AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/95-1/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 FARMIGEA S.P.A.
Site address VIA G.B. OLIVA, 8 - 56121 PISA (PI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 202/2017 dated 11/17/2017 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50.

From theknowledge gained during inspection of this manufacturer, the latest of which was conducted on 07/07/2017, 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 : 2577

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site:	FARMIGEA S.P.A. - VIA G.B. OLIVA, 8 , 56121 PISA(PI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)
Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**		
	1.1.1	*Aseptically prepared*	
		1.1.1.3	Semi-solids Special Requirements: Hormones or substances with hormonal activity
		1.1.1.4	Small volume liquids Special Requirements: Hormones or substances with hormonal activity Prostaglandins/Cytokines
	1.1.3	*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**		
	1.5.2	*Secondary packing*	
1.6	**Quality control testing**		
	1.6.1	*Microbiological: sterility*	
	1.6.3	*Chemical/Physical*	
	1.6.4	*Biological*	

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

1.1.1.3 Semi-solids: Hormones or substances with hormonal activity: only corticosteroids ;
1.1.1.4 Small volume liquids: also animal extracted products, Prostaglandins, Hormones or substances with hormonal activity: only corticosteroids.;
1.3.1.6 Human or animal extracted products: animal extracted products;
1.3.2.6 Human or animal extracted products: Animal exctracted products in aseptically prepared small volume liquids;
1.6.4 Biological: LAL test; In vitro testing;

PART 2 - IMPORTATION OF MEDICAL PRODUCTS		
2.1	**Quality control testing of imported medical products**	
	2.1.1	*Microbiological: sterility*
	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
2.3	**Other importation activities**	
	2.3.1	*Site of physical importation*

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

2.2.1.1 Aseptically prepared products : small volume liquids;

Rome, 04/09/2018

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AGENZIA ITALIANA DEL FARMACO

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

E' copia conforme all'originale
composta di n. ..... fogli
Roma il ..... 11 MAR 2019

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

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Prefettura -Ufficio Territoriale del Governo di Roma

Legalizzazione Area IV Quinquies

Apostille **(Convention de La Haye du 5 octobre 1961)**	
1. Stato (Country/Pays/Pais):	**ITALIA**
il presente atto pubblico (This public document / Le preséntancte public / El presente documento público)	
2. E' stato firmato da: (Has been signed by/A été signé par/ Ha sido firmado por)	**MASSIMI RENATO**
3. Operante in Qualità di : (Acting in the capacity of/Agissant en qualité de/Quein actue en calidad de)	**DIRIGENTE**
4. E' munito del sigillo/bollo di : (Bears the seal/stamp of/Est revêtu du sceac/ timbre de / Y esta' revestito del sello/ timbre de)	**AIFA - AGENZIA ITALIANA DEL FARMACO**
Attestato (Certified/Attesté/Certificado)	
5. in: Roma (At/A'/En)	**6. il: 15/03/2019 10:44** (On/Le/El dia)
7. da: Prefettura di Roma - Ufficio Territoriale del Governo di Roma (Precture of Rome - Local Governement in Rome / Préfecture de Rome - Le gouvernement local à Rome / Prefectura de Roma - Gabierno Local en Roma	
8. col numero (No / Sous no / Bajo el nùmero)	**3911 / 2019**
9. Sigillo / Bollo (Seal / Stamp / Sceau / Timbre / Sello / Timbre)	
10. Firma (Signature) **FUNZIONARIO DELEGATO** **ANTONELLA SERGIO**	

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

This Apostille only certifies the signature, the capacity of the signer and the seal or stamp it bears. It does not certify the content of the document which it was issued.

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