

National Authority of Medicines and Health Products, I.P.

CERTIFICATE NUMBER: *F055/SI/SA/01/2014*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER ^{1, 2}

Part 1

Issued following an inspection in accordance with :

Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Portugal confirms the following:

The manufacturer: *QC Pharma - ISQ*

Site address: *Avenida Professor Doutor Cavaco Silva, n.º 33, Taguspark, Porto Salvo, 2740-120, Portugal*

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:

Art.176.º n.º 1 a) of Decree-Law n.º 176/2006, 30 of August

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2014-02-27**, it is considered that it complies with :

- The principles of GMP for active substances ³ referred to in Article 47 of Directive 2001/83/EC .

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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).

Part 2

1 MANUFACTURING OPERATIONS	
1.6	Quality control testing
	1.6.3 Chemical/Physical

2014-03-27

Name and signature of the authorised person of the
Competent Authority of Portugal



Ms Maria Fernanda Ralha Henriques Matos
National Authority of Medicines and Health Products,
I.P.
Directora da Direcção
Inspeção e Licenciamentos
Tel: +351 21 7987278
Fax: +351 21 7987257

National Authority of Medicines and Health Products, I.P.

CERTIFICATE NUMBER: *F055/S1/MH/01/2014*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER ^{1, 2}

Part 1

Issued following an inspection in accordance with :

Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Portugal confirms the following:

The manufacturer: *QC Pharma - ISQ*

Site address: *Avenida Professor Doutor Cavaco Silva, n.º 33, Taguspark, Porto Salvo, 2740-120, Portugal*

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. *F055/01/2014* in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

Art. 55.º of Decree-Law n.º 176/2006, 30 of August

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2014-02-27**, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC ³

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.6	Quality control testing
	1.6.3 Chemical/Physical

2014-03-27

Name and signature of the authorised person of the
Competent Authority of Portugal



Ms Maria Fernanda Ralha Henriques Matos
National Authority of Medicines and Health Products,
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Tel: +351 21 7987278
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Directora da Direcção
Inspeção e Licenciamentos

National Authority of Medicines and Health Products, I.P.

CERTIFICATE NUMBER: **F055/S1/ME/01/2014**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER ^{1, 2}

Part 1

Issued following an inspection in accordance with :

Art. 15 of Directive 2001/20/EC

The competent authority of Portugal confirms the following:

The manufacturer: ***QC Pharma - ISQ***

Site address: ***Avenida Professor Doutor Cavaco Silva, n.º 33, Taguspark, Porto Salvo, 2740-120, Portugal***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **F055/01/2014** in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation:

Art. 29 of Law n.º 46/2004, de 19 of August

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2014-02-27**, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC ³

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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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).

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS

1.6	Quality control testing
	1.6.3 Chemical/Physical


2014-03-27

Name and signature of the authorised person of the
Competent Authority of Portugal



Ms Maria Fernanda Ralha Henriques Matos
National Authority of Medicines and Health Products,
I.P. **Director of the Directorate**
Inspection and Licensing
Tel: +351 21 7987278
Fax: +351 21 7987257

MANUFACTURER'S^{1, 2} AUTHORISATION

1. Authorisation Number F055/01/2014
2. Name of authorisation holder QC Pharma - ISQ
3. Address(es) of manufacturing site(s) QC Pharma - ISQ, Avenida Professor Doutor Cavaco Silva, n.º 33, Taguspark, Porto Salvo, 2740-120, Portugal
4. Legally registered address of authorisation holder Avenida Professor Doutor Cavaco Silva, n.º 33 Taguspark, Porto Salvo, 2740-120, 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 
Fernanda Ralha
Directora da Direcção
Inspeção e Licenciamentos
9. Date 2014-03-27
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 : QC Pharma - ISQ, Avenida Professor Doutor Cavaco Silva, n.º
33, Taguspark, Porto Salvo, 2740-120, Portugal

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.6	Quality control testing
	1.6.3 Chemical/Physical

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : QC Pharma - ISQ, Avenida Professor Doutor Cavaco Silva, n.º
33, Taguspark, Porto Salvo, 2740-120, Portugal

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.6 Quality control testing

1.6.3 Chemical/Physical