

Certificate No: IT/234/H/2022

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 FARMIGEA S.P.A.

Site address VIA G.B. OLIVA, 8 - 56121 PISA (PI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 166/2022 dated 11/30/2022 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 03/10/2022, 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: FARMIGEA S.P.A. - VIA G.B. OLIVA, 8 , 56121 PISA(PI)

Human Medicinal Products

Authorised Operations	
Manufacturing Operations (Part 1)	
PART 1 - MANUFACTURING OPERATIONS	
1.1	Sterile Products
	<p>1.1.1 <i>Aseptically prepared</i></p> <p>1.1.1.3 Semi-solids Special Requirements: Other : Hormones or substances with hormonal activity</p> <p>1.1.1.4 Small volume liquids Special Requirements: Other : Hormones or substances with hormonal activity</p> <p>1.1.3 <i>Batch certification</i></p>
1.3	Biological medicinal products
	<p>1.3.1 <i>Biological medicinal products</i></p> <p>1.3.1.6 Human or animal extracted products</p> <p>1.3.2 <i>Batch certification</i></p> <p>1.3.2.6 Human or animal extracted products</p>
1.5	Packaging
	1.5.2 <i>Secondary packing</i>
1.6	Quality control testing
	<p>1.6.1 <i>Microbiological: sterility</i></p> <p>1.6.3 <i>Chemical/Physical</i></p> <p>1.6.4 <i>Biological</i></p>

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

- 1.1.1.4 Small volume liquids: also animal extracted biological products;
- 1.3.1.6 Human or animal extracted products: animal extracted products;
- 1.3.2.6 Human or animal extracted products: Animal extracted products in aseptically prepared small volume liquids;
- 1.6.4 Biological: In vitro testing;

Name and address of the site: FARMIGEA S.P.A. - VIA G.B. OLIVA, 8 , 56121 PISA(PI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.1	Sterile investigational medical products
	1.1.1 <i>Aseptically prepared</i>
	1.1.1.4 Small volume liquids
	1.1.3 <i>Batch certification</i>

PART 2 - IMPORTATION OF INVESTIGATIONAL MEDICAL PRODUCTS

2.1	Quality control testing of imported investigational medical products
	2.1.1 <i>Microbiological: sterility</i>
	2.1.3 <i>Chemical/Physical</i>



Rome, 11/30/2022

**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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