AGENZIA ITALIANA DEL FARMACO

Ministero dell'Economia e delle Finanze
MARCA DA BOLLO
€16,00
SEDICI/00
Agenzia Entrate
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00041648 14/06/2018 12:24:35
4578-00088 328BCEDA78B2EEE5
IDENTIFICATIVO: 01171416613301

AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/134/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 ALFA OMEGA S.R.L.
Site address VIA LEONARDO DA VINCI, 57 - 44034 COPPARO (FE)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 94/2019 dated 07/04/2019 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 03/08/2019, 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 : 1261

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Part 2

Name and address of the site: ALFA OMEGA S.R.L. - VIA LEONARDO DA VINCI, 57 , 44034 COPPARO(FE)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**		
	1.1.2	*Terminally sterilised*	
		1.1.2.3	Small volume liquids
	1.1.3	*Batch certification*	
1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products*	
		1.2.1.1	Capsules, hard shell
		1.2.1.6	Liquids for internal use Special Requirements: Hormones or substances with hormonal activity
		1.2.1.8	Other solid dosage forms
	1.2.2	*Batch certification*	
1.4	**Other products or manufacturing activity**		
	1.4.1	*Manufacturing of:*	
		1.4.1.2	Homoeopathic products
		1.4.1.4	Other: stocks: mother tincture and glycerol macerate undergone to further processing within the manufacturing site for the internal use and/or released to other manufacturing site for further processing
1.5	**Packaging**		
	1.5.1	*Primary packing*	
		1.5.1.1	Capsules, hard shell
		1.5.1.6	Liquids for internal use Special Requirements:


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		Hormones or substances with hormonal activity
		1.5.1.8 Other solid dosage forms
	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:

1.1.2.3 Small volume liquids: only homeopathic, even from starting materials of animal, botanical, chemical and mineral origin ;

1.2.1.1 Capsules, hard shell: only homeopathic, even from starting materials of animal, botanical, chemical, mineral, immunological and allergens origin ;

1.2.1.6 Liquids for internal use: only homeopathic, even from starting materials of animal, botanical, chemical, mineral, immunological and allergens origin ;

1.2.1.8 Other solid dosage forms: globules/granules: only homeopathic,impregnation even from starting materials of animal, botanical, chemical, mineral, immunological and allergens origin ;

1.5.1.1 Capsules, hard shell: only homeopathic, even from starting materials of animal, botanical, chemical, mineral, immunological and allergens origin ;

1.5.1.6 Liquids for internal use: only homeopathic, even from starting materials of animal, botanical, chemical, mineral, immunological and allergens origin ;

1.5.1.8 Other solid dosage forms: globules/granules: only homeopathic,impregnation even from starting materials of animal, botanical, chemical, mineral, immunological and allergens origin ;

1.6.4 Biological: LAL test;

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Rome, 07/17/2019

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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Roma il .....
02 SET. 2019

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