Certificate No: IT/242/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 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 - 175/2024 dated 12/02/2024 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50, Art. 13 of Directive 2001/20/EC transposed in the following national legislation: D. Lvo 211/2003 Art. 13 and Art. 63 of the Regulation (EU) 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 11/13/2024, 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.

AIFA: Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784357 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 2577

IV
GMP

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**		
	1.1.1	*Aseptically prepared*	
		1.1.1.3	Semi-solids Special Requirements: Other : Hormones or substances with hormonal activity
		1.1.1.4	Small volume liquids Special Requirements: Other : Hormones or substances with hormonal activity
	1.1.3	*Batch certification*	
1.3	**Biological medicinal products**		
	1.3.1	*Biological medicinal products*	
		1.3.1.6	Human or animal extracted products
	1.3.2	*Batch certification*	
		1.3.2.6	Human or animal extracted products
1.5	**Packaging**		
	1.5.2	*Secondary packing*	
1.6	**Quality control testing**		
	1.6.1	*Microbiological: sterility*	
	1.6.3	*Chemical/Physical*	
	1.6.4	*Biological*	

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;

1.1.3 Batch certification: only for sterile products aseptically produced;

1.3.1.6 Human or animal extracted products: animal extracted products in small volume liquids aseptically produced;

1.3.2.6 Human or animal extracted products: Animal exctracted products ;

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)	
PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS	
1.1	**Sterile investigational medicinal products**
	1.1.1 *Aseptically prepared* 1.1.1.4 Small volume liquids *1.1.3* *Batch certification*

Rome, 12/02/2024

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

DEL VECCHIO
ANGELA
AIFA - AGENZIA ITALIANA DEL FARMACO
Dirigente
09.12.2024
16:34:37
GMT+01:00

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

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW

AIFA Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784357 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 2577