AGENZIA ITALIANA DEL FARMACO

Ministero dell'Economia e delle Finanze
MARCA DA BOLLO
€16,00
SEDICI/00
Agenzia Entrate
00032259 00002818 WQTS3001
00283609 28/12/2018 09:57:52
4578-00088 898CB0810F6FAAC3
IDENTIFICATIVO : 01180491685978
0 1 18 049168 597 8

Certificate No: IT/33/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 COLUMBUS PHARMA S.R.L.
Site address VIA DELL'ARTIGIANATO, 1 - 20032 CORMANO (MI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 37/2018 dated 03/08/2018 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 12/15/2017, 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 : 4611

PC
GMP

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site:	COLUMBUS PHARMA S.R.L. - VIA DELL'ARTIGIANATO, 1 , 20032 CORMANO(MI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**	
	1.1.3	*Batch certification*
1.2	**Non-sterile products**	
	1.2.2	*Batch certification*
1.5	**Packaging**	
	1.5.2	*Secondary packing*

Rome, 02/12/2019

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

AGENZIA ITALIANA DEL FARMACO

E' copia conforme all'originale composta di n. 2 fogli
Roma il 12/12/2019

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

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 : 4611