AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/40/H/2021

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 BIOFARMA S.R.L.
Site address VIA CASTELLIERE,2 - 33036 MERETO DI TOMBA (UD)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aAMM - 28/2021 dated 02/09/2021 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 05/31/2018, 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.+390659784410 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 4707

RS
GMP

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site:	BIOFARMA S.R.L. VIA CASTELLIERE,2 33036 MERETO DI TOMBA (UD)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products*	
		1.2.1.1	Capsules, hard shell
		1.2.1.8	Other solid dosage forms
		1.2.1.13	Tablets
1.3	**Biological medicinal products**		
	1.3.1	*Biological medicinal products*	
		1.3.1.7	Tissue engineering products
1.5	**Packaging**		
	1.5.1	*Primary packing*	
		1.5.1.1	Capsules, hard shell
		1.5.1.6	Liquids for internal use
		1.5.1.8	Other solid dosage forms
		1.5.1.13	Tablets
	1.5.2	*Secondary packing*	
1.6	**Quality control testing**		
	1.6.2	*Microbiological: non-sterility*	
	1.6.3	*Chemical/Physical*	

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

1.2.1.1 Capsules, hard shell: only live biotherapeutic products;

1.2.1.8 Other solid dosage forms: powder: only live biotherapeutic products;

1.2.1.13 Tablets: only live biotherapeutic products;

1.3.1.7 Tissue engineering products: only live biotherapeutic products: hard shells, tablets, powder, liquids for internal use;
1.5.1.1 Capsules, hard shell: only live biotherapeutic products;
1.5.1.6 Liquids for internal use: only live biotherapeutic products;
1.5.1.8 Other solid dosage forms: powder: only live biotherapeutic products;
1.5.1.13 Tablets: only live biotherapeutic products.

Rome, 03/29/2021

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

E' copia conforme all'originale
composta di n. 3 fogli
Roma il 29 MAR 2021

Renato Massimi
GMP Inspections and Manufacturing
Authorizations of Medicinal Products Office

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