

## National Organization For Medicines

CERTIFICATE NUMBER: **116818/1-11-2023**

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

### Part 1

Issued following an inspection in accordance with  
Art. 94(1) of Regulation (EU) 2019/6 as amended  
Art. 15 of Directive 2001/20/EC  
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Greece confirms the following:

The manufacturer: **Qualimetrix S.A.**

Site address: **Mesogeion Avenue 579, Agia Paraskevi, Athens, 153 43, Greece, GPS: 38.01221, 23.815573**

OMS Organisation Id. / OMS Location Id.: **ORG-100021115 / LOC-100029818**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **0000012546/23/1** in accordance with Art. 88 of Regulation (EU) 2019/6, Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2023-09-18**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 <sup>3</sup>
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>).

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 Art. 80(5) of Directive 2001/82/EC, Art. 15 of Directive 2001/20/EC and Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

<sup>2</sup>Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

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

## Part 2

Veterinary Medicinal Products
Human Investigational Medicinal Products
Human Medicinal Products

<b>1 MANUFACTURING OPERATIONS</b>	
<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>1.2.2 Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<i>1.3.2 Batch Certification (list of product types)</i> <i>1.3.2.6 Human or animal extracted products</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

<b>2 IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	<i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i> <i>2.1.4 Biological</i>
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1 Sterile products</i> <i>2.2.1.1 Aseptically prepared</i> <i>2.2.1.2 Terminally sterilised</i>
	<i>2.2.2 Non-sterile products</i>
	<i>2.2.3 Biological medicinal products</i> <i>2.2.3.6 Human or animal extracted products</i>

Clarifying remarks (for public users)

**1. The microbiological and biological testings are carried out in the microbiological laboratory of the site, located at 36 Marathonos Avenue, 15354, Glyka Nera, Attica. 2. Under Biological controls LAL test is also included.**

**2023-12-14**

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

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