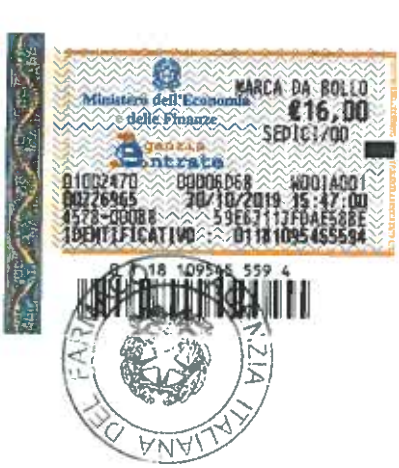
AGENZIA ITALIANA DEL FARMACO



Certificate No: IT/222/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 IBSA FARMACEUTICI ITALIA S.R.L.
Site address Via Martiri di Cefalonia, 2 - 26900 LODI (LO)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 162/2019 dated 11/26/2019 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 05/24/2019, 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 : 7166

RS
GMP

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site:	IBSA FARMACEUTICI ITALIA S.R.L. Via Martiri di Cefalonia, 2 26900 LODI (LO)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)
Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**		
	1.1.1	*Aseptically prepared*	
		1.1.1.4	Small volume liquids
	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*	
		1.2.1.2	Capsules, soft shell
		1.2.1.9	Pressurised preparations
		1.2.1.11	Semi-solids Special Requirements: Other: Hormones or substances with hormonal activity
		1.2.1.12	Suppositories
	1.2.2	*Batch certification*	
1.5	**Packaging**		
	1.5.1	*Primary packing*	
		1.5.1.2	Capsules, soft shell
		1.5.1.9	Pressurised preparations
		1.5.1.11	Semi-solids Special Requirements: Other: Hormones or substances with hormonal

		activity
		1.5.1.12 Suppositories
	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:

1.2.1.11 Semi-solids: Hormones or substances with hormonal activity: corticosteroid hormones;

1.5.1.11 Semi-solids: Hormones or substances with hormonal activity: corticosteroid hormones;

1.6.4 Biological: LAL test.

PART 2 - IMPORTATION OF MEDICAL PRODUCTS		
2.2	**Batch certification only (list of product types)**	
	2.2.1	*Sterile products*
		2.2.1.1 Aseptically prepared products
		2.2.1.2 Terminally sterilised
	2.2.2	*Non-sterile products*
	2.2.3	*Biological medicinal products*
		2.2.3.6 Human or animal extracted products

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

2.2.1.1 Aseptically prepared products : Lyophilised: also human extracted products; Small volume liquids;

2.2.1.2 Terminally sterilised : Solids and implants;

AGENZIA ITALIANA DEL FARMACO

2.2.2 Non-sterile products: Capsules, hard shell; Capsules, soft shell; Liquids for internal use; granules; Semi-solids ; tablets;
2.2.3.6 Human or animal extracted products: human extracted products: aseptically prepared lyophilisates.

Name and address of the site:	MAGAZZINO - VIA DEI MANISCALCHI, 37 26900 - LODI (LO)

Human Medicinal Products

Authorised Operations Manufacturing Operations (Part 1)	
PART 1 - MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.3 Others: Storage

Name and address of the	IBSA FARMACEUTICI ITALIA S.R.L.

AGENZIA ITALIANA DEL FARMACO

site: Via Martiri di Cefalonia, 2
26900 LODI (LO)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)
Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.1	**Sterile investigational medical products**	
	1.1.1	*Aseptically prepared*
		1.1.1.4 Small volume liquids
	1.1.2	*Terminally sterilised*
		1.1.2.3 Small volume liquids
1.2	**Non-sterile investigational medical products**	
	1.2.1	*Non-sterile products*
		1.2.1.2 Capsules, soft shell
1.5	**Packaging**	
	1.5.1	*Primary packing*
		1.5.1.2 Capsules, soft shell
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:

1.6.4 Biological: LAL test.

PART 2 - IMPORTATION OF INVESTIGATIONAL MEDICAL

PRODUCTS		
2.2	Batch certification of imported of investigational medical products	
	2.2.1	*Sterile products*
	2.2.1.1	Aseptically prepared products
	2.2.2	*Non-sterile products*
	2.2.3	*Biological medicinal products*
	2.2.3.6	Human or animal extracted products

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

2.2.1.1 Aseptically prepared products : Lyiophilised: also human extracted products; Small volume liquids;

2.2.2 Non-sterile products: Capsules, soft shell; Liquids for internal use;

2.2.3.6 Human or animal extracted products: human extracted products: aseptically prepared lyophilisates.

Rome, 12/03/2019

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

E' copia conforme all'originale composta di n. 6 fogli
Roma il 14/12/19

Renato Massimi
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office

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