NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY

Directorate for Drug Inspection

National Centre For Public Health And Pharmacy

CERTIFICATE NUMBER: *NNGYK/19116-2/2026*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Hungary confirms the following:
The manufacturer: ***Bharat Serums And Vaccines Limited***
Site address: ***Plot No K-27 K-27 Part And K-27/1, Anand Nagar Jambivili Village M.I.D.C., Ambernath East, Thane, Maharashtra, 421506, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100033757 / LOC-100053100***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-12-12***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *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) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids 1.1.1.6 Other: Powder for Injection / Infusion(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products 1.3.1.8 Other: Animal Testing Laboratory(en)
1.5	**Packaging**
	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*

Any restrictions related to the scope of this certificate:

Clarifying remarks (for registered users)

During the inspection the following Units & Production Lines were inspected indicating the scope products: Unit-I Production A products - Liposomal Amphotericin B powder for solution for infusion 50 mg (including its intermedier: Amphotericin B lipid powder) - Polymyxin B injection - Sterilized water for injection 10 ml - Sodium chloride injection Unit-I Production B products - Rabies antiserum equine 1000 IU Unit-I Production C products - Ulinastatin for injection 100 000 IU Unit-I Production D products - Leuprolide acetate for injection 3.75 mg (depot) Unit-II Production A products: - Menotrophin for injection IP/B.P.-75 IU (lyophilized) - Trinbelimab injection 300 mcg PFS (recombinant Anti-RhoD immunoglobulin injection 300 mcg)

2026-03-03

Name and signature of the authorised person of the Competent Authority of Hungary

Zakariás El Koulali
National Centre For Public Health And Pharmacy
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Fax: