Certificate No: IT/163/H/2022

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 ESAPHARMA S.P.A.
Site address VIA A. DE GASPERI, 13 - 20066 MELZO (MI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 129/2022 dated 08/31/2022 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 12/15/2021, 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 : 1384

PC
GMP

Part 2

Name and address of the site: ESAPHARMA S.P.A. - VIA A. DE GASPERI, 13 , 20066 MELZO(MI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.2	**Non-sterile products**	
	1.2.1	*Non-sterile products*
		1.2.1.11 Semi-solids
	1.2.2	*Batch certification*
1.5	**Packaging**	
	1.5.1	*Primary packing*
		1.5.1.11 Semi-solids
	1.5.2	*Secondary packing*
1.6	**Quality control testing**	
	1.6.3	*Chemical/Physical*

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

1.2.1.11 Semi-solids: Hormones or substances with ormonal activity;

1.5.1.11 Semi-solids: Hormones or substances with ormonal activity;

Name and address of the site: ESAPHARMA S.P.A. - VIA A. DE GASPERI, 13 , 20066 MELZO(MI)

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*
		1.2.1.11 Semi-solids
	1.2.2	*Batch certification*
1.5	**Packaging**	
	1.5.1	*Primary packing*
		1.5.1.11 Semi-solids
	1.5.2	*Secondary packing*
1.6	**Quality control testing**	
	1.6.3	*Chemical/Physical*

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

1.2.1.11 Semi-solids: Hormons or substances with hormonal activity;

1.5.1.11 Semi-solids: Hormons or substances with hormonal activity;

Rome, 08/31/2022

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
01.09.2022
11:34:48
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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