

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

CERTIFICATE NUMBER : ***F007/S1/MH/001/2021***

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 : ***Hovione FarmaCiência, S.A.***

Site address : ***Sete Casas, Loures, 2674-506, Portugal***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***F007/001/2021*** 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 ***2018-06-08*** , 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.

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: Powders(en) 1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: Powders(en) 1.5.1.13 Tablets
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

Any restrictions related to the scope of this certificate :

1.1.3. Iohexol. - Based on the outcome of the inspection performed on 08th to 12th November 2021, by hybrid method, and in order to conclude the inspection process, this GMP certificate is valid until 21/03/2022. - The raw materials and excipients for manufacturing will also be stored at the facilities of wholesaler DILOFAR - DISTRIBUIÇÃO, TRANSPORTES E LOGÍSTICA, LDA., located at Quinta do Pinheiro, nº 5 - 2615-184 Alverca, Portugal.

Clarifying remarks (for public users)

1.1.3. Iohexol. - Based on the outcome of the inspection performed on 08th to 12th November 2021, by hybrid method, and in order to conclude the inspection process, this GMP certificate is valid until 21/03/2022. - The raw materials and excipients for manufacturing will also be stored at the facilities of wholesaler DILOFAR - DISTRIBUIÇÃO, TRANSPORTES E LOGÍSTICA, LDA., located at Quinta do Pinheiro, nº 5 - 2615-184 Alverca, Portugal.

2022-01-07

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

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L.P.

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