Certificate No: IT/55/H/2023

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 - 50/2023 dated 03/28/2023 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 10/27/2022, 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.+390659784357 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 4940

IV
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

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
1.4	**Other products or manufacturing activity**		
	1.4.1	*Manufacturing of:*	
		1.4.1.1	Herbal products
1.5	**Packaging**		
	1.5.1	*Primary packing*	
		1.5.1.1	Capsules, hard shell
		1.5.1.8	Other solid dosage forms
		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: 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, pastilles;

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
2.3	**Other importation activities**
	2.3.1 Site of physical importation *2.3.2 Importation of intermediate which undergoes further processing*

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

2.3.2 Importation of intermediate which undergoes further processing: tablets (bulk) for the following production steps: primary and secondary packaging, storage, batch certification and microbial and chemical/physical testing.;

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

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.2	**Non-sterile investigational medical products**	
	1.2.1	*Non-sterile products*
		1.2.1.1 Capsules, hard shell
		1.2.1.13 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*

Rome, 03/28/2023

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

DEL VECCHIO ANGELA
AIFA - AGENZIA ITALIANA DEL FARMACO
Dirigente
28.03.2023 11:11:51
GMT+00:00

Angela Del Vecchio
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW

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