AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/146/H/2019

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 ABBVIE S.R.L.
Site address S.R. 148 PONTINA KM 52, SNC -CAMPOVERDE DI APRILIA (loc. APRILIA) - 04011 APRILIA (LT)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 83/2019 dated 06/04/2019 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 11/21/2017, 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 : 3732

PC
GMP

Digitally signed by Chirtoacă Iurie
Date: 2021.09.10 08:50:40 MSK
Reason: MoldSign Signature
Location: Moldova

Part 2

Name and address of the site:	ABBVIE S.R.L. - S.R. 148 PONTINA KM 52, SNC - CAMPOVERDE DI APRILIA (loc. APRILIA) , 04011 APRILIA(LT)

Human Medicinal Products

Authorised Operations

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

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**	
	1.1.3	*Batch certification*
1.2	**Non-sterile products**	
	1.2.1	*Non-sterile products*
		1.2.1.5 Liquids for external use
		1.2.1.6 Liquids for internal use
		1.2.1.8 Other solid dosage forms
		1.2.1.13 Tablets
	1.2.2	*Batch certification*
1.3	**Biological medicinal products**	
	1.3.2	*Batch certification*
		1.3.2.5 Biotechnology products
1.4	**Other products or manufacturing activity**	
	1.4.2	*Sterilisation of active substances/excipients/finished product*
		1.4.2.3 Moist heat
1.5	**Packaging**	
	1.5.1	*Primary packing*
		1.5.1.5 Liquids for external use
		1.5.1.6 Liquids for internal use
		1.5.1.8 Other solid dosage forms
		1.5.1.13 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:

1.1.3 Batch certification: Lyophilisates and Small volume liquids aseptically prepared;

1.2.1.8 Other solid dosage forms: granules;

1.3.2.5 Biotechnology products: Lyophilisates and small volume liquids aseptically prepared;

1.5.1.8 Other solid dosage forms: granules;

1.6.4 Biological: LAL test;

PART 2 - IMPORTATION OF MEDICAL PRODUCTS

2.1	**Quality control testing of imported medical products**	
	2.1.1	*Microbiological: sterility*
	2.1.2	*Microbiological: non-sterility*
	2.1.3	*Chemical/Physical*
	2.1.4	*Biological*

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

Lyophilisates aseptically prepared; small volume liquids terminally sterilised; intestinal gel;
2.1.4 Biological: LAL test;

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Human Medicinal Products

Authorised Operations

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

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.5	Packaging	
	1.5.1	*Primary packing*
		1.5.1.8 Other solid dosage forms
		1.5.1.13 Tablets

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

1.5.1.8 Other solid dosage forms: film-coated granules;

1.5.1.13 Tablets: pellet of mini coated tablet in sachet, without labelling;

PART 2 - IMPORTATION OF INVESTIGATIONAL MEDICAL PRODUCTS

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: pellet (coated mini tablet) in bulk for primary packaging activities. Film-coated granules in bulk for primary packaging activities.;

Rome, 08/06/2019

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

È copia conforme all'originale composta di n. 4 fogli
Roma il 7.01.2020

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

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