Certificate No: IT/53/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 HERING S.R.L
Site address V.LE DELLO SVILUPPO,6C.DA FARGIONE ZONAINDUSTRIALE - 97015 MODICA (RG)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 48/2023 dated 03/27/2023 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 11/26/2021, 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 : 3420

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Part 2

Name and address of the site:	HERING S.R.L - V.LE DELLO SVILUPPO,6C.DA FARGIONE ZONAINDUSTRIALE , 97015 MODICA(RG)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products*	
		1.2.1.1	Capsules, hard shell Special Requirements: Other : Hormones or substances with hormonal activity
		1.2.1.5	Liquids for external use
		1.2.1.6	Liquids for internal use Special Requirements: Other : Hormones or substances with hormonal activity
		1.2.1.8	Other solid dosage forms
		1.2.1.11	Semi-solids Special Requirements: Other : Hormones or substances with hormonal activity
		1.2.1.12	Suppositories
		1.2.1.13	Tablets
	1.2.2	*Batch certification*	
1.4	**Other products or manufacturing activity**		
	1.4.1	*Manufacturing of:*	
		1.4.1.2	Homoeopathic products
1.5	**Packaging**		

	1.5.1	*Primary packing* 1.5.1.1 Capsules, hard shell Special Requirements: Other : Hormones or substances with hormonal activity 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use Special Requirements: Other : Hormones or substances with hormonal activity 1.5.1.8 Other solid dosage forms 1.5.1.11 Semi-solids Special Requirements: Other : Hormones or substances with hormonal activity 1.5.1.12 Suppositories 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:

only homeopathic products;

1.2.1.1 Capsules, hard shell: starting material of animal origin,allergen,inactivated vaccine;

1.2.1.5 Liquids for external use: animal origin;

1.2.1.6 Liquids for internal use: starting materia of animal/bacterial origin,allergen,hormones;

1.2.1.8 Other solid dosage forms: pillules and granules even from starting material of animal/bacterial origin,allergen,inactivated vaccine; powders;

1.2.1.11 Semi-solids: animal origin and hormones;

1.2.1.12 Suppositories: animal origin;

1.2.1.13 Tablets: impregnation;

1.5.1.1 Capsules, hard shell: animal origin,allergene,inactivated vaccine,hormones;

1.5.1.5 Liquids for external use: animal origin;
1.5.1.6 Liquids for internal use: starting material of animal or bacterial origin,allergens,inactivated vaccines,hormones;
1.5.1.8 Other solid dosage forms: pillules and granules even from starting materials of animal/bacterial origin,bacterial origin,allergens,inactivated vaccines;powders;
1.5.1.11 Semi-solids: animal origin and hormones;
1.5.1.12 Suppositories: animal origin;
1.5.1.13 Tablets: impregnation;

Rome, 03/27/2023

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
27.03.2023 14:20:48
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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