AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/194/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 LABORATORIO CHIMICO FARMACEUTICO A. SELLA S.R.L.
Site address VIA VICENZA, 67 - 36015 SCHIO (VI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 154/2023 dated 11/23/2023 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 12/22/2022, 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 thanthree 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 : 3399

RS
GMP

Part 2

Name and address of the site:	LABORATORIO CHIMICO FARMACEUTICO A. SELLA S.R.L. VIA VICENZA, 67 - 36015 SCHIO (VI)

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*	
		1.2.1.5	Liquids for external use
		1.2.1.6	Liquids for internal use
		1.2.1.8	Other solid dosage forms
		1.2.1.11	Semi-solids
		1.2.1.12	Suppositories
		1.2.1.13	Tablets
	1.2.2	*Batch certification*	
1.5	**Packaging**		
	1.5.1	*Primary packing*	
		1.5.1.5	Liquids for external use
		1.5.1.6	Liquids for internal use
		1.5.1.8	Other solid dosage forms
		1.5.1.11	Semi-solids
		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:

1.2.1.8 Other solid dosage forms: powders, granules and cutaneous sticks;

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

1.5.1.8 Other solid dosage forms: powders, granules and cutaneous sticks.

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:

2.3.1 Site of physical importation: Importation of finished product (impregnated matrices) from Swiss;

2.3.2 Importation of intermediate which undergoes further processing: granules for production of tablets.

Rome, 11/23/2023

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
24.11.2023 10:55:22
GMT+00:00

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

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW

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 : 3399

RS
GMP