CHILE

Agenzia Italiana del Farmaco

AIFA

Certificate No: IT/167-4/H/2017

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 - 145/2017 dated 07/21/2017 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 03/25/2016 (another inspection was conducted on 03/31/2017), 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

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Agenzia Italiana del Farmaco

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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: Hormones or substances with hormonal activity
		1.1.1.4	Small volume liquids Special Requirements: Hormones or substances with hormonal activity
		1.1.1.6	Other aseptically prepared products: polveri
	1.1.2	*Terminally sterilised*	
		1.1.2.3	Small volume liquids Special Requirements: Hormones or substances with hormonal activity
	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*	
		1.3.1.1	Blood products
		1.3.1.6	Human or animal extracted products
	1.3.2	*Batch certification*	
		1.3.2.1	Blood products
		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:

1.1.1.2 Lyophilisates: hormones or substances with hormonal activity sexual hormones excluded ;

1.1.2.3 Small volume liquids: hormones or substances with hormonal activity sexual hormones excluded;

1.2.1.8 Other solid dosage forms: Granules, powders;

1.3.1.1 Blood products: aseptically prepared small volume liquids;

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 ;

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: Hormones or substances with hormonal activity
		1.1.1.4	Small volume liquids Special Requirements: Hormones or substances with hormonal activity
		1.1.1.6	Other aseptically prepared products: powders
	1.1.2	*Terminally sterilised*	
		1.1.2.3	Small volume liquids Special Requirements: Hormones or substances with hormonal activity
	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
	1.5.2	*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:

1.1.1.2 Lyophilisates: hormones or substances with hormonal activity sexual hormones excluded;

1.1.1.4 Small volume liquids: hormones or substances with hormonal activity sexual hormones excluded;

1.1.2.3 Small volume liquids: hormones or substances with hormonal activity sexual hormones excluded;

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;

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Agenzia Italiana del Farmaco

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Rome, 09/01/2017

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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Apostille

(Convention de La Haye du 5 octobre 1961)

1. Stato: Italia

Il presente atto pubblico

2 . è stato firmato da: **MASSIMI RENATO**

3.operante in qualità di: **FUNZIONARIO**

4. è munito del sigillo/bollo di : **A I F A**

Attestato

5.in : Roma 6: **10 OTTOBRE 2017**

7. da: Prefettura di Roma – Ufficio Territoriale del Governo di Roma

8. col numero **7286**

9. Sigillo/bollo :

Prefettura di Roma – Ufficio Territoriale del Governo di Roma

10. Firma

Funzionario Delegato

Giuseppe Patanè

*_

Questa Apostille certifica solo la qualità del firmatario e il sigillo/timbro che è stato apposto. Non certifica il contenuto del documento per il quale è stata rilasciata.