AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/184/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 JANSSEN CILAG S.P.A.
Site address VIA C. JANSSEN (loc. BORGO S. MICHELE) - 04100 LATINA (LT)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 89/2018 dated 07/27/2018 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 05/18/2018, 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.

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site: JANSSEN CILAG S.P.A. - VIA C. JANSSEN (loc. BORGO S. MICHELE) , 04100 LATINA (LT)

Human Medicinal Products

Authorised Operations

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

PART 1 - MANUFACTURING OPERATIONS

1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products*	
		1.2.1.1	Capsules, hard shell
		1.2.1.9	Pressurised preparations
		1.2.1.13	Tablets
	1.2.2	*Batch certification*	
1.5	**Packaging**		
	1.5.1	*Primary packing*	
		1.5.1.1	Capsules, hard shell
		1.5.1.9	Pressurised preparations
		1.5.1.13	Tablets Special Requirements: Hormones or substances with hormonal activity
	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:

1.5.1.13 Tablets: sexual hormones only;

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 : 1445

AGENZIA ITALIANA DEL FARMACO

PART 2 - IMPORTATION OF MEDICAL PRODUCTS		
2.1	**Quality control testing of imported medical products**	
	2.1.2	*Microbiological: non-sterility*
	2.1.3	*Chemical/Physical*
.2	**Batch certification only (list of product types)**	
	2.2.2	*Non-sterile products*
	2.2.4	*Other importation activities (any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases, herbal or homeopathic products, etc.)*
	2.2.4.6	Other: primary and secondary packaging;

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

2.2.2 Non-sterile products: tablets and capsules in bulk, in blister packs, in bottles;
2.2.4.6 Other (primary and secondary packaging;): primary and secondary packaging of hard capsules in bulk; primary and secondary packaging of tablets in bulk; secondary packaging of tablets in blister packs and in bottles ;

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Name and address of the site:	JANSSEN CILAG S.P.A. - VIA C. JANSSEN (loc. BORGO S. MICHELE) , 04100 LATINA (LT)

Human Medicinal Products

Authorised Operations

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

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.2	**Non-sterile investigational medical 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
1.5	**Packaging**		
	1.5.1	*Primary packing*	
		1.5.1.1	Capsules, hard shell
		1.5.1.13	Tablets Special Requirements: Hormones or substances with hormonal activity
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;

1.2.1.8 Other solid dosage forms: granules in bulk;
1.5.1.13 Tablets: sexual hormones only;

AGENZIA ITALIANA DEL FARMACO

PART 2 - IMPORTATION OF INVESTIGATIONAL MEDICAL PRODUCTS

2.1	**Quality control testing of imported investigational medical products**	
	2.1.2	*Microbiological: non-sterility*
	2.1.3	*Chemical/Physical*
2.3	**Other importation activities**	
	2.3.2	*Importation of intermediate which undergoes further processing*

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

2.3.2 Importation of intermediate which undergoes further processing: primary packaging of imported bulk: capsules and tablets;

Rome, 08/08/2018

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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COMUNE DI LATINA

Ai sensi e per gli effetti dell'art. 18 del D.P.R. 445 del 28/12/2000

ATTESTO

che la presente copia, composta da n. 5 (cinque) fogli è conforme all'originale esibitomi e che ho restituito dopo la collazione.

Latina, li 27/3/2020

IL FUNZIONARIO INCARICATO DAL SINDACO

IL FUNZIONARIO INCARICATO DAL SINDACO
Dr.ssa Mariafrancesca D'Adamo

COMUNE DI LATINA * UFFICIO ANAGRAFE *

APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1) Stato: **Italia**

Il Presente Atto Pubblico

2) è stato sottoscritto da **D'Adamo Maria Francesca**

3) agente in qualità di **Ufficiale di Stato Civile**

4) è assegnato dal sigillo/bollo **Comune di Latina**

ATTESTATO

5) a **Latina**

6) il **27/03/2020**

7) da **Viceprefetto Domenico Talani**

8) sotto il numero **53497** del Registro Apostille

9) sigillo/bollo

10) Timbro e firma

IL VICE PREFETTO
Dott. Domenico Talani

PREFETTURA - U.T.G. LATINA