

Certificate No: IT/112/H/2024

## 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 FARMOL HEALTH CARE SRL

Site address VIA DEL MAGLIO, 6 - 23868 VALMADRERA (LC)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 87/2024 dated 05/30/2024 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 01/18/2024, it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/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, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

**Part 2**

Name and address of the site: FARMOL HEALTH CARE SRL - VIA DEL MAGLIO, 6 , 23868 VALMADRERA(LC)

Human Medicinal Products
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<b>Authorised Operations</b>	
Manufacturing Operations (Part 1)	
<b>PART 1 - MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile Products</b>
	<p>1.1.2 <i>Terminally sterilised</i></p> <p>1.1.2.5 Other terminally sterilised prepared products Special Requirements: Other : hormones or substances with hormonal activity</p> <p>1.1.3 <i>Batch certification</i></p>
<b>1.2</b>	<b>Non-sterile products</b>
	<p>1.2.1 <i>Non-sterile products</i></p> <p>1.2.1.5 Liquids for external use Special Requirements: Other : hormones or substances with hormonal activities</p> <p>1.2.1.9 Pressurised preparations Special Requirements: Other : hormones or substances with hormonal activity</p> <p>1.2.2 <i>Batch certification</i></p>
<b>1.5</b>	<b>Packaging</b>
	<p>1.5.1 <i>Primary packing</i></p> <p>1.5.1.5 Liquids for external use Special Requirements: Other : hormones or substances with hormonal activities</p>

	1.5.1.9	Pressurised preparations Special Requirements: Other : hormones or substance with hormonal activities
	1.5.2	<i>Secondary packing</i>
<b>1.6</b>	<b>Quality control testing</b>	
	1.6.3	<i>Chemical/Physical</i>

**Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:**

1.1.2.5 Other terminally sterilised prepared products: cutaneous sprays - excluding sterilization activity;

1.1.3 Batch certification: terminally sterilized products;

Rome, 05/30/2024

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

Angela Del Vecchio  
GMP Inspections and Manufacturing  
Authorizations of Medicinal Products Office

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW

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PC  
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