

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

CERTIFICATE NUMBER: ***F016/S1/MH/001/2020***

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: ***Laboratórios Basi - Indústria Farmacêutica, S.A.***

Site address: ***Parque Industrial Manuel Lourenço Ferreira, Lotes 8, 15 e 16, Mortágua, 3450-232, Portugal***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***F016/001/2020*** 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 ***2019-09-06*** , 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.

¹ 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.

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

³ These requirements fulfil the GMP recommendations of WHO.

ACF 2020

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids
	1.2.2 Batch certification
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids
	1.5.2 Secondary packaging
1.6	Quality control testing
	1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical
2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	2.1.1 Microbiological: sterility 2.1.2 Microbiological: non-sterility 2.1.3 Chemical/Physical

2.2	Batch certification of imported medicinal products
	2.2.1 <i>Sterile products</i> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 <i>Non-sterile products</i>
2.3	Other importation activities
	2.3.1 <i>Site of physical importation</i>

Any restrictions related to the scope of this certificate :

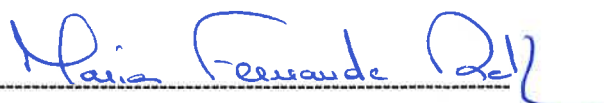
1.1.1.4 - Considering the COVID-19 pandemic that has affected and/or prevented the conduct of on-site GMP inspections, this dosage form was included in the GMP certificate based on a distant assessment performed on June 2020. 1.5.2 - Tablets and capsules (hard shell and soft shell); sterile products: lyophilisates. 1.6 - Sterile products: lyophilisates.

Clarifying remarks (for public users)

1.1.1.4 - Considering the COVID-19 pandemic that has affected and/or prevented the conduct of on-site GMP inspections, this dosage form was included in the GMP certificate based on a distant assessment performed on June 2020. 1.5.2 - Tablets and capsules (hard shell and soft shell); sterile products: lyophilisates. 1.6 - Sterile products: lyophilisates.

2020-07-27

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.

Tel: +351 21 7987278

Fax: +351 21 7987257