

Certificate No: IT-API/183/H/2023

## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

### Part 1

#### Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:

The manufacturer I.M.S. S.R.L.

Site address Via Venezia Giulia, 23 (loc. MILANO) - 20157 MILANO (MI)

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: **D.L. n. 219 of 24<sup>th</sup> April 2006 art. 53**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2022/12/22, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substances 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. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

**Part 2**

**Name and address of the site:**

**I.M.S. S.R.L. - Via Venezia Giulia, 23 (loc.MILANO), 20157 MILANO (MI)**

Name of the active Substances manufactured or imported:

ACTIVE SUBSTANCES (NON STERILE AND/OR NON BIOLOGICAL, NON FROM HUMAN AND ANIMAL TISSUES, ORGANS, FLUIDS)

ACTIVE SUBSTANCES (STERILE AND/OR BIOLOGICAL AND/OR FROM HUMAN AND ANIMAL TISSUES, ORGANS, FLUIDS)

### **3. Manufacturing Operations - Active Substances**

#### **3 - Manufacturing Operations - Active Substances**

**ACTIVE SUBSTANCES (NON STERILE AND/OR NON BIOLOGICAL, NON FROM HUMAN AND ANIMAL TISSUES, ORGANS, FLUIDS)**

<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1.</b> Physical processing steps milling/micronisation, sieving Special Requirements Other: Hormones or substances with hormonal activity</p> <p><b>3.5.2.</b> Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.3.</b> Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<b>3.6.1.</b> Physical / Chemical testing

### 3 - Manufacturing Operations - Active Substances

#### ACTIVE SUBSTANCES (STERILE AND/OR BIOLOGICAL AND/OR FROM HUMAN AND ANIMAL TISSUES, ORGANS, FLUIDS)

<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1.</b> Physical processing steps milling/micronisation, sieving</p> <p><b>3.5.2.</b> Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.3.</b> Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<b>3.6.1.</b> Physical / Chemical testing

#### Restrictions or clarifying remarks:

According to Italian legislation, all the biological active substances and/or active substances deriving from human and animal tissues, organs, fluids are authorized according to art. 40 of Dir. 2001/83/EC. On a risk-based approach, the validity of the GMP certificate for this manufacturing site is not more than 42 months from the latest general GMP inspection, conducted on 2022/Dicember/22, except for AIFA's re-evaluation of the risk profile. No batch certification

Rome, 2023/07/24

**Name and signature of the authorised person of  
the Competent Authority of Republic of Italy**

Dott. Michele Marangi  
AIFA - GMP Inspections and Manufacturing  
Authorizations of APIs Office  
Electronically signed according to the Italian legislation

**Stamp duty paid according to the current Italian legislation.**

AIFA - Italian Medicines Agency  
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