Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 16929 Insp GMP 16929/8740-0002[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 : HEMOFARM A.D.

Site address : HEMOFARM A.D., BEOGRADSKI PUT BB, VRSAC, RS-26300, SERBIA

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 29/04/2020, 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

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.3] Small volume liquids

[1.4] Other products or manufacturing activity

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

[1.4.2.3] Moist heat

Restrictions or Remarks

This certificate is issued based on a remote inspection of GMP compliance during COVID-19 travel restrictions. The scope of the remote inspection was limited to activities relating to terminal sterilisation of small volume parenteral products in ampoules in building 23 (PIP) and should be considered in conjunction with GMP certificates reference: DE_HE_01_GMP_2018_0067 and DE_HE_01_GMP_2019_0154

A risk-based site inspection programme remains in force.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
Building 23 (PIP)				

07/05/2020	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential