



Certificate No: IT/74/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 NEOTRON S.P.A.

Site address VIA STRADELLO AGGAZZOTTI, 104 - 41126 MODENA (MO)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aAMM - 158/2021 dated 10/26/2021 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 12/11/2019, 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. +390659784357 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 6751

Part 2

Name and address of the site: NEOTRON S.P.A. - VIA STRADELLO AGGAZZOTTI,
104, 41126 MODENA (MO)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
	1.6.3 <i>Chemical/Physical</i>

Name and address of the site: NEOTRON S.P.A. - VIA STRADELLO AGGAZZOTTI, 104, 41126 MODENA (MO)

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

Rome, 04/05/2022

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

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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