AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/26/H/2020

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 ALFASIGMA S.P.A.
Site address VIA ENRICO FERMI, 1 - 65020 ALANNO (PE)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 10/2020 dated 01/31/2020 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 12/19/2019, 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 : 4375

PC
GMP

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site: ALFASIGMA S.P.A. - VIA ENRICO FERMI, 1 , 65020 ALANNO(PE)

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 Special Requirements: Other : hormones or substances with hormonal activities
		1.1.1.4	Small volume liquids Special Requirements: Other : hormones or substances with hormonal activities
		1.1.1.6	Other aseptically prepared products: polveri
	1.1.2	*Terminally sterilised*	
		1.1.2.3	Small volume liquids Special Requirements: Other : hormones or substances with hormonal activities
	1.1.3	*Batch certification*	
1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products*	
		1.2.1.1	Capsules, hard shell
		1.2.1.5	Liquids for external use
		1.2.1.6	Liquids for internal use
		1.2.1.8	Other solid dosage forms
		1.2.1.11	Semi-solids

		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
		1.5.1.2 Capsules, soft shell
		1.5.1.5 Liquids for external use
		1.5.1.6 Liquids for internal use
		1.5.1.8 Other solid dosage forms
		1.5.1.11 Semi-solids
		1.5.1.13 Tablets
	1.5.2	*Secondary packing*
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:

1.2.1.8 Other solid dosage forms: Granules, powders;

1.3.1.6 Human or animal extracted products: Drug products containing extracts form animal tissues and/or cells: soft shell capsules,aseptically prepared small volume liquids , terminally sterilised small volume liquids ;

1.6.4 Biological: in vitro test, LAL test ;

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 : 4375

AGENZIA ITALIANA DEL FARMACO

Name and address of the site: MAGAZZINO - Strada Pantiera s.n.c. - 65020 - ROSCIANO (PE)

Human Medicinal Products

Authorised Operations Manufacturing Operations (Part 1)		
PART 1 - MANUFACTURING OPERATIONS		
1.4	**Other products or manufacturing activity**	
	1.4.3	*Others*

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

1.4.3 Others: Storage;

Name and address of the site: ALFASIGMA S.P.A. - VIA ENRICO FERMI, 1 , 65020 ALANNO(PE)

Human Medicinal Products

Authorised Operations Manufacturing Operations (Part 1)			
PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS			
1.1	**Sterile investigational medical products**		
	1.1.1	*Aseptically prepared*	
		1.1.1.2	Lyophilisates Special Requirements: Other : hormones or substances with hormonal activities
		1.1.1.4	Small volume liquids Special Requirements: Other : hormones or substances with hormonal

		activities
	1.1.1.6	Other aseptically prepared products: powders
1.1.2	*Terminally sterilised*	
	1.1.2.3	Small volume liquids Special Requirements: Other : hormones or substances with hormonal activities
1.1.3	*Batch certification*	
1.2	**Non-sterile investigational medical products**	
1.2.1	*Non-sterile products*	
	1.2.1.1	Capsules, hard shell
	1.2.1.5	Liquids for external use
	1.2.1.6	Liquids for internal use
	1.2.1.8	Other solid dosage forms
	1.2.1.11	Semi-solids
	1.2.1.13	Tablets
1.2.2	*Batch certification*	
1.3	**Biological investigational 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
	1.5.1.2	Capsules, soft shell
	1.5.1.5	Liquids for external use
	1.5.1.6	Liquids for internal use
	1.5.1.8	Other solid dosage forms
	1.5.1.11	Semi-solids
	1.5.1.13	Tablets
1.6	**Quality control testing**	
1.6.1	*Microbiological: sterility*	
1.6.2	*Microbiological: non-sterility*	
1.6.3	*Chemical/Physical*	

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 : 4375

1.6.4	*Biological*

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

1.2.1.8 Other solid dosage forms: Granules, powders;
1.3.1.6 Human or animal extracted products: Medicinal products containing, derived or extracted from animal tissue/cells, Drug products containing extracts form animal tissues and/or cells: soft shell capsules,aseptically prepared small volume liquids , terminally sterilised small volume liquids ;
1.6.4 Biological: in vitro test, LAL test;

Rome, 02/25/2020

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

Renato Massimi
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office

E' copia conforme all'originale
composta di n. ..... fogli
Roma il .....

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 : 4375