Agenzia Italiana del Farmaco

AIFA

Ministero dell'Economia e delle Finanze
MARCA DA BOLLO
€16,00
SEDICI/00
Agenzia Entrate
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00099911 07/12/2017 11:43:22
4578-00088 0092E5689EC8E000
IDENTIFICATIVO : 01161007094085
0 1 16 100709 408 5

Certificate No: IT/235-1/H/2017

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 S.A.L.F. SPA LABORATORIO FARMACOLOGICO
Site address VIA G. MAZZINI, 9 - 24069 CENATE SOTTO (BG)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 205/2017 dated 11/23/2017 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 07/22/2016, 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 : 141

GF
GMP

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Part 2

Name and address of the site: S.A.L.F. SPA LABORATORIO FARMACOLOGICO - VIA G. MAZZINI, 9 , 24069 CENATE SOTTO(BG)

Human Medicinal Products		
Authorised Operations Manufacturing Operations (Part 1)		
PART 1 - MANUFACTURING OPERATIONS		
1.1	**Sterile Products**	
	1.1.2	*Terminally sterilised*
	1.1.2.1	Large volume liquids
	1.1.2.3	Small volume liquids
	1.1.3	*Batch certification*
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:

1.1.3 Batch certification: Sterile products terminally sterilised;

1.6.4 Biological: LAL test only;

Rome, 12/21/2017

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

Dott. Renato Massimi

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