Agenzia Italiana del Farmaco

AIFA

Certificate No: IT/201-1/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 FINE FOODS & PHARMACEUTICALS N.T.M. S.P.A.
Site address VIA R. FOLLEREAU, 25 - 24027 NEMBRO (BG)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 149/2017 dated 07/27/2017 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 03/15/2017, 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 : 7134

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Part 2

Name and address of the site:	FINE FOODS & PHARMACEUTICALS N.T.M. S.P.A. - VIA R. FOLLEREAU, 25 ,24027 NEMBRO(BG)

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
	1.2.1.8	Other solid dosage forms
	1.2.1.13	Tablets
	1.2.2	*Batch certification*
1.3	**Biological medicinal products**	
	1.3.1	*Biological medicinal products*
	1.3.1.6	Human or animal extracted 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
	1.5.1.13	Tablets
	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:

1.2.1.8 Other solid dosage forms: Powder and granules;

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1.2.1.13 Tablets: also products from animal extracts;
1.3.1.6 Human or animal extracted products: products from animal extracts;
1.3.2.6 Human or animal extracted products: tablets;
1.5.1.13 Tablets: also products from animal extracts;

PART 2 - IMPORTATION OF MEDICAL PRODUCTS		
2.1	**Quality control testing of imported medical products**	
	2.1.2	*Microbiological: non-sterility*
	2.1.3	*Chemical/Physical*
2.2	**Batch certification only (list of product types)**	
	2.2.2	*Non-sterile products*
	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: Site of physical importation of tablets in bulk for primary and secondary packaging

Any restrictions or clarifying remarks related to the scope of these importing operations:
2.1.2 Microbiological: non-sterility: tablets;
2.1.3 Chemical/Physical: tablets;
2.2.2 Non-sterile products: tablets;

Name and address of the site: FINE FOODS & PHARMACEUTICALS N.T.M. S.P.A. - VIA R. FOLLEREAU, 25 , 24027 NEMBRO(BG)

HumanMedicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS OF

Agenzia Italiana del Farmaco

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INVESTIGATIONAL MEDICINAL PRODUCTS		
1.2	**Non-sterile investigational medical products**	
	1.2.1	*Non-sterile products*
		1.2.1.1 Capsules, hard shell
		1.2.1.8 Other solid dosage forms
		1.2.1.13 Tablets
	1.2.2	*Batch certification*
1.5	**Packaging**	
	1.5.1	*Primary packing*
		1.5.1.1 Capsules, hard shell
		1.5.1.13 Tablets
	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:

1.2.1.8 Other solid dosage forms: Powder and granules;

Rome, 10/31/2017

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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