaCiência, S.A., Sete Casas, Loures, 2674-506, Portugal
Hovione FarmaCiência, S.A., Rua Comandante Carvalho Araújo, Km 35.22, Sete Casas, Loures, 2674-540, Portugal
4. Legally registered address of authorisation holder Sete Casas, Loures, 2674-506, Portugal
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 Ms. Maria Fernanda Ralha Henriques Matos
8. Signature
9. Date 2020-09-24
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 : Hovione FarmaCiência, S.A., Sete Casas, Loures, 2674-506,
Portugal

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: Powders(en) 1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: Powders(en) 1.5.1.13 Tablets
1.6	Quality control testing
	<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

1.1.3. Iohexol

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

1.1.3. Iohexol

SCOPE OF AUTHORISATION**ANNEX 2**

Name and address of the site : Hovione FarmaCiência, S.A., Sete Casas, Loures, 2674-506,
Portugal

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS

1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.6 Liquids for internal use 1.2.1.13 Tablets 1.2.1.15 Other: powders(en)
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.5 Biotechnology products
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.6 Liquids for internal use 1.5.1.13 Tablets 1.5.1.15 Other non-sterile medicinal products: powders(en)
1.6	Quality control testing
	1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site : Hovione FarmaCiência, S.A., Rua Comandante Carvalho
Araújo, Km 35.22, Sete Casas, Loures, 2674-540, Portugal

Human Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell Special Requirements 7 Other: Also include medicinal products containing highly potent substances(en) 1.2.1.13 Tablets Special Requirements 7 Other: Also include medicinal products containing highly potent substances(en) 1.2.1.17 Other: Powders(en)
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

SCOPE OF AUTHORISATION**ANNEX 2**

Name and address of the site : Hovione FarmaCiência, S.A., Rua Comandante Carvalho
Araújo, Km 35.22, Sete Casas, Loures, 2674-540, Portugal

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.2	Non-sterile products
	<p><i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i></p> <p>1.2.1.1 Capsules, hard shell Special Requirements 7 Other: Also include investigational products containing highly potent substances(en)</p> <p>1.2.1.13 Tablets Special Requirements 7 Other: Also include investigational products containing highly potent substances(en)</p> <p>1.2.1.15 Other: Powders(en)</p>
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<p><i>1.5.1 Primary Packaging</i></p> <p>1.5.1.1 Capsules, hard shell Special Requirements 7 Other: Also include investigational products containing highly potent substances(en)</p> <p>1.5.1.13 Tablets Special Requirements 7 Other: Also include investigational products containing highly potent substances(en)</p> <p>1.5.1.15 Other non-sterile medicinal products: Powders(en)</p>
1.6	Quality control testing
	1.6.3 Chemical/Physical