CERTIFIED TRANSLATION FROM SERBIAN INTO ENGLISH

[coat of arms of the Republic of Serbia]

Republic of Serbia
MINISTRY OF HEALTH
Number: 515-04-10231/2022-11
Date: 03 March 2023
B e l g r a d e, 22-26 Nemanjina St.
Tel. 011/2600-749
VV/SI

Deciding upon a request of pharmaceutical manufacturer 'HEMOFARM' a.d. Vršac, Beogradski put bb, for issuing a Good Manufacturing Practice Certificate, and pursuant to Article 212, paragraph 6 of the Law on Medicines and Medical Devices ('Official Gazette of RS' No. 30/10, 107/12, 105/17 – other law, 113/17 – other law), article 37 of the Law on Inspection Control ('Official Gazette of the RS' No. 36/15) as well as article 136 of the Law on General Administrative Procedure ('Official Gazette of the RS' number 18/16), the Minister of Health of the Republic of Serbia passes the following

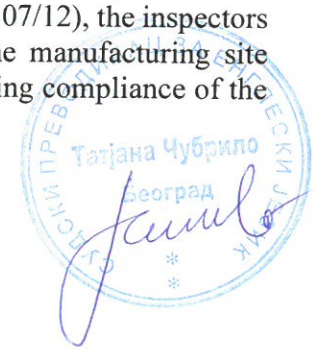
DECISION

1. **Good Manufacturing Practice CERTIFICATE NUMBER 52 IS ISSUED** to the pharmaceutical manufacturer 'HEMOFARM' a.d. Vršac, Beogradski put bb, for **the manufacturing site - 'HEMOFARM' a.d. Vršac, Beogradski put bb.**
2. This Certificate for the indicated manufacturing site is valid through **15 December 2025**, after which its validity is terminated.

R a t i o n a l e

Pharmaceutical manufacturer 'HEMOFARM' a.d. Vršac, Beogradski put bb submitted a request to the Ministry of Health for issuing a Good Manufacturing Practice Certificate for the manufacturing site - 'HEMOFARM' a.d. Vršac, Beogradski put bb, specifically for **the manufacturing (complete manufacturing procedure) of sterile liquid pharmaceutical forms, quality control and parametric batch release for the following products**: Glucosi infundibile HF, infusion solution, 5%, plastic bottle, 1x500ml, Glucosi infundibile HF, infusion solution, 10%, plastic bottle, 1x500 ml, Hartmann's solution HF, infusion solution, 6.02g/L+0.373g/L+0.294g/L+6.276g/L, plastic bottle, 1x500ml, Natrii chloride infundibile HF, infusion solution, 9g/L, plastic bottle, 1x500ml, Natrii chloridi infundibile compositum (Ringer's solution HF), infusion solution, 8.6g/L+0.3g/L+0.33g/L, plastic bottle, 1x500ml.

On 12/12-15/12/2022, pursuant to Articles 208 and 213, paragraph 1, item 1) of the Law on Medicines and Medical Devices ('Official Gazette of RS' no. 30/10 and 107/12), the inspectors for medicines and medical devices performed the direct inspection at the manufacturing site 'HEMOFARM' a.d. Vršac, Beogradski put bb, for the purpose of establishing compliance of the



pharmaceutical manufacturing with the Good Manufacturing Practice Guidelines ('Official Gazette of the RS' No. 97/17), about which the final report with the conclusion on compliance number 515-04-10231/2022-11 of 21/02/2023 was made. The manufacturer did not have any objections to the facts stated in the record.

The subject of establishment of compliance of pharmaceutical manufacture with the Good Manufacturing Practice Guidelines referred to the manufacture, quality control and parametric batch release for the products specified in the request.

Based on the directly established facts as well as insight into documentation checked during inspection, the inspectors stated incompliances during the inspection control, for which the pharmaceutical manufacturer, in line with the provision of the Article 113, paragraph 5 of the Law on Medicines and Medical Devices ('Official Gazette of the Republic of Serbia' No. 30/10 and 107/12), delivered proposal for remediation of incompliances established during the performed inspection, together with the deadlines for implementation.

Based on the assessment of the delivered documentation the inspectors stated that manufacture of the above indicated medicines is compliant with the Good Manufacturing Practice Guidelines, about which final report was made with the conclusion on compliance, number 515-04-10231-1/2022-11 of 21/02/2023 which was delivered to the manufacturer.

Based on the final report number 515-04-10231-1/2022-11 of 21/02/2023 and in accordance with Article 113, paragraph 7, of the Law on Medicines and Medical Devices, the decision was made as set forth in item 1 of the wording hereof.

Pharmaceutical manufacturer is responsible for the quality of manufactured medicines in accordance with Article 111 of the Law on Medicines and Medical Devices.

Pursuant to Article 114, paragraph 5 of the Law on Medicines and Medical Devices, the decision was made as set forth in item 2 of the wording hereof.

This decision is final in administrative procedure.

Administrative dispute can be instigated against this decision with the competent court within 30 days from the decision receipt date.

The applicant has paid the fee for this decision pursuant to the Law on Republic Administrative Fees ('Official Gazette of the RS' number 62/21).

Distribution:
1. 'HEMOFARM' a.d. Vršac
Beogradski put bb
2. Archives

MINISTER
Prof. dr Danica Grujičić
/signed and stamped/

GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE

Certificate no:	**52**
Date:	**03 March 2023**

Name of the Marketing Authorisation Holder (pharmaceutical manufacturer):	**'HEMOFARM' AD VRŠAC**
Headquarters address of the Marketing Authorisation Holder (pharmaceutical manufacturer):	**Vršac,** **Beogradski put bb**
Address of production site:	**'HEMOFARM' a.d. Vršac** **Beogradski put bb**
Place of medicinal product batch release:	**'HEMOFARM' a.d. Vršac** **Beogradski put bb**
Legal grounds for issuing the certificate:	Article 114 of the Law on Medicines and Medical Devices ('Official Gazette of RS' number 30/10 and 107/12)
Date of inspection control on the basis of which the certificate is issued:	12/12-15/12/2022
Certificate validity:	The Certificate of Good Manufacturing Practice is issued for a period of **three years** and it ceases being valid in case of changes to the production process, i.e. quality control and batch release of medicinal product in a certain pharmaceutical dosage form which is indicated in the certificate.

The pharmaceutical manufacturer **'HEMOFARM' a.d. Vršac, Beogradski put bb,** which has been issued the pharmaceutical **manufacturing license** number 515-04-08342/2022-11 dated November 08, 2022, **for the production site - 'HEMOFARM' a.d. Vršac, Beogradski put bb** is issued a **Good Manufacturing Practice Certificate:**

☒ on the basis of inspection control of pharmaceutical manufacturing site, performed in accordance with Article 213 of the Law on Medicines and Medical Devices ('Official Gazette of RS', number 30/10), and the final report number 515-04-10231-1/2022-11 of February 21, 2023, on the compliance of pharmaceutical manufacturing with the Good Manufacturing Practice Guidelines ('Official Gazette of RS', number 97/17),

☐ on the basis of inspection control of the manufacturer the medicine of which is in the process of obtaining authorisation, amendments, or addenda, i.e. renewal of a marketing authorisation in the Republic of Serbia, conducted in accordance with Article 2015 of the Law on Medicines and Medical Devices ('Official Gazette of RS', number 30/10and 107/12), and the final report number ..... of ..... on the compliance of manufacturing with the Good Manufacturing Practice Guidelines ('Official Gazette of RS', number 97/17),

☐ on the basis of inspection control of active substance manufacturing at the pharmaceutical manufacturing site, conducted in accordance with Article 112, paragraph 3 of the Law on Medicines and Medical Devices ('Official Gazette of RS', number 30/10 and 107/12).

This Certificate confirms the compliance of pharmaceutical manufacturing with the Good Manufacturing Practice Guidelines on the inspection control date.

Distribution:
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2. Archives

MINISTER
Prof. dr Danica Grujičić
/signed and stamped/

Annex 1

BASIC INFORMATION (fill in using capital letters)	
Production of the following types of medicinal products:	☒ Medicinal products ☐ Immunological medicinal products ☐ Medicinal products from blood and blood plasma of human origin ☐ Biotechnological medicinal products ☐ Radiopharmaceutical medicinal products ☐ Herbal medicinal products ☐ Medicinal products intended for clinical trial ☐ Other medicinal products
Production of medicinal products containing psychoactive controlled substances:	☐ Yes ☐ No

Annex 2

Approved pharmaceutical manufacturing processes, i.e. procedures	
☒ 1. **Sterile production**	☐ 1.1 Aseptic preparation ☒ 1.2 Final sterilization ☐ 1.3 Medicine batch release only
☒ 2. **Production of non-sterile pharmaceutical products**	☐ 2.1 Solid pharmaceutical forms ☐ 2.2 Semi-solid pharmaceutical forms ☒ 2.3 Liquid pharmaceutical forms ☐ 2.4 Other ☐ 2.5 Medicine batch release only
☐ **3. Production of biological medicines**	☐ 3.1 Medicines from human blood and plasma ☐ 3.2 Immunological medicines ☐ 3.3 Biotechnological medicines ☐ 3.4 Extracts of human or animal origin ☐ 3.5 Medicine batch release only
☒ **4. Packaging**	☒ 4.1 Primary packaging ☒ 4.2 Secondary packaging
☒ **5. Quality control**	☒ 5.1 Own control laboratory ☐ 5.2 Contract control laboratory
☒ **6. Manner of supply with active substances and intermediates (*bulk* products)**	☐ 6.1 Own manufacture ☐ 6.2 Market of the Republic of Serbia ☒ 6.3 Import

Annex 3

Comments, i.e. additional explanations regarding the content of the Certificate:

This Certificate of compliance of pharmaceutical manufacturing with the Good Manufacturing Practice Guidelines refers to: manufacturing (complete manufacturing process) of sterile liquid pharmaceutical forms, quality control and parametric batch release of the following products: Glucosi infundibile HF, infusion solution, 5%, plastic bottle, 1x500ml, Glucosi infundibile HF, infusion solution, 10%, plastic bottle, 1x500ml, Hartmann's solution HF, infusion solution, 6.02g/L+0.373g/L+0.294g/L+6.276g/L, plastic bottle, 1x500ml, Natrii chloridi infundibile HF, infusion solution, 9g/L, plastic bottle, 1x500 ml, Natrii chloridi infundibile compositum (Ringer's solution HF), infusion solution, 8.6g/L+0.3g/L+0.33g/L, plastic bottle, 1x500ml.

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This is to certify that the English translation is true and identical to the original text made in the Serbian language. Tatjana Čubrilo, sworn-to-court translator for the English language, appointed by Ministry of Justice, the Decision No. 101-74-00018/2007-61 of 17/12/2007.