

Certificate No: IT/150/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 PHARMAPROGRESS S.R.L.

Site address VIA EMILIA ROMAGNA, 28-30-32 - 60030 MONSANO (AN)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 127/2025 dated 09/04/2025 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50 and Art. 61 of the Regulation (EU) 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 11/14/2023, 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: PHARMAPROGRESS S.R.L. - VIA EMILIA
ROMAGNA, 28-30-32 , 60030 MONSANO(AN)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS

1.1	Sterile Products
	1.1.3 Batch certification
1.2	Non-sterile products
	1.2.2 Batch certification
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 quality controls for active substances release;

PART 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.1	Quality control testing of imported medicinal products
	2.1.3 Chemical/Physical
2.2	Batch certification only (list of product types)
	2.2.1 Sterile products
	2.2.1.1 Aseptically prepared products
	2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products

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

2.1.3 Chemical/Physical: also quality controls for active substances release;

Name and address of the site: PHARMAPROGRESS S.R.L. - VIA EMILIA
ROMAGNA, 28-30-32 , 60030 MONSANO(AN)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS
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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 quality controls for active substances release;

Rome, 09/04/2025

**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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