



## PROCURADORIA-GERAL DA REPÚBLICA

Ref.ª/réf./ref.

### APOSTILLE

#### Convention de La Haye du 5 octobre 1961

1. País/Pays/Country: **Portugal**  
Este documento público/Le présent acte public/This public document
2. Foi assinado por/a été signé par/has been signed by **assinatura digital**
3. Agindo na qualidade de/agissant dans la qualité de/acting in the capacity of
4. E tem o selo de/est revêtu du sceau de/bears the seal of **INFARMED**

#### Reconhecido/Attesté/Certified

5. Em/à/at **Lisboa**
6. A /le /the **23 de março de 2021**
7. Pela Procuradora-Geral da República /par le Procureur général de la République/by the Attorney General
8. Sob o nº /sous le nº /Nº **6000-2021**
9. Selo/sceau/seal
10. Assinatura/signature/signature

Lucília Maria das Neves Franco Morgadinho Gago

*A presente Apostila apenas certifica a assinatura, a qualidade em que o signatário do ato atuou e o selo/carimbo que consta do ato. Não certifica o conteúdo do documento para o qual foi emitida.*

*Cette Apostille ne certifie que la signature, la qualité en laquelle le signataire de l'acte a agi et le sceau/timbre dont cet acte est revêtu. Elle ne certifie pas le contenu du document pour lequel elle a été émise.*

*This Apostille only certifies the signature, the capacity of the signer and the seal/stamp it bears. It does not certify the content of the document for which it was issued.*

*La presente Apostilla sólo certifica la firma, la capacidad del signatario y el sello/timbre que ostenta. La Apostilla no certifica el contenido del documento para el cual se expidió.*

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

CERTIFICATE NUMBER :**F036/S1/MH/001/2018**

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**<sup>1, 2</sup>

**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:**Atlantic Pharma - Produções Farmacêuticas, S.A.**

Site address:**Rua da Tapada Grande, n° 2, Abrunheira, Sintra, 2710-089, Portugal**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **F036/001/2018** 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 **2017-12-07**, it is considered that it complies with:

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

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.

<sup>1</sup> The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> These requirements fulfil the GMP recommendations of WHO.

## Part 2

### Human Medicinal Products

#### 1 MANUFACTURING OPERATIONS

|            |                                                                                                                                                                                                                                                                        |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1.1</b> | <b>Sterile products</b>                                                                                                                                                                                                                                                |
|            | <i>1.1.3 Batch certification</i>                                                                                                                                                                                                                                       |
| <b>1.2</b> | <b>Non-sterile products</b>                                                                                                                                                                                                                                            |
|            | <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i><br>1.2.1.1 Capsules, hard shell<br>1.2.1.6 Liquids for internal use<br>1.2.1.8 Other solid dosage forms: Powders and granules(en)<br>1.2.1.11 Semi-solids<br>1.2.1.13 Tablets |
|            | <i>1.2.2 Batch certification</i>                                                                                                                                                                                                                                       |
| <b>1.5</b> | <b>Packaging</b>                                                                                                                                                                                                                                                       |
|            | <i>1.5.1 Primary Packaging</i><br>1.5.1.1 Capsules, hard shell<br>1.5.1.6 Liquids for internal use<br>1.5.1.8 Other solid dosage forms: Powders and granules(en)<br>1.5.1.11 Semi-solids<br>1.5.1.13 Tablets                                                           |
|            | <i>1.5.2 Secondary packaging</i>                                                                                                                                                                                                                                       |
| <b>1.6</b> | <b>Quality control testing</b>                                                                                                                                                                                                                                         |
|            | <i>1.6.2 Microbiological: non-sterility</i><br><i>1.6.3 Chemical/Physical</i>                                                                                                                                                                                          |

#### 2 IMPORTATION OF MEDICINAL PRODUCTS

|            |                                                                                                |
|------------|------------------------------------------------------------------------------------------------|
| <b>2.1</b> | <b>Quality control testing of imported medicinal products</b>                                  |
|            | <i>2.1.2 Microbiological: non-sterility</i><br><i>2.1.3 Chemical/Physical</i>                  |
| <b>2.2</b> | <b>Batch certification of imported medicinal products</b>                                      |
|            | <i>2.2.1 Sterile products</i><br>2.2.1.1 Aseptically prepared<br>2.2.1.2 Terminally sterilised |
|            | <i>2.2.2 Non-sterile products</i>                                                              |

|       |                                     |
|-------|-------------------------------------|
| 5     | <b>Other importation activities</b> |
| 2.3.1 | <i>Site of physical importation</i> |

Any restrictions related to the scope of this certificate :

*Based on the outcome of the distant assessment of 4th to 6th November 2020, and in order to conclude the inspection process, this GMP certificate is valid until 07/06/2021.*

Clarifying remarks (for public users)

*Based on the outcome of the distant assessment of 4th to 6th November 2020, and in order to conclude the inspection process, this GMP certificate is valid until 07/06/2021.*

2021-03-05

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

Maria Fernanda  
Ralha  
Henriques  
Matos

Assinado de forma  
digital por Maria  
Fernanda Ralha  
Henriques Matos  
Dados: 2021.03.05  
18:17:48 Z

***Ms. Maria Fernanda Ralha Henriques Matos***  
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***L.P.***

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