



Certificate No: IT/131/H/2018

## 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 GRIGNANO, 43 - 24041 BREMBATE (BG)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 64/2018 dated 05/16/2018 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 02/23/2018, 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](http://www.agenziafarmaco.it)  
SIS: 7134

BN  
GMP



**Part 2**

Name and address of the site: FINE FOODS & PHARMACEUTICALS N.T.M. S.P.A.  
VIA GRIGNANO, 43 24041 BREMBATE (BG)

Human Medicinal Products

<b>Authorised Operations</b>	
<b>Manufacturing Operations (Part 1)</b>	
<b>PART 1 - MANUFACTURING OPERATIONS</b>	
<b>1.2</b>	<b>Non-sterile products</b>
	1.2.1 <i>Non-sterile products</i>
	1.2.1.8 Other solid dosage forms
	1.2.1.13 Tablets
	1.2.2 <i>Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products</b>
	1.3.1 <i>Biological medicinal products</i>
	1.3.1.6 Human or animal extracted products
	1.3.2 <i>Batch certification</i>
	1.3.2.6 Human or animal extracted products
<b>1.4</b>	<b>Other products or manufacturing activity</b>
	1.4.1 <i>Manufacturing of:</i>
	1.4.1.1 Herbal products
<b>1.5</b>	<b>Packaging</b>
	1.5.1 <i>Primary packing</i>
	1.5.1.1 Capsules, hard shell
	1.5.1.8 Other solid dosage forms
	1.5.1.13 Tablets
	1.5.2 <i>Secondary packing</i>
<b>1.6</b>	<b>Quality control testing</b>
	1.6.2 <i>Microbiological: non-sterility</i>
	1.6.3 <i>Chemical/Physical</i>





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

1.2.1.8 Other solid dosage forms: powders and granules; also products from human and animal extracts ;

1.3.1.6 Human or animal extracted products: products from animal extracts: powders and granules;

1.3.2.6 Human or animal extracted products: products from animal extracts: powders and granules;

1.4.1.1 Herbal products: powders and granules;

1.5.1.8 Other solid dosage forms: powders and granules.



Name and address of the site:      REPARTO DISTACCATO - VIA BERLINO, 39  
24040 - VERDELLINO (BG)

Human Medicinal Products

<b>Authorised Operations</b>	
Manufacturing Operations (Part 1)	
<b>PART 1 - MANUFACTURING OPERATIONS</b>	
<b>1.6</b>	<b>Quality control testing</b>
	1.6.2 <i>Microbiological: non-sterility</i>
	1.6.3 <i>Chemical/Physical</i>



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VIA GRIGNANO, 43 - 24041 BREMBATE (BG)

Human Medicinal Products

<b>Authorised Operations</b>	
<b>Manufacturing Operations (Part 1)</b>	
<b>PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS</b>	
<b>1.2</b>	<b>Non-sterile investigational medical products</b>
	1.2.1 <i>Non-sterile products</i>
	1.2.1.8 Other solid dosage forms
	1.2.1.13 Tablets
	1.2.2 <i>Batch certification</i>
<b>1.5</b>	<b>Packaging</b>
	1.5.1 <i>Primary packing</i>
	1.5.1.8 Other solid dosage forms
	1.5.1.13 Tablets
	1.5.2 <i>Secondary packing</i>
<b>1.6</b>	<b>Quality control testing</b>
	1.6.2 <i>Microbiological: non-sterility</i>
	1.6.3 <i>Chemical/Physical</i>

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

1.2.1.8 Other solid dosage forms: powders and granules;

1.5.1.8 Other solid dosage forms: powders and granules.



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# AIFA

AGENZIA ITALIANA DEL FARMACO



Name and address of the site: **REPARTO DISTACCATO - VIA BERLINO, 39 - 24040 - VERDELLINO (BG)**

Human Medicinal Products

<b>Authorised Operations</b>	
<b>Manufacturing Operations (Part 1)</b>	
<b>PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS</b>	
<b>1.6</b>	<b>Quality control testing</b>
	1.6.2 <i>Microbiological: non-sterility</i>
	1.6.3 <i>Chemical/Physical</i>



Rome, 05/30/2018



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

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

22 GIU 2018



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