AIFA
AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/49/H/2020

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

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 28/2020 dated 03/04/2020 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.+390659784410 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 4805

RS
GMP

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site:	NEOTRON PHARMA SPA 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 Chemical/Physical

AGENZIA ITALIANA DEL FARMACO

Name and address of the site:	NEOTRON PHARMA SPA 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, 03/26/2020

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

Renato Massimi
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office

E' copia conforme all'originale composta di n. 3 fogli
Roma il 23/06/20

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