AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/142/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 REDOX S.R.L
Site address VIALE STUCCHI ,62/26 - 20900 MONZA (MB)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 117/2023 dated 09/01/2023 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 03/08/2023, 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 : 2964

RS
GMP

Part 2

Name and address of the site:	REDOX S.R.L - VIALE STUCCHI ,62/26 , 20900 MONZA (MB)

Human Medicinal Products

Authorised Operations Manufacturing Operations (Part 1)	
PART 1 - MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

1.6.3 Chemical/Physical: Also quality control for API release.

Name and address of the site:	REPARTO DISTACCATO - Via Cascina Greppi, 73 - 20845 - SOVICO (MB)

Human Medicinal Products

Authorised Operations Manufacturing Operations (Part 1)	
PART 1 - MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.3 Others: Stability chambers for stability studies

Name and address of the site:	REPARTO DITACCATO - VIALE STUCCHI 62/1 - 20900 - MONZA (MB)

Human Medicinal Products

Authorised Operations Manufacturing Operations (Part 1)	
PART 1 - MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

1.6.3 Chemical/Physical: also quality control for release of active substances.

Name and address of the site:	REDOX S.R.L - VIALE STUCCHI ,62/26 , 20900 MONZA(MB)

Human Medicinal Products

Authorised Operations Manufacturing Operations (Part 1)	
PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

1.6.3 Chemical/Physical: Also quality control for API release.

Name and address of the site:	REPARTO DISTACCATO - Via Cascina Greppi, 73 - 20845 - SOVICO (MB)

Human Medicinal Products

Authorised Operations Manufacturing Operations (Part 1)	
PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS	
1.4	**Other investigational medical products or manufacturing activity**
	1.4.3 Others

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

1.4.3 Others: Stability chambers.

Name and address of the site:	REPARTO DITACCATO - VIALE STUCCHI 62/1 - 20900 - MONZA (MB)

Human Medicinal Products

Authorised Operations Manufacturing Operations (Part 1)	
PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

1.6.3 Chemical/Physical: also quality control for release of active substances.

Rome, 09/01/2023

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
04.09.2023
12:06:52
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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