AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/218/H/2018

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 BIOINDUSTRIA LABORATORIO ITALIANO MEDICINALI S.P.A.
Site address VIA DE AMBROSIIS 2/6 - 15067 NOVI LIGURE (AL)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 122/2018 dated 09/25/2018 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 06/15/2018, 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 : 823

PC
GMP

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site:	BIOINDUSTRIA LABORATORIO ITALIANO MEDICINALI S.P.A. - VIA DE AMBROSIIS 2/6 , 15067 NOVI LIGURE(AL)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**	
	1.1.1	*Aseptically prepared*
	1.1.1.2	Lyophilisates
	1.1.1.4	Small volume liquids
	1.1.2	*Terminally sterilised*
	1.1.2.1	Large volume liquids
	1.1.2.3	Small volume liquids
	1.1.3	*Batch certification*
1.2	**Non-sterile products**	
	1.2.1	*Non-sterile products*
	1.2.1.1	Capsules, hard shell
	1.2.1.13	Tablets
	1.2.2	*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**	
	1.5.1	*Primary packing*
	1.5.1.1	Capsules, hard shell
	1.5.1.13	Tablets
	1.5.2	*Secondary packing*
1.6	**Quality control testing**	

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	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:

1.1.1.2 Lyophilisates: Medicinal products containing, derived or extracted from animal tissue/cells, also medicinal products containing substances derived or extracted from tissue/animal cells;

1.3.1.6 Human or animal extracted products: animal exctracted products;

1.6.2 Microbiological: non-sterility: also QC testing for active substances release;

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

1.6.4 Biological: LAL test;

Rome, 10/15/2018

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

Dott. Renato Massimi
GMP Inspections and Manufacturing
Authorizations of Medicinal Products Office

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