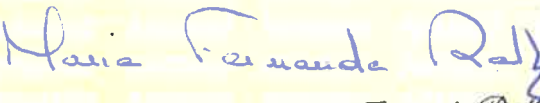


MANUFACTURER'S AUTHORISATION ^{1, 2}

1. Authorisation Number F034/001/2017
2. Name of authorisation holder D.L.A. Farmacêutica, S.A.
3. Address(es) of manufacturing site(s) D.L.A. Farmacêutica, S.A., Estrada da Quinta, 148 - Manique de Baixo, Alcabideche, 2645-436, Portugal
4. Legally registered address of authorisation holder Estrada Nacional, 117 - Edifício Azevedos, Alfragide, 2614-503 Amadora, Portugal
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 Ms. Maria Fernanda Ralha Henriques Matos
8. Signature 
Maria Fernanda Ralha
Directora da Direcção
Inspeção e Licenciamentos
9. Date 2017-03-21
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 : D.L.A. Farmacêutica, S.A., Estrada da Quinta, 148 - Manique de Baixo, Alcabideche, 2645-436, 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>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.2 Secondary packing</i>

10/2/12
Fernanda Ralha
Directora da Direcção
Inspeção e Licenciamentos

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : D.L.A. Farmacêutica, S.A., Estrada da Quinta, 148 - Manique de Baixo, Alcabideche, 2645-436, Portugal

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.2 Secondary packing</i>

Fernanda Ralha
Directora da Direcção
Inspeção e Licenciamentos

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

Dr. Thebar David de Oliveira Miranda


Fernanda Ralha
29 Directora da Direcção
Inspeção e Licenciamentos