



Republic of Serbia  
**MINISTRY OF HEALTH**  
Number: 515-04-08927/2022-11  
Date: 20 February 2024  
Belgrade, 22-26 Nemanjina St.  
Tel. 011/2600-749  
VV/SI

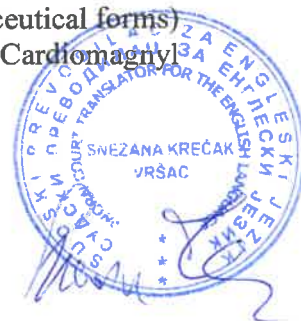
Acting upon a request of the pharmaceutical manufacturer 'HEMOFARM' a.d. Vršac, Beogradski put bb, for issuing a Good Manufacturing Practice Certificate, and pursuant to Article 212, paragraph 6 of the Law on Medicines and Medical Devices ('Official Gazette of RS' No. 30/10, 107/12, 105/17 – other law, 113/17 – other law), Article 37 of the Law on Inspection Supervision ('Official Gazette of the Republic of Serbia' No. 36/15), 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 67 IS ISSUED** to the pharmaceutical manufacturer 'HEMOFARM' a.d. Vršac, Beogradski put bb, for **manufacturing site 'HEMOFARM' a.d. Vršac, Beogradski put bb.**
- 2. This Certificate is valid for the indicated manufacturing site through 15 December 2026, after which its validity is terminated.**

### **R a t i o n a l e**

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 the production of non-sterile solid pharmaceutical forms, quality control and batch release of the medicinal products which are manufactured in the Solid Dosage Forms Plant at the above indicated address. The submitted request refers to the following production of: **1. Medicinal products manufactured up to the bulk level (non-sterile pharmaceutical forms) at Vršac site – complete production in the Solid Dosage Forms Plant: Cardiomagnyl**



(acetylsalicylic acid + magnesium hydroxide) STADA 75mg, film-coated tablets, Cardiomagnyl (acetylsalicylic acid + magnesium hydroxide) STADA 150mg, film-coated tablets, Metoten (fluphenazine), coated tablet, 1mg, bottle, 1x25 pcs, Metoten (fluphenazine), coated tablet, 5mg, 1x25pcs, Vitamin C (ascorbic acid), effervescent tablet, 1000mg, container tube, 20pcs; 2 Medicinal products manufactured up to the bulk level at Vršac site in Solid Dosage Forms Plant and packed in the Packaging Centre: Aflothenol® (levetiracetam), film-coated tablet, 250mg, blister, 6x10 pcs, Aflothenol® (levetiracetam), film-coated tablet, 500mg, blister, 6x10 pcs, Aflothenol® (levetiracetam), film-coated tablet, 1000mg, blister, 6x10 pcs, Caveda® (tadalafil), film-coated tablet, 2.5mg, blister, 30 pcs, Caveda® (tadalafil), film-coated tablet, 5mg, blister, 30 pcs, Caveda® (tadalafil), film-coated tablet, 10mg, blister, 4 pcs, Caveda® (tadalafil), film-coated tablet, 20mg, blister, 2 pcs, Cholipam® (simvastatin), film-coated tablet, 10mg, blister, 2x10 pcs, Cholipam® (simvastatin), film-coated tablet, 10mg, blister, 3x10 pcs, Cholipam® (simvastatin), film-coated tablet, 20mg, blister, 2x10 pcs, Cholipam® (simvastatin), film-coated tablet, 20mg, blister, 3x10 pcs, Clopidix (clopidogrel), film-coated tablet, 75mg, blister, 2x14 pcs, Cornelin (lercanidipine), film-coated tablet, 10mg, blister, 2x14 pcs, Cornelin (lercanidipine), film-coated tablet, 20mg, blister, 2x14 pcs, Cornelin (lercanidipine), film-coated tablet, 10mg, blister, 6x10 pcs, Cornelin (lercanidipine), film-coated tablet, 20mg, blister, 6x10 pcs, Cortiazem retard® (diltiazem), 90mg, prolonged release tablet, blister, 3x10 pcs, Diklofenak Forte HF (diclofenac sodium), modified release tablet, 100mg, blister, 2x10 pcs, Dilcoran (pentaerithrityl tetranitrate), prolonged release tablet, 80mg, blister, 2x10 pcs, Elfonis® (moxifloxacin hydrochloride), film-coated tablet, blister, 400mg, 2x5 pcs, Elfonis® (moxifloxacin hydrochloride), film-coated tablet, blister, 400mg, 1x7 pcs, Enalapril H Alkaloid, 20 tablets; 10mg+25mg, Enzix® (enalapril, indapamide), tablet+ film-coated tablet, 10mg+2.5mg, blister, 3x10 pcs, Enzix® duo (enalapril, indapamide), tablet+ film-coated tablet, 10mg+2.5mg, blister, 3x15 pcs, Enzix® duo forte (enalapril, indapamide), tablet+ film-coated tablet, 20mg+2.5mg, blister, 3x 15 pcs, Erynorm® (losartan), film-coated tablet, 50mg, blister, 2x14 pcs, Erynorm® (losartan), film-coated tablet, 100mg, blister, 2x14 pcs, Erynorm® (losartan), film-coated tablet, 50mg, blister, 3x10 pcs, Erynorm® (losartan), film-coated tablet, 100mg, blister, 3x10 pcs, Famotidin HF (Famotidine), film-coated tablet, 20mg, blister, 3x10 pcs, Famotidin HF (famotidine), film-coated tablet, 40mg, blister, 3x10 pcs, Fiumin® (sildenafil), film-coated tablet, 20mg, blister, 90 pcs, Fluconal® (fluconazole), capsule hard, 50mg, blister, 1x7 pcs, Fluconal® (fluconazole), capsule hard, 150mg, blister, 1x1 pc, Flunisan® (fluoxetine), tablet, 20mg, blister, 3x10 pcs, Fomela (aluminum magnesium silicate hydrate), tablet, 500mg, blister, 4x10 pcs, Fomela (aluminum magnesium silicate hydrate), tablet, 500mg, blister, 2x10 pcs, Gluformin® (metformin), 1000 mg, film-coated tablet, blister, 2x15 pcs, Gutana® (febuxostat), film-coated tablet, 80mg, blister, 3x10pcs, Gutana® (febuxostat), film-coated tablet, 120mg, blister, 3x10 pcs, Hemokvin® (quinapril), film-coated tablet, 10mg, blister, 2x10 pcs, Hemokvin plus® (quinapril, hydrochlorothiazide), film-coated tablet, 20mg+12.5mg, blister, 2x10 pcs, Hemokvin® (quinapril), film-coated tablet, 20mg, blister, 2x10 pcs, Hemomycin® (azithromycin), film-coated tablet, 500mg, blister, 1x3 pcs, Hemopres® (hydrochlorothiazide, amiloride), tablet, 50mg+5mg, blister, 4x10 pcs, Hypolip, (atorvastatin) film-coated tablet, 10mg, blister, 3x10 pcs, Hypolip (atorvastatin), film-coated tablet, 20mg, blister, 3x10 pcs, Hypolip (atorvastatin), film-coated tablet, 40mg, blister, 3x10 pcs, Indapamid (indapamide), film-coated tablet, 2.5mg, blister, 3x10 pcs, Irbenida



(irbesartan), film-coated tablet, 150mg, blister, 3x10 pcs, Irbenida (irbesartan), film-coated tablet, 300mg, blister, 3x10 pcs, Irbenida plus (irbesartan, hydrochlorothiazide), film-coated tablet, 150mg+12.5mg, blister, 3x10 pcs, Irbenida plus (irbesartan, hydrochlorothiazide), film-coated tablet, 300mg+12.5mg, blister, 3x10 pcs, Jaramera® (ezetimibe), tablet, 10mg, blister, 30 pcs, Midol® (acetylsalicylic acid), gastro-resistant tablet, 100mg, blister, 3x10 pcs, Midol® (acetylsalicylic acid), gastro-resistant tablet, 75mg, blister, 3x10 pcs, Milenol® (carvedilol), tablet, 12.5mg, blister, 2x14 pcs, Milenol® (carvedilol), tablet, 25mg, blister, 2x14 pcs, Milenol® (carvedilol), tablet, 12.5mg, blister, 3x10 pcs, Milenol® (carvedilol), tablet, 25mg, blister, 3x10 pcs, Nystatin HF (nystatin), coated tablet, 500 000i.u.; blister, 1x10 pcs, Omnitus® (butamirate), modified release film-coated tablet, 20mg, blister, 1x10 pcs, Omnitus® (butamirate), modified release film-coated tablet, 50mg, blister, 1x10 pcs, Panlax® (bisacodyl), gastro-resistant tablet, 5mg, blister, 3x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 5mg, blister, 3x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 10mg, 3x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 20mg, 3x10 pcs, Presolol® (metoprolol), film-coated tablet, 100mg, blister, 3x10 pcs, Pressing® (loratadine), tablet, 10mg, blister, 1x10 pcs, Prilenap® (enalapril maleate), tablet, 5mg, blister, 2x10 pcs, Prilenap® (enalapril maleate), tablet, 5mg, blister, 3x10 pcs, Prilenap® (enalapril maleate), tablet, 10mg, blister, 2x10 pcs, Prilenap® (enalapril maleate), tablet, 10mg, blister, 3x10 pcs, Prilenap® (enalapril maleate), tablet, 20mg, blister, 2x10 pcs, Prilenap® (enalapril maleate), tablet, 20mg, blister, 3x10 pcs, Prilenap® H (enalapril, hydrochlorothiazide), tablet, 10mg+25mg, blister, 2x10 pcs, Prilenap® H (enalapril, hydrochlorothiazide), tablet, 10mg+25mg, blister, 3x10 pcs, Prilenap® HL (enalapril, hydrochlorothiazide), tablet, 10mg+12.5mg, blister, 2x10 pcs, Prilenap® HL (enalapril, hydrochlorothiazide), tablet, 10mg+12.5mg, blister, 3x10 pcs, Prilinda® (ramipril), tablet, 2.5mg, blister, 4x7 pcs, Prilinda® (ramipril), tablet, 5mg, blister, 4x7 pcs, Prilinda® (ramipril), tablet, 10mg, blister, 4x7 pcs, Prilinda® plus (ramipril, hydrochlorothiazide), tablet, blister, 2.5mg+12.5mg, 4x7 pcs, Prilinda® plus (ramipril, hydrochlorothiazide), tablet, blister, 5mg+25mg, 4x7 pcs, Rapten Duo (diclofenac sodium), modified release tablet, 75mg, blister, 3x10 pcs, Rapten Duo (diclofenac sodium), modified release tablet, 75mg, blister, 1x10 pcs, Rivaroxaban HF (rivaroxaban), 10mg, film-coated tablet, 1x10 pcs, Rivaroxaban HF (rivaroxaban), 10mg, film-coated tablet, 3x10 pcs, Rivaroxaban HF (rivaroxaban), 15mg, film-coated tablet, 3x10 pcs, Rivaroxaban HF (rivaroxaban), 20mg, film-coated tablet, 3x10 pcs, Sidata® (sertraline), film-coated tablet, 50mg, blister, 2x14 pcs, Sidata® (sertraline), film-coated tablet, 100mg, blister, 2x14 pcs, Sildena® (sildenafil), film-coated tablet, 25mg, blister, 1x1 pc, Sildena® (sildenafil), film-coated tablet, 50mg, blister, 1x1 pc, Sildena® (sildenafil), film-coated tablet, 100mg, blister, 1x1 pc, Sildena® (sildenafil), film-coated tablet, 100mg, 1x2 pcs, Sildena® (sildenafil), film-coated tablet, 100mg, 2x2 pcs, Sildena® (sildenafil), film-coated tablet, 100mg, 1x8 pcs, Ticagrex® (ticagrelor), film-coated tablet, 60mg, blister, 4x15 pcs, Ticagrex® (ticagrelor), film-coated tablet, 90mg, blister, 4x15 pcs, Treana® (olanzapine), film-coated tablet, 5mg, blister, 3x10 pcs, Treana® (olanzapine), film-coated tablet, 10mg, blister, 3 x 10 pcs, Trecar® (zolmitriptan), orodispersible tablet, 2.5mg, blister, 1x3 pcs, Trecar® (zolmitriptan), orodispersible tablet, 5mg, blister, 1x3 pcs, Trecar® (zolmitriptan), orodispersible tablet, 5mg, blister, 2x3 pcs, Tregona® (donepezil), film-coated tablet, 5mg, blister, 2x14 pcs, Tregona® (donepezil), film-coated tablet, 10mg, blister, 2x14 pcs, Trefero® (aripiprazole), orodispersible



tablet, 10mg, 30 pcs, Trefero® (aripiprazole), orodispersible tablet, 15mg, 30 pcs, Verapamil HF (verapamil), film-coated tablet, 40mg, blister, 3x10 pcs, Verapamil HF (verapamil), film-coated tablet, 80mg, blister; 5x10 pcs, Xepar® (prasugrel), film-coated tablet, 5mg, blister, 2x15 pcs, Xepar® (prasugrel), film-coated tablet, 10mg, blister, 2x15 pcs, Yanida (valsartan), film-coated tablet, 80mg, 2x14 pcs, Yanida (valsartan), film-coated tablet, 160mg, 2x14 pcs, Yanida® (valsartan), film-coated tablet, 80mg, blister, 3x10 pcs, Yanida® (valsartan), film-coated tablet, 160mg, blister, 3x10 pcs, Yanida® plus (valsartan, hydrochlorothiazide), film-coated tablet, 80mg+12.5mg, 28 pcs, Yanida® plus (valsartan, hydrochlorothiazide), film-coated tablet, 160mg+12.5mg, 28 pcs, Yanida® plus (valsartan, hydrochlorothiazide), film-coated tablet, 160mg+25mg, 28 pcs, Yanida® plus (valsartan, hydrochlorothiazide), 80mg+12.5mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus (valsartan, hydrochlorothiazide), 160mg+12.5mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus (valsartan, hydrochlorothiazide), 160mg+25mg, film-coated tablet, blister, 3x10 pcs, Yanida® trio (amlodipine, valsartan, hydrochlorothiazide), film-coated tablet, 5mg+160mg+12.5mg, 30 pcs, Yanida® trio (amlodipine, valsartan, hydrochlorothiazide), film-coated tablet, 5mg+160mg+25mg, 30 pcs, Yanida® trio (amlodipine, valsartan, hydrochlorothiazide), film-coated tablet, 10mg+160mg+12.5mg, 30 pcs, Yanida® combo (amlodipine, valsartan), film-coated tablet, 5mg+80mg, blister, 2x15 pcs, Yanida® combo (amlodipine, valsartan), film-coated tablet, 5mg+160mg, blister, 2x15 pcs, Yanida® combo (amlodipine, valsartan), film-coated tablet, 10mg+160mg, blister, 2x15 pcs, Yurinex® (bumetanide), tablet, 1mg, blister, 2x10 pcs, Zenix® (linezolid), film-coated tablet, blister, 10x600mg, Zobox (cilazapril), 2.5mg, film-coated tablet, blister, 3x10 pcs, Zolmitriptan (zolmitriptan), orodispersible tablet, 2.5mg, blister, 1x3 pcs; Medicines containing psychoactive substances: Demetrin® (prazepam), tablet, 10mg, blister, 2x10 pcs, Diazepam HF (diazepam), tablet, 10mg, blister, 3x10 pcs, Diazepam HF (diazepam), tablet, 2mg, blister, 3x10 pcs, Diazepam HF (diazepam), tablet, 5mg, blister, 3x10 pcs, Phenobarbiton (phenobarbital), tablet, 15mg, blister, 3x10 pcs and Phenobarbiton (phenobarbital), tablet, 100mg, blister, 3x10 pcs, and the intermediates which are manufactured in 'HEMOFARM' A.D. Vršac, which do not contain an active component, but are rather used as such at other manufacturing sites, as 3. Intermediates which are included in the composition of a medicinal product from the product range of 'HEMOFARM' A.D. Vršac: Sugar granulate for production of the medicinal product: Amoksicilin HF, granules for oral suspension; 250mg/5ml; glass bottle, 1x100ml, Sugar granulate for production of the medicinal product: Cefaleksin HF, granules for oral suspension; 250mg/5ml; glass bottle, 1x100ml, Sugar granulate for production of the medicinal products: Cefaklor, granules for oral suspension; 250mg/5ml; bottle, 1x60ml and Cefaklor, granules for oral suspension; 125mg/5ml; bottle, 1x60ml.

In the period from 12/12 until 15/12/2023, the inspectors for medicines and medical devices conducted a direct inspection at 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 compliance of the pharmaceutical production with the Good Manufacturing Practice Guidelines ('Official Gazette of the Republic of Serbia' number 97/17), about which the Protocol number: 515-04-08927/2022-11 of 26/01/2024 was made. There were no objections to the factual status stated in the Protocol on the part of the manufacturer.



*Certified translation from Serbian into English*

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

Based on the directly established factual status, as well as an insight into the documentation reviewed during the inspection, no critical non-conformances have been established, therefore it has been concluded 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 515-04-08927-1/2022-11 of 14 February 2024, was prepared, and delivered to the manufacturer.

Based on the final report number 515-04-08927-1/2022-11 of 14 February 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.

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)**

<b>Certificate number:</b>	<b>67</b>
<b>Date:</b>	<b>20 February 2024</b>

Name of manufacturing license holder (pharmaceutical manufacturer):	<b>'HEMOFARM' a.d. Vršac</b>
Address of manufacturing license holder (pharmaceutical manufacturer) seat:	<b>Vršac, Beogradski put bb</b>
Address of manufacturing site:	<b>'HEMOFARM' a.d. Vršac Beogradski put bb</b>
Medicine batch release site:	<b>'HEMOFARM' a.d. Vršac Beogradski put bb</b>
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 - 15/12/2023
Validity of certificate:	Good Manufacturing Practice Certificate is issued for a <b>three-year period</b> 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*

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The pharmaceutical manufacturer '**HEMOFARM**' a.d. Vršac, Beogradski put bb, to which the **pharmaceutical manufacturing license** number: 000423459 2023 11900 008 004 000 001 of 26/12/2023, 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 107/12), and the final report number 515-04-08927-1/2022-11 of 14 February 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 2015 of the Law on Medicines and Medical Devices ('Official Gazette of RS', number 30/10 and 107/12), 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).

This Certificate confirms the compliance of pharmaceutical manufacturing 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**

<b>BASIC INFORMATION</b> (fill out in block letters)	
<b>Production of the following types of medicines:</b>	<input checked="" type="checkbox"/> medicines <input type="checkbox"/> immunological medicines <input type="checkbox"/> medicines from blood and blood plasma of human origin <input type="checkbox"/> biotechnological medicines <input type="checkbox"/> radiopharmaceutical medicines <input type="checkbox"/> herbal medicines <input type="checkbox"/> medicines intended for clinical studies <input type="checkbox"/> other types of medicines
<b>Production of medicines which contain psychoactive controlled substances:</b>	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no





Annex 2

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



### 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: Manufacture of non-sterile solid pharmaceutical forms, quality control and batch release of medicines, specifically: 1. Medicinal products manufactured up to the bulk level (non-sterile pharmaceutical forms) at Vršac site – complete production in the Solid Dosage Forms Plant: Cardiomagnyl (acetylsalicylic acid + magnesium hydroxide) STADA 75mg, film-coated tablets, Cardiomagnyl (acetylsalicylic acid + magnesium hydroxide) STADA 150mg, film-coated tablets, Metoten (fluphenazine), coated tablet, 1mg, bottle, 1x25 pcs, Metoten (fluphenazine), coated tablet, 5mg, 1x25pcs, Vitamin C (ascorbic acid), effervescent tablet, 1000mg, container tube, 20pcs; 2 Medicinal products manufactured up to the bulk level at Vršac site in Solid Dosage Forms Plant and packed in the Packaging Centre: Aflothenol® (levetiracetam), film-coated tablet, 250mg, blister, 6x10 pcs, Aflothenol® (levetiracetam), film-coated tablet, 500mg, blister, 6x10 pcs, Aflothenol® (levetiracetam), film-coated tablet, 1000mg, blister, 6x10 pcs, Caveda® (tadalafil), film-coated tablet, 2.5mg, blister, 30 pcs, Caveda® (tadalafil), film-coated tablet, 5mg, blister, 30 pcs, Caveda® (tadalafil), film-coated tablet, 10mg, blister, 4 pcs, Caveda® (tadalafil), film-coated tablet, 20mg, blister, 2 pcs, Cholipam® (simvastatin), film-coated tablet, 10mg, blister, 2x10 pcs, Cholipam® (simvastatin), film-coated tablet, 10mg, blister, 3x10 pcs, Cholipam® (simvastatin), film-coated tablet, 20mg, blister, 2x10 pcs, Cholipam® (simvastatin), film-coated tablet, 20mg, blister, 3x10 pcs, Clopidix (clopidogrel), film-coated tablet, 75mg, blister, 2x14 pcs, Cornelin (lercanidipine), film-coated tablet, 10mg, blister, 2x14 pcs, Cornelin (lercanidipine), film-coated tablet, 20mg, blister, 2x14 pcs, Cornelin (lercanidipine), film-coated tablet, 10mg, blister, 6x10 pcs, Cornelin (lercanidipine), film-coated tablet, 20mg, blister, 6x10 pcs, Cortiazem retard® (diltiazem), 90mg, prolonged release tablet, blister, 3x10 pcs, Diklofenak Forte HF (diclofenac sodium), modified release tablet, 100mg, blister, 2x10 pcs, Dilcoran (pentaerithryl tetranitrate), prolonged release tablet, 80mg, blister, 2x10 pcs, Elfonis® (moxifloxacin hydrochloride), film-coated tablet, blister, 400mg, 2x5 pcs, Elfonis® (moxifloxacin hydrochloride), film-coated tablet, blister, 400mg, 1x7 pcs, Enalapril H Alkaloid, 20 tablets; 10mg+25mg, Enzix® (enalapril, indapamide), tablet+ film-coated tablet, 10mg+2.5mg, blister, 3x10 pcs, Enzix® duo (enalapril, indapamide), tablet+ film-coated tablet, 10mg+2.5mg, blister, 3x15 pcs, Enzix® duo forte (enalapril, indapamide), tablet+ film-coated tablet, 20mg+2.5mg, blister, 3x15 pcs, Erynorm® (losartan), film-coated tablet, 50mg, blister, 2x14 pcs, Erynorm® (losartan), film-coated tablet, 100mg, blister, 2x14 pcs, Erynorm® (losartan), film-coated tablet, 50mg, blister, 3x10 pcs, Erynorm® (losartan), film-coated tablet, 100mg, blister, 3x10 pcs, Famotidin HF (Famotidine), film-coated tablet, 20mg, blister, 3x10 pcs, Famotidin HF (famotidine), film-coated tablet, 40mg, blister, 3x10 pcs, Fiumin® (sildenafil), film-coated tablet, 20mg, blister, 90 pcs, Fluconal® (fluconazole), capsule hard, 50mg, blister, 1x7 pcs, Fluconal® (fluconazole), capsule hard, 150mg, blister, 1x1 pc, Flunisan® (fluoxetine), tablet, 20mg, blister, 3x10 pcs, Fomela (aluminum magnesium silicate hydrate), tablet, 500mg, blister, 4x10 pcs, Fomela (aluminum magnesium silicate hydrate), tablet, 500mg, blister, 2x10 pcs, Gluformin® (metformin), 1000 mg, film-coated



tablet, blister, 2x15 pcs, Gutana® (febuxostat), film-coated tablet, 80mg, blister, 3x10pcs, Gutana® (febuxostat), film-coated tablet, 120mg, blister, 3x10 pcs, Hemokvin® (quinapril), film-coated tablet, 10mg, blister, 2x10 pcs, Hemokvin plus® (quinapril, hydrochlorothiazide), film-coated tablet, 20mg+12.5mg, blister, 2x10 pcs, Hemokvin® (quinapril), film-coated tablet, 20mg, blister, 2x10 pcs, Hemomycin® (azithromycin), film-coated tablet, 500mg, blister, 1x3 pcs, Hemopres® (hydrochlorothiazide, amiloride), tablet, 50mg+5mg, blister, 4x10 pcs, Hypolip, (atorvastatin) film-coated tablet, 10mg, blister, 3x10 pcs, Hypolip (atorvastatin), film-coated tablet, 20mg, blister, 3x10 pcs, Hypolip (atorvastatin), film-coated tablet, 40mg, blister, 3x10 pcs, Indapamid (indapamide), film-coated tablet, 2.5mg, blister, 3x10 pcs, Irbenida (irbesartan), film-coated tablet, 150mg, blister, 3x10 pcs, Irbenida (irbesartan), film-coated tablet, 300mg, blister, 3x10 pcs, Irbenida plus (irbesartan, hydrochlorothiazide), film-coated tablet, 150mg+12.5mg, blister, 3x10 pcs, Irbenida plus (irbesartan, hydrochlorothiazide), film-coated tablet, 300mg+12.5mg, blister, 3x10 pcs, Jaramera® (ezetimibe), tablet, 10mg, blister, 30 pcs, Midol® (acetylsalicylic acid), gastro-resistant tablet, 100mg, blister, 3x10 pcs, Midol® (acetylsalicylic acid), gastro-resistant tablet, 75mg, blister, 3x10 pcs, Milenol® (carvedilol), tablet, 12.5mg, blister, 2x14 pcs, Milenol® (carvedilol), tablet, 25mg, blister, 2x14 pcs, Milenol® (carvedilol), tablet, 12.5mg, blister, 3x10 pcs, Milenol® (carvedilol), tablet, 25mg, blister, 3x10 pcs, Nystatin HF (nystatin), coated tablet, 500 000i.u.; blister, 1x10 pcs, Omnitus® (butamirate), modified release film-coated tablet, 20mg, blister, 1x10 pcs, Omnitus® (butamirate), modified release film-coated tablet, 50mg, blister, 1x10 pcs, Panlax® (bisacodyl), gastro-resistant tablet, 5mg, blister, 3x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 5mg, blister, 3x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 10mg, 3x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 20mg, 3x10 pcs, Presolol® (metoprolol), film-coated tablet, 100mg, blister, 3x10 pcs, Pressing® (loratadine), tablet, 10mg, blister, 1x10 pcs, Prilenap® (enalapril maleate), tablet, 5mg, blister, 2x10 pcs, Prilenap® (enalapril maleate), tablet, 5mg, blister, 3x10 pcs, Prilenap® (enalapril maleate), tablet, 10mg, blister, 2x10 pcs, Prilenap® (enalapril maleate), tablet, 10mg, blister, 3x10 pcs, Prilenap® (enalapril maleate), tablet, 20mg, blister, 2x10 pcs, Prilenap® (enalapril maleate), tablet, 20mg, blister, 3x10 pcs, Prilenap® H (enalapril, hydrochlorothiazide), tablet, 10mg+25mg, blister, 2x10 pcs, Prilenap® H (enalapril, hydrochlorothiazide), tablet, 10mg+25mg, blister, 3x10 pcs, Prilenap® HL (enalapril, hydrochlorothiazide), tablet, 10mg+12.5mg, blister, 2x10 pcs, Prilenap® HL (enalapril, hydrochlorothiazide), tablet, 10mg+12.5mg, blister, 3x10 pcs, Prilinda® (ramipril), tablet, 2.5mg, blister, 4x7 pcs, Prilinda® (ramipril), tablet, 5mg, blister, 4x7 pcs, Prilinda® (ramipril), tablet, 10mg, blister, 4x7 pcs, Prilinda® plus (ramipril, hydrochlorothiazide), tablet, blister, 2.5mg+12.5mg, 4x7 pcs, Prilinda® plus (ramipril, hydrochlorothiazide), tablet, blister, 5mg+25mg, 4x7 pcs, Rapten Duo (diclofenac sodium), modified release tablet, 75mg, blister, 3x10 pcs, Rapten Duo (diclofenac sodium), modified release tablet, 75mg, blister, 1x10 pcs, Rivaroxaban HF (rivaroxaban), 10mg, film-coated tablet, 1x10 pcs, Rivaroxaban HF (rivaroxaban), 10mg, film-coated tablet, 3x10 pcs, Rivaroxaban HF (rivaroxaban), 15mg, film-coated tablet, 3x10 pcs, Rivaroxaban HF (rivaroxaban), 20mg, film-coated tablet, 3x10 pcs, Sidata® (sertraline), film-coated tablet, 50mg, blister, 2x14 pcs, Sidata® (sertraline), film-coated tablet, 100mg, blister, 2x14 pcs, Sildena® (sildenafil), film-coated tablet, 25mg, blister, 1x1 pc, Sildena® (sildenafil), film-coated tablet, 50mg, blister, 1x1 pc, Sildena® (sildenafil), film-coated tablet, 100mg, blister,



1x1 pc, Sildena® (sildenafil), film-coated tablet, 100mg, 1x2 pcs, Sildena® (sildenafil), film-coated tablet, 100mg, 2x2 pcs, Sildena® (sildenafil), film-coated tablet, 100mg, 1x8 pcs, Ticagrex® (ticagrelor), film-coated tablet, 60mg, blister, 4x15 pcs, Ticagrex® (ticagrelor), film-coated tablet, 90mg, blister, 4x15 pcs, Treana® (olanzapine), film-coated tablet, 5mg, blister, 3x10 pcs, Treana® (olanzapine), film-coated tablet, 10mg, blister, 3 x 10 pcs, Trecar® (zolmitriptan), orodispersible tablet, 2.5mg, blister, 1x3 pcs, Trecar® (zolmitriptan), orodispersible tablet, 5mg, blister, 1x3 pcs, Trecar® (zolmitriptan), orodispersible tablet, 5mg, blister, 2x3 pcs, Tregona® (donepezil), film-coated tablet, 5mg, blister, 2x14 pcs, Tregona® (donepezil), film-coated tablet, 10mg, blister, 2x14 pcs, Trefero® (aripiprazole), orodispersible tablet, 10mg, 30 pcs, Trefero® (aripiprazole), orodispersible tablet, 15mg, 30 pcs, Verapamil HF (verapamil), film-coated tablet, 40mg, blister, 3x10 pcs, Verapamil HF (verapamil), film-coated tablet, 80mg, blister; 5x10 pcs, Xepar® (prasugrel), film-coated tablet, 5mg, blister, 2x15 pcs, Xepar® (prasugrel), film-coated tablet, 10mg, blister, 2x15 pcs, Yanida (valsartan), film-coated tablet, 80mg, 2x14 pcs, Yanida (valsartan), film-coated tablet, 160mg, 2x14 pcs, Yanida® (valsartan), film-coated tablet, 80mg, blister, 3x10 pcs, Yanida® (valsartan), film-coated tablet, 160mg, blister, 3x10 pcs, Yanida® plus (valsartan, hydrochlorothiazide), film-coated tablet, 80mg+12.5mg, 28 pcs, Yanida® plus (valsartan, hydrochlorothiazide), film-coated tablet, 160mg+12.5mg, 28 pcs, Yanida® plus (valsartan, hydrochlorothiazide), film-coated tablet, 160mg+25mg, 28 pcs, Yanida® plus (valsartan, hydrochlorothiazide), 80mg+12.5mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus (valsartan, hydrochlorothiazide), 160mg+12.5mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus (valsartan, hydrochlorothiazide), 160mg+25mg, film-coated tablet, blister, 3x10 pcs, Yanida® trio (amlodipine, valsartan, hydrochlorothiazide), film-coated tablet, 5mg+160mg+12.5mg, 30 pcs, Yanida® trio (amlodipine, valsartan, hydrochlorothiazide), film-coated tablet, 5mg+160mg+25mg, 30 pcs, Yanida® trio (amlodipine, valsartan, hydrochlorothiazide), film-coated tablet, 10mg+160mg+12.5mg, 30 pcs, Yanida® combo (amlodipine, valsartan), film-coated tablet, 5mg+80mg, blister, 2x15 pcs, Yanida® combo (amlodipine, valsartan), film-coated tablet, 5mg+160mg, blister, 2x15 pcs, Yanida® combo (amlodipine, valsartan), film-coated tablet, 10mg+160mg, blister, 2x15 pcs, Yurinex® (bumetanide), tablet, 1mg, blister, 2x10 pcs, Zenix® (linezolid), film-coated tablet, blister, 10x600mg, Zobox (cilazapril), 2.5mg, film-coated tablet, blister, 3x10 pcs, Zolmitriptan (zolmitriptan), orodispersible tablet, 2.5mg, blister, 1x3 pcs; Medicines containing psychoactive substances: Demetrim® (prazepam), tablet, 10mg, blister, 2x10 pcs, Diazepam HF (diazepam), tablet, 10mg, blister, 3x10 pcs, Diazepam HF (diazepam), tablet, 2mg, blister, 3x10 pcs, Diazepam HF (diazepam), tablet, 5mg, blister, 3x10 pcs, Phenobarbiton (phenobarbital), tablet, 15mg, blister, 3x10 pcs and Phenobarbiton (phenobarbital), tablet, 100mg, blister, 3x10 pcs, and 3. Intermediates which are manufactured in 'HEMOFARM' A.D. Vršac, which do not contain an active component, but are rather used as such at other manufacturing sites as an intermediate which is included in the composition of the medicinal products from the product range of 'HEMOFARM' A.D. Vršac: Sugar granulate for production of the medicinal product: Amoksicilin HF, granules for oral suspension; 250mg/5ml; glass bottle, 1x100ml, Sugar granulate for production of the medicinal product: Cefaleksin HF, granules for oral suspension; 250mg/5ml; glass bottle, 1x100ml, Sugar granulate for production of the medicinal products: Cefaklor, granules for oral suspension; 250mg/5ml; bottle, 1x60ml and Cefaklor, granules for oral suspension; 125mg/5ml; bottle, 1x60ml.



*Certified translation from Serbian into English*

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-----end of translation-----  
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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.

