AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/138/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 PFIZER ITALIA S.R.L.
Site address LOCALITÀ MARINO DEL TRONTO - 63100 ASCOLI PICENO (AP)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 57/2018 dated 05/08/2018 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 02/09/2018, 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 : 40

RS
GMP

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site: PFIZER ITALIA S.R.L.
LOCALITÀ MARINO DEL TRONTO
63100 ASCOLI PICENO (AP)

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 Special Requirements: Cytotoxics/cytostatics
		1.2.1.13	Tablets Special Requirements: Hormones or substances with hormonal activity
	1.2.2	*Batch certification*	
1.3	**Biological medicinal 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 Special Requirements: Cytotoxics/cytostatics
		1.5.1.2	Capsules, soft shell
		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:

1.2.1.1 Capsules, hard shell: Cytotoxics/cytostatics: cytotoxics;

1.2.1.13 Tablets: hormones or substances with hormonal activity: corticosteroids and sexual hormones;

1.3.2.6 Human or animal extracted products: tablets;

1.5.1.1 Capsules, hard shell: Cytotoxics/cytostatics: cytotoxics;

1.5.1.13 Tablets: hormones or substances with hormonal activity: corticosteroids and sexual hormones; also products from animal extracts.

PART 2 - IMPORTATION OF MEDICAL PRODUCTS

2.2	**Batch certification only (list of product types)**	
	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: Importation of intermediate which undergoes further processing

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

2.2.4.6 Other (Importation of intermediate which undergoes further processing): Capsules, hard shell and tablets bulk.

AGENZIA ITALIANA DEL FARMACO

Name and address of the site: PFIZER ITALIA S.R.L.
LOCALITÀ MARINO DEL TRONTO
63100 ASCOLI PICENO (AP)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

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
	1.2.1.13	Tablets
1.5	**Packaging**	
	1.5.1	*Primary packing*
	1.5.1.1	Capsules, hard shell
	1.5.1.13	Tablets
1.6	**Quality control testing**	
	1.6.2	*Microbiological: non-sterility*
	1.6.3	*Chemical/Physical*

Rome, 06/06/2018

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

Dr. 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(Country/Pays/País): **Italia**	
Il presente atto pubblico (This public document/ Le preséntacte public/ El presente documento público)	
2.È stato firmato da: (Has been signed by/ A été signé par/ Ha sido firmado por)	**MASSIMI RENATO**
3.Operante in Qualità di:	**DIRIGENTE**
4. È munito del sigillo/bollo di: (Bears the seal/stamp of/Est revêtu du sceac/ timbre de/ Y esta´ revestito del sello/ timbre de)	**AIFA**
Attestato(Certified/Attesté/Certificado)	
5.in: Roma (At/A´/En)	**6. 16 luglio 2018**
7. da: Prefettura di Roma – Ufficio Territoriale del Governo di Roma(Prefecture of Rome - Local Government in Rome/Préfecture de Rome - Le gouvernement local à Rome/Prefectura de Roma - Gobierno Local en Roma	
8. col numero(No/Sous no/Bajo el número) : :	**2822**
9. Sigillo/bollo(Seal/Stamp/Sceau/timbre/ Sello/timbre) :	
10. Firma(Signature) **Funzionario Delegato** **Antonella Sergio**	

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