Certified Translation from Serbian into English

Coat of Arms
Republic of Serbia
MINISTRY OF HEALTH
Number: 515-04-08720/2022-11
Date: 7 April 2023
Belgrade, 22-26 Nemanjina St.
Tel. 011/2600-749
VV/SI

Acting upon a request of the 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-oth. law, 113/17-oth. law) and Article 37 of the Low on Inspection Supervision ('Official Gazette of RS' No. 36/15) and Article 136 of the Law on General Administrative Procedure ('Official Gazette of RS' No. 18/16), the Minister of Health of the Republic of Serbia passes the following

DECISION

1. **Good Manufacturing Practice CERTIFICATE number 55 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 **8 March 2026**, after which its validity is terminated.

E x p l a n a t i o n

Pharmaceutical manufacturer 'HEMOFARM' a.d. Vršac, Beogradski put bb, has 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: 1. Manufacturing of sterile liquid pharmaceutical forms, quality control and batch release for the following products: Glucosi infundibile HF solution for infusion; 5%; plastic bottle; 1x500mL, Glucosi infundibile HF solution for infusion; 10%; plastic bottle; 1x500mL, Hartmann's solution HF, solution for infusion; 6.02g/L+0.373g/L+0.294g/L+6.276g/L; plastic bottle; 1x500mL, Natrii chloridi infundibile HF solution for infusion; 9g/L; plastic bottle; 1x500mL, Natrii chloridi infundibile compositum (Ringer's solution) solution for infusion; 8.6g/L+0.3g/L+0.33g/L; plastic bottle; 1x500mL, Natrii chloridi infundibile cum glucoso 5%, solution for infusion, 1X500mL, plastic bottle and Ispirol, bladder irrigation solution; 5.4g/L+27g/L; bag, 1x5L, Phenobarbiton-sodium HF powder and solvent for injection solution; 220mg/2mL; vial with powder and ampoule with solvent; 5x2mL, Hidrokortizon HF powder and solvent for injection solution; 100mg/2mL; vial with powder and ampoule with solvent; lx2mL, Lemod®-Solu powder and solvent for

injection/infusion solution; 20mg/mL; vial with powder and ampoule with solvent; 15xlmL, Lemod®-Solu powder and solvent for injection/infusion solution; 40mg/mL; vial with powder and ampoule with solvent; 15xlmL, Peptix®, powder for injection/infusion solution, 40mg, glass vial, 10x40mg, Hemomycin® powder for concentrate for solution for infusion 500mg glass vial 1x500mg, Hidrokortizon HF powder and solvent for injection solution; 100mg/2mL; vial with powder and ampoule with solvent; lx2mL, Beviplex® powder for injection solution 40mg+4mg+8mg+100mg+l0mg+0.004mg, glass vial, up to the 'bulk' phase for the contractual partner Galenika AD Beograd, Remifentanil B.Braun, powder for concentrate for injection/infusion solution; 1mg; glass vial, 5x1mg, Remifentanil B.Braun, powder for concentrate for injection/infusion solution; 2mg; glass vial, 5x2mg, Remifentanil B.Braun, powder for concentrate for injection/infusion solution; 5mg; glass vial, 5x5mg, Diklofenak HF solution for injection; 75mg/3mL; ampoule; 5x3mL, Nirmin® concentrate za solution for infusion; 5mg/1.6mL; ampoule; Marocen® concentrate for solution for infusion; 100mg/10mL; ampoule; 5x10mL, Water for Injection with 0.9% Benzyl alcohol, ampoule 1ml, Water for Injection with 0.9% Benzyl alcohol, ampoule 2 ml, Water for Injection with 0.9% Benzyl alcohol, ampoule 7.8 ml, Aqua redestillata injection solvent, ampoule 2 ml, APO-GO POD, 5mg/ml, solution for infusion in a cartridge, 5x20ml, Methylergometrin HF solution for injection; 0.2mg/mL; ampoule; 50x1mL, Klindamicin solution for injection; 300mg/2mL; ampoule; 10x2mL, Gentamicin HF solution for injection; 80mg/2mL; ampoule; 10x2mL, Gentamicin HF solution for injection; 120mg/2mL; ampoule; 10x2mL, Presolol® solution for injection; 5mg/5mL; ampoule; 5x5mL, Trodon solution for injection/infusion; 100mg/2mL; ampoule; 5x2mL, Trodon solution for injection/infusion; 50mg/mL; ampoule; 5x1mL, Hemomycin®, powder for concentrate for solution for infusion; 500mg; glass vial; 1x500mg, Hidrokortizon HF powder and solvent for solution for injection; 100mg/2mL; vial with powder and ampoule with solvent; 1x2mL, Lemod®-Solu powder and solvent for injection/infusion solution; 20mg/mL; vial with powder and ampoule with solvent; 15xlmL, Lemod®-Solu powder and solvent for injection/infusion solution; 40mg/mL; vial with powder and ampoule with solvent; 15xlmL, Lemod®-Solu powder and solvent for injection/infusion solution; 125mg/2mL; vial with powder and ampoule with solvent; 1x2mL, Lemod®-Solu powder and solvent for injection/infusion solution; 500mg/7.8mL; vial with powder and ampoule with solvent; lx7.8mL; 2. Part of manufacturing procedure – secondary packaging of sterile liquid pharmaceutical forms, quality control and batch release for the following products: Eqralys® injection solution in pre-filled syringe, 2000IU/0.6ml, pre-filled syringe 6x0.6ml, Ademola® (voriconazole) powder for infusion solution, 200mg, glass vial, 1x200mg, Zodol® solution for injection; 30mg/mL; ampoule; 5x1mL, Corpos® (ocrelizumab), concentrate for infusion solution, 300mg/10ml, glass vial 1x10ml, Enoxaparin HF 2000 IU, injection solution in pre-filled syringe, pack with 10 syringes, Enoxaparin HF 4000 IU, injection solution in pre-filled syringe, pack with 10 syringes, Enoxaparin HF 6000 IU, injection solution in pre-filled syringe, pack with 10 syringes, and Enoxaparin HF 8000 IU, injection solution in pre-filled syringe, pack with 10 syringes.

In the period 12/12 - 15/12/2022, and 7/03 – 8/03/2023, the inspectors for medicines and medical devices conducted a personal inspection of the manufacturing site 'HEMOFARM' a.d. Vršac, Beogradski put bb, in accordance with 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), for the purpose of establishing the compliance of production of medicines with Good Manufacturing Practice Guidelines ('Official Gazette of RS' number 97/17), about which the Protocol with report

number: 515-04-08720/2022-11 of 6/04/2023 was made. There were no objections to the factual status stated in the Protocol on the part of the manufacturer.

The subject of establishing the compliance of pharmaceutical manufacturing with Good Manufacturing Practice Guidelines referred to the production, quality control and batch release of the medicines indicated in the request.

Based on the personally established factual status, as well as an insight into the documentation reviewed during the inspection, no critical or other non-compliances were identified, so it has been established that the production of the above indicated medicines complies with the Good Manufacturing Practice Guidelines, about which a final report with a conclusion on compliance, number 515-04-08720-1/2022-11 of 6/04/2023, was prepared, and delivered to the manufacturer.

Based on the final report number 515-04-08720-1/2022-11 of 6/04/2023, 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 RS' number 62/21).

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

MINISTER

/stamped and signed/

Prof. Dr Danica Grujičić

/stamp reading: The Republic of Serbia;
Ministry of Health; Belgrade/

GOOD MANUFACTURING PRACTICE CERTIFICATE (*GMP* CERTIFICATE)

Certificate number:	**55**
Date:	**7 April 2023**

Name of manufacturing license holder (pharmaceutical manufacturer):	**'HEMOFARM' a.d. Vršac**
Address of manufacturing license holder (pharmaceutical manufacturer) seat:	**Vršac** **Beogradski put bb**
Address of manufacturing site:	**'HEMOFARM' a.d. Vršac** **Beogradski put bb**
Medicine batch release site:	**'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 based on which the certificate is issued:	12/12 - 15/12/2022, and 7/03 – 8/03/2023
Validity of certificate:	Good Manufacturing Practice Certificate is issued for a **three-year period** and its validity is terminated in case of changes in the process of medicinal product manufacturing or quality control, and batch release of a particular pharmaceutical form specified in the certificate.

Certified Translation from Serbian into English

The pharmaceutical manufacturer **'HEMOFARM' a.d. Vršac, Beogradski put bb,** to which the pharmaceutical **manufacturing license** number: 515-04-02176/2023-11 of 29/03/2023, has been issued, **for the manufacturing site – 'HEMOFARM' a.d. Vršac, Beogradski put bb**

is issued a **Good Manufacturing Practice Certificate**:

☒ on the basis of the inspection of pharmaceutical manufacturing site, conducted 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 515-04-08720-1/2022-11 of 6/04/2023 on the compliance of pharmaceutical manufacturing with the Good Manufacturing Practice Guidelines ('Official Gazette of RS', no. 97/17),

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

☐ on the basis of the inspection 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 manufacture with the Good Manufacturing Practice Guidelines on the inspection date.

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

MINISTER
/stamped and signed/
Prof. Dr Danica Grujičić

/stamp reading: The Republic of Serbia;
Ministry of Health; Belgrade/

Annex 1

BASIC INFORMATION (fill out in block letters)	
Production of the following types of medicines:	☒ medicines ☐ immunological medicines ☐ medicines from blood and blood plasma of human origin ☐ biotechnological medicines ☐ radiopharmaceutical medicines ☐ herbal medicines ☐ medicines intended for clinical studies ☐ other types of medicines
Production of medicines which contain psychoactive controlled substances:	☐ yes ☐ no

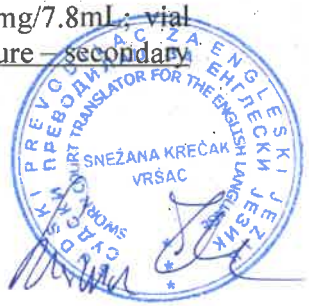
Annex 2

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. Manufacture 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: 1. Manufacturing of sterile liquid pharmaceutical forms, quality control and batch release for the following products: Glucosi infundibile HF solution for infusion; 5%; plastic bottle; 1x500mL, Glucosi infundibile HF solution for infusion; 10%; plastic bottle; 1x500mL, Hartmann's solution HF, solution for infusion; 6.02g/L+0.373g/L+0.294g/L+6.276g/L; plastic bottle; 1x500mL, Natrii chloridi infundibile HF solution for infusion; 9g/L; plastic bottle; 1x500mL, Natrii chloridi infundibile compositum (Ringer's solution) solution for infusion; 8.6g/L+0.3g/L+0.33g/L; plastic bottle; 1x500mL, Natrii chloridi infundibile cum glucoso 5%, solution for infusion, 1X500mL, plastic bottle and Ispirol, bladder irrigation solution; 5.4g/L+27g/L; bag, 1x5L, Phenobarbiton-sodium HF powder and solvent for injection solution; 220mg/2mL; vial with powder and ampoule with solvent; 5x2mL, Hidrokortizon HF powder and solvent for injection solution; 100mg/2mL; vial with powder and ampoule with solvent; lx2mL, Lemod®-Solu powder and solvent for injection/infusion solution; 20mg/mL; vial with powder and ampoule with solvent; 15xlmL, Lemod®-Solu powder and solvent for injection/infusion solution; 40mg/mL; vial with powder and ampoule with solvent; 15xlmL, Peptix®, powder for injection/infusion solution, 40mg, glass vial, 10x40mg, Hemomycin® powder for concentrate for solution for infusion 500mg glass vial 1x500mg, Hidrokortizon HF powder and solvent for injection solution; 100mg/2mL; vial with powder and ampoule with solvent; lx2mL, Beviplex® powder for injection solution 40mg+4mg+8mg+100mg+l0mg+0.004mg, glass vial, up to the 'bulk' phase for the contractual partner Galenika AD Beograd, Remifentanil B.Braun, powder for concentrate for injection/infusion solution; 1mg; glass vial, 5x1mg, Remifentanil B.Braun, powder for concentrate for injection/infusion solution; 2mg; glass vial, 5x2mg, Remifentanil B.Braun, powder for concentrate for injection/infusion solution; 5mg; glass vial, 5x5mg, Diklofenak HF solution for injection; 75mg/3mL; ampoule; 5x3mL, Nirmin® concentrate za solution for infusion; 5mg/1.6mL; ampoule; Marocen® concentrate for solution for infusion; 100mg/10mL; ampoule; 5x10mL, Water for Injection with 0.9% Benzyl alcohol, ampoule 1ml, Water for Injection with 0.9% Benzyl alcohol, ampoule 2 ml, Water for Injection with 0.9% Benzyl alcohol, ampoule 7.8 ml, Aqua redestillata injection solvent, ampoule 2 ml, APO-GO POD, 5mg/ml, solution for infusion in a cartridge, 5x20ml, Methylergometrin HF solution for injection; 0.2mg/mL; ampoule; 50x1mL, Klindamicin solution for injection; 300mg/2mL; ampoule; 10x2mL, Gentamicin HF solution for injection; 80mg/2mL; ampoule; 10x2mL, Gentamicin HF solution for injection; 120mg/2mL; ampoule; 10x2mL, Presolol® solution for injection; 5mg/5mL; ampoule; 5x5mL, Trodon solution for injection/infusion; 100mg/2mL; ampoule; 5x2mL, Trodon solution for injection/infusion; 50mg/mL; ampoule; 5x1mL, Hemomycin®, powder for concentrate for solution for infusion; 500mg; glass vial; 1x500mg, Hidrokortizon HF powder and solvent for solution for injection; 100mg/2mL; vial with powder and ampoule with solvent; 1x2mL, Lemod®-Solu powder and solvent for injection/infusion solution; 20mg/mL; vial with powder and ampoule with solvent; 15xlmL, Lemod®-Solu powder and solvent for injection/infusion solution; 40mg/mL; vial with powder and ampoule with solvent; 15xlmL, Lemod®-Solu powder and solvent for injection/infusion solution; 125mg/2mL; vial with powder and ampoule with solvent; 1x2mL, Lemod®-Solu powder and solvent for injection/infusion solution; 500mg/7.8mL; vial with powder and ampoule with solvent; lx7.8mL; 2. Part of manufacturing procedure – secondary



packaging of sterile liquid pharmaceutical forms, quality control and batch release for the following products: Eqralys® injection solution in pre-filled syringe, 2000IU/0.6ml, pre-filled syringe 6x0.6ml, Ademola® (voriconazole) powder for infusion solution, 200mg, glass vial, 1x200mg, Zodol® solution for injection; 30mg/mL; ampoule; 5x1mL, Corpos® (ocrelizumab), concentrate for infusion solution, 300mg/10ml, glass vial 1x10ml, Enoxaparin HF 2000 IU, injection solution in pre-filled syringe, pack with 10 syringes, Enoxaparin HF 4000 IU, injection solution in pre-filled syringe, pack with 10 syringes, Enoxaparin HF 6000 IU, injection solution in pre-filled syringe, pack with 10 syringes, and Enoxaparin HF 8000 IU, injection solution in pre-filled syringe, pack with 10 syringes.

end of translation

I hereby certify by my seal and signature that the above translation is in full conformity with the original document presented to me in the Serbian language.
SNEŽANA KREČAK, Permanent Sworn-in Court Translator for the English language appointed by the Decision of the Regional Secretariat for Education, Governance and National Communities of the Autonomous Province Vojvodina No. 128-74-54/2011 of 30/03/2012.