

Certificate No: IT/90/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 PLC RESEARCH & MANUFACTURING SRL

Site address VIA F.S. FABRI, 127/1 - 40059 MEDICINA (BO)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aAMM - 83/2025 dated 07/01/2025 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50 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 10/20/2023, 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: PLC RESEARCH & MANUFACTURING SRL- VIA F.S. FABRI, 127/1 , 40059 MEDICINA(BO)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
	1.6.3 Chemical/Physical

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

1.6.3 Chemical/Physical: also QC testing for active substances;

Name and address of the site: PLC RESEARCH & MANUFACTURING SRL - VIA F.S. FABRI, 127/1 , 40059 MEDICINA(BO)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.6	Quality control testing
	1.6.3 Chemical/Physical

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

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 : 7282

1.6.3 Chemical/Physical: also QC testing for active substances ;

Rome, 07/01/2025

**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
01.07.2025 12:58:56
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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