Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 13274 Insp GMP 13274/58149-0003[H]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : SERUM INSTITUTE OF INDIA PRIVATE LIMITED

Site address : SERUM INSTITUTE OF INDIA PRIVATE LIMITED, 212/2 HADAPSAR, OFF SOLI POONAWALLA ROAD, PUNE, IN-411028, INDIA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Part 16 of The Human Medicines Regulations 2012 (SI 2012/1916)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 08/02/2021, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.4] Small volume liquids

[1.3] Biological medicinal products

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[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.3.1.5] Biotechnology products

[1.4] Other products or manufacturing activity

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

Restrictions or Remarks

The following buildings are authorised for the manufacture of Covid-19 related products:
SEZ-1B Second Floor
SEZ-5- Ground Floor
SEZ-6- 1st Floor
SEZ -7- 2nd Floor
MSEZ-1 2nd Floor
MSEZ-2 2nd Floor
M-SEZ-1 Ground Floor (MMA-4)
Building 14 First Floor (Hadapsar)
M-SEZ-1 Ground Floor BFC

Secondary Packaging operations within:
M-SEZ-1 Ground Floor
M-SEZ-3 Ground Floor
M-SEZ-3 First Floor
SEZ-10 Ground Floor
SEZ-5 Ground Floor
Plus all support functions for the above including laboratories.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products

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This certificate applies to both the Hadapsar (address above) and Manjari facility: S. No. 105-110 Manjari BK Tal -Haveli Pune 412307 India

27/10/2021	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

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