




MANUFACTURER'S AUTHORISATION ^{1, 2}

1. Authorisation Number F032/V/AF/MV/003/2015
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
4. Legally registered address of authorisation holder Sete Casas, Loures, 2674-506, Portugal
5. Scope of authorisation and dosage forms ² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 44 of Directive 2001/82/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Dr. Alvaro Pegado Mendonca
8. Signature 
PAULA CRUZ DE CARVALHO
SUBDIRETORA-GERAL
Por despacho de delegação de competências nº 9297/2014
publicado no DRE, II série nº 136 de julho de 2014
9. Date 2015-04-08
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

Veterinary Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i>
	1.2.1.8 Other solid dosage forms: Powders(en)
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

Includes Veterinary Investigational Medicinal Products: article 90° of the Decreto-Lei nº 148/2008 of 29 july, as amended by the Decreto-Lei nº 314/2009 of 28 October

Online EudraGMP, Ref Key: 16913

ANEXO 5 / ANNEX 5

Nome e morada do local de fabrico: Hovione FarmaCiência, S.A., Sete Casas, Loures, 2674-506, Portugal

Name and address of the site:

Medicamentos de Uso Veterinário / Veterinary Medicinal Products

Diretor Técnico / Qualified Person

Nome(s) do(s) Diretor(es) Técnico(s) / Name(s) of Qualified Person(s)

Dr. Fernando Manuel Mateus Revés

pe

O Diretor Geral de Alimentação e Veterinária,



08.04.2015

Álvaro Pegado Mendonça

PAULA CRUZ DE CARVALHO

SUBDIRETORA-GERAL

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