Certificate No: IT/38/H/2025

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 EUROFINS BIOLAB SRL
Site address VIA B. BUOZZI, 2 - 20055 VIMODRONE (MI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 30/2025 dated 04/07/2025 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 09/13/2024, 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 : 963

IV
GMP

Part 2

Name and address of the site:	EUROFINS BIOLAB SRL - VIA B. BUOZZI, 2 , 20055 VIMODRONE(MI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)
Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS

1.6	**Quality control testing**	
	1.6.1	*Microbiological: sterility*
	1.6.2	*Microbiological: non-sterility*
	1.6.3	*Chemical/Physical*
	1.6.4	*Biological*

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

Also quality control testing for active substances batch certification;
1.6.4 Biological: In vivo test, In vitro test and Endotoxins test (LAL test);

PART 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.1	**Quality control testing of imported medicinal products**	
	2.1.1	*Microbiological: sterility*
	2.1.2	*Microbiological: non-sterility*
	2.1.3	*Chemical/Physical*
	2.1.4	*Biological*

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

Also quality control testing for active substances batch certification;

2.1.4 Biological: In vivo test, In vitro test, Endotoxins test (LAL test);

Name and address of the site:	EUROFINS BIOLAB SRL - VIA B. BUOZZI, 2 , 20055 VIMODRONE(MI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)
Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.6	**Quality control testing**	
	1.6.1	*Microbiological: sterility*
	1.6.2	*Microbiological: non-sterility*
	1.6.3	*Chemical/Physical*
	1.6.4	*Biological*

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

Also quality control testing for active substances batch certification;
1.6.4 Biological: In vivo test, in vitro test and Endotoxin test (LAL test);

PART 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

2.1	**Quality control testing of imported investigational medicinal products**	
	2.1.1	*Microbiological: sterility*
	2.1.2	*Microbiological: non-sterility*
	2.1.3	*Chemical/Physical*
	2.1.4	*Biological*

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

2.1.4 Biological: in vivo and in vitro test; bacterial endotoxin test (LAL test);

Rome, 04/07/2025

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
07.04.2025 15:22:13
GMT+01:00

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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