Certified translation from Serbian into English

[Coat of Arms]
Republic of Serbia
MINISTRY OF HEALTH
Number: 515-04-08266/2022-11
Date: 21/03/2024
Belgrade, 22-26 Nemanjina St.
Tel. 26 00 749
JPM/SI

Acting upon a request of the Joint Stock Company Pharmaceutical-Chemical Industry HEMOFARM 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, and 113/17 – other law), as well as Article 136 of the Law on General Administrative Procedure ('Official Gazette of the Republic of Serbia' number 18/16), the Minister of Health of the Republic of Serbia passes the following

DECISION

1. **Good Manufacturing Practice CERTIFICATE number 71 IS ISSUED** to the pharmaceutical manufacturer - Joint Stock Company Pharmaceutical-Chemical Industry HEMOFARM Vršac, Vršac, Beogradski put bb, for the manufacturing site **'HEMOFARM' AD Vršac, manufacturing site Antibiotics Plant Dubovac, in Dubovac, Cara Lazara bb.**

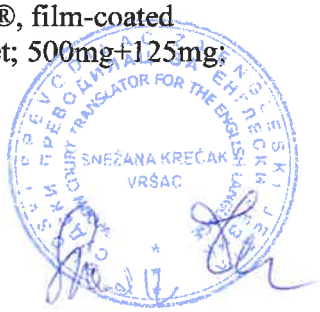
2. This Certificate is valid for the indicated manufacturing site through **28 November 2026**, after which its validity is terminated.

R a t i o n a l e

Pharmaceutical manufacturer Joint Stock Company Pharmaceutical-Chemical Industry HEMOFARM Vršac, has submitted a request to the Ministry of Health of the Republic of Serbia for issuing a Good Manufacturing Practice Certificate for the manufacturing site - Antibiotics Plant Dubovac, in Dubovac, Cara Lazara bb, for:

1. Manufacturing of medicines:

1.1 non-sterile solid pharmaceutical forms – film-coated tablets, capsules, powder for oral suspension and granules for oral suspension: Amoksicilin HF, capsule, hard; 250mg; blister, 2x8pcs; Amoksicilin HF, capsule, hard; 500mg; blister, 2x8pcs; Amoksicilin HF, granules for oral suspension; 250mg/5ml; glass bottle, 1x100ml; Panklav®, film-coated tablet; 250mg+125mg; glass bottle, 1x15pcs; Panklav®, film-coated tablet; 500mg+125mg;



---

glass bottle, 1x20pcs, Panklav®, film-coated tablet; 500mg+125mg; glass bottle 1x15pcs; Panklav®, film-coated tablet; 500mg+125mg; glass bottle, 1x10pcs (export); Panklav®, powder for oral suspension; 125mg/5ml+31.25/5ml; glass bottle, 1x100ml; Panklav® forte, powder for oral suspension; 250mg/5ml+62.5mg/5ml; glass bottle, 1x100ml; Panklav 2X, film-coated tablet; 875mg+125mg; jar, 1x14pcs; Panklav 2X, film-coated tablet; 875mg+125mg; jar, 1x10pcs; Panklav 2X, powder for oral suspension; 400mg/5ml+57mg/5ml; glass bottle, 1x140ml; Panklav 2X, powder for oral suspension; 400mg/5ml+57mg/5ml; glass bottle, lx70ml;

2. Part of manufacturing procedure: labelling and secondary packaging of medicines:
   2.1 sterile solid pharmaceutical forms: powder for suspension for injection: Pancillin®, powder for suspension for injection; 200000 IU + 600000 IU; bottle, 50x800000 IU
   2.2. non-sterile solid pharmaceutical forms: tablet: Largocilin®, film-coated tablet, 660 mg, blister 3x10 pcs; Largocilin®, film-coated tablet, 1000 mg, blister 3x10 pcs, Largocilin®, 250mg/5ml powder for oral solution, bottle 100ml;

3. quality control and batch release of medicinal products indicated in items 1. and 2. of this paragraph, which are carried out in Vršac, Beogradski put bb;

4. List of medicines produced according to contract manufacturing agreement: Pentrexyl® capsule, hard, 16 x 500mg, Pentrexyl® capsule, hard, 8 x 500mg, blister; Sinacilin® capsule, hard, 16 x 250mg, blister; Sinacilin® capsule, hard, 8 x 250mg, blister; Sinacilin® capsule, hard, 16 x 500mg, blister; Sinacilin® capsule, hard, 8 x 500mg, blister; Sinacilin® powder for oral suspension, 250mg/5ml, glass bottle 100ml; Sinacilin® powder for oral suspension, 250mg/5ml, glass bottle 100ml; Sinacilin® baby powder for oral suspension, 250mg/5ml, glass bottle 100ml.

On 28 and 29/11/2023, the inspectors for medicines and medical devices conducted an inspection at the manufacturing site Antibiotics Plant Dubovac, in Dubovac, Cara Lazara bb, as well as at the medicinal products quality control and batch release site 'HEMOFARM' a.d. in 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, 105/17 – other law, 113/17 – other law), for the purpose of establishing compliance of pharmaceutical manufacturing with the Good Manufacturing Practice Guidelines ('Official Gazette of the Republic of Serbia' number 97/17), about which the final report with the conclusion on the compliance number: 515-04-08266/2022-11 of 20/03/2024 was prepared. There were no objections to the factual status stated in the protocol on the part of the manufacturer.

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

Certified translation from Serbian into English

Based on the directly established factual status, as well as an insight into the documentation reviewed during the inspection, it has been established that the production of the above indicated medicines complies with the Good Manufacturing Practice Guidelines, about which the final report with the conclusion on the compliance number 515-04-08266/2022-11 of 20/03/2024, was prepared, and delivered to the manufacturer.

Based on the final report number 515-04-08266/2022-11 of 20/03/2024, 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.

The subject of establishing the compliance of pharmaceutical manufacturing with the Good Manufacturing Practice Guidelines referred to: 1. Manufacturing of medicines: 1.1 non-sterile solid pharmaceutical forms – film-coated tablets, capsules, powder for oral suspension and granules for oral suspension; 2. Part of manufacturing procedure: labelling and secondary packaging of medicines: 2.1 sterile solid pharmaceutical forms; 2.2 non-sterile solid pharmaceutical forms: tablets, at the manufacturing site Antibiotics Plant Dubovac, in Dubovac, Cara Lazara bb, and in 'HEMOFARM' a.d. in Vršac, Beogradski put bb, as well as 3. quality control and batch release of medicinal products indicated in items 1. and 2. of this paragraph, which are carried out in Vršac, Beogradski put bb; 4. List of medicines produced according to contract manufacturing agreement.

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 republic administrative fee for this decision pursuant to the Law on Republic Administrative Fees ('Official Gazette of RS' number 43/03, 51/03, 83/15, 112/15, 50/16 - other law, 113/17, 3/18 - amendment, 50/18 - other law, 95/18, 38/19 - other law, 86/19, 90/19 - amendment, 98/20 - other law).

Distribution:
1. **'HEMOFARM' AD 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]

Certified translation from Serbian into English

GOOD MANUFACTURING PRACTICE CERTIFICATE
(*GMP* CERTIFICATE)

Certificate number:	**71**
Date:	**21/03/2024**

Name of manufacturing license holder (pharmaceutical manufacturer):	**'HEMOFARM' AD Vršac**
Address of manufacturing license holder (pharmaceutical manufacturer) seat:	**Vršac, Beogradski put bb**
Address of manufacturing site:	**Dubovac, Cara Lazara 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, 105/17 – other law, and 113/17 – other law)
Date of inspection based on which the certificate is issued:	28 - 29/11/2023
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' AD VRŠAC, Beogradski put bb, to which the pharmaceutical manufacturing license number: 515-04-05130/2023-11 of 3 July 2023, has been issued, **for the manufacturing site – 'HEMOFARM' AD Vršac, Antibiotics Plant Dubovac, in Dubovac, Cara Lazara 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 107/12, 105/17 – other law, and 113/17 – other law), and the final report number 515-04-08266/2022-11 of 20/03/2024 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 215 of the Law on Medicines and Medical Devices ('Official Gazette of RS', number 30/10 and 107/12, 105/17 – other law, and 113/17 – other law), and the final report number .....of ..... 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, 105/17 – other law, and 113/17 – other law).

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

Distribution:
1. **'HEMOFARM' AD 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]

PREVODILAC ZA ENGLESKI JEZIK
ПРЕВОДИЛАЦ ЗА ЕНГЛЕСКИ
COURT TRANSLATOR FOR THE ENGLISH LANGUAGE
SNEŽANA KREČAK
VRŠAC

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

Certified translation from Serbian into English

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

Certified translation from Serbian into English

Annex 3

Notes, i.e. additional explanations concerning the contents of the certificate:

This certificate on compliance of pharmaceutical manufacture with the Good Manufacturing Practice Guidelines refers to 1. Manufacturing of medicines: 1.1 non-sterile solid pharmaceutical forms – film-coated tablets, capsules, powder for oral suspension and granules for oral suspension: Amoksicilin HF, capsule, hard; 250mg; blister, 2x8pcs; Amoksicilin HF, capsule, hard; 500mg; blister, 2x8pcs; Amoksicilin HF, granules for oral suspension; 250mg/5ml; glass bottle, 1x100ml; Panklav®, film-coated tablet; 250mg+125mg; glass bottle, 1x15pcs; Panklav®, film-coated tablet; 500mg+125mg; glass bottle, 1x20pcs, Panklav®, film-coated tablet; 500mg+125mg; glass bottle 1x15pcs; Panklav®, film-coated tablet; 500mg+125mg; glass bottle, 1x10pcs (export); Panklav®, powder for oral suspension; 125mg/5ml+31.25/5ml; glass bottle, 1x100ml; Panklav® forte, powder for oral suspension; 250mg/5ml+62.5mg/5ml; glass bottle, 1x100ml; Panklav 2X, film-coated tablet; 875mg+125mg; jar, 1x14pcs; Panklav 2X, film-coated tablet; 875mg+125mg; jar, 1x10pcs; Panklav 2X, powder for oral suspension; 400mg/5ml+57mg/5ml; glass bottle, 1x140ml; Panklav 2X, powder for oral suspension; 400mg/5ml+57mg/5ml; glass bottle, lx70ml;
2. Part of manufacturing procedure: labelling and secondary packaging of medicines:

2.1 sterile solid pharmaceutical forms: powder for suspension for injection: Pancillin®, powder for suspension for injection; 200000 IU + 600000 IU; bottle, 50x800000 IU

2.2. non-sterile solid pharmaceutical forms: tablet: Largocilin®, film-coated tablet, 660 mg, blister 3x10 pcs; Largocilin®, film-coated tablet, 1000 mg, blister 3x10 pcs, Largocilin®, 250mg/5ml powder for oral solution, bottle 100ml;

3. quality control and batch release of medicinal products indicated in items 1. and 2. of this paragraph, which are carried out in Vršac, Beogradski put bb;

4. List of medicines produced according to contract manufacturing agreement: Pentrexyl® capsule, hard, 16 x 500mg, Pentrexyl® capsule, hard, 8 x 500mg, blister; Sinacilin® capsule, hard, 16 x 250mg, blister; Sinacilin® capsule, hard, 8 x 250mg, blister; Sinacilin® capsule, hard, 16 x 500mg, blister; Sinacilin® capsule, hard, 8 x 500mg, blister; Sinacilin® powder for oral suspension, 250mg/5ml, glass bottle 100ml; Sinacilin® powder for oral suspension, 250mg/5ml, glass bottle 100ml; Sinacilin® baby powder for oral suspension, 250mg/5ml, glass bottle 100ml.

----------*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.