

[coat of arms]
Republic of Serbia
MINISTRY OF HEALTH
Number: 515-04-03786/2020-11
Date: 20 February 2024
Belgrade, 22-26 Nemanjina St.
Tel. 011/2600-749
VV/SI

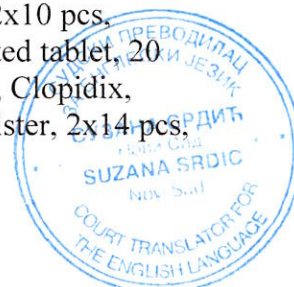
Acting upon a request of the pharmaceutical manufacturer 'HEMOFARM' a.d. Vršac, Beogradski put bb, for issuing a Good Manufacturing Practice Certificate, and pursuant to Article 212, paragraph 6 of the Law on Medicines and Medical Devices ('Official Gazette of RS' No. 30/10, 107/12, 105/17 – other law, 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 68 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, in the production plant of the Packaging Centre, with the aim of establishing compliance of pharmaceutical production as a Part of manufacturing procedure – primary and secondary packaging and a Part of manufacturing procedure – secondary packaging of medicinal products, quality control and batch release, specifically for: 1. Medicinal products which are manufactured in Hemofarm AD Vršac, with packaging site, quality control and batch release at Hemofarm Vršac: Aflothenol®, film-coated tablet, 250 mg, blister, 6x10 pcs, Aflothenol® film-coated tablet, 500 mg, blister, 6x10 pcs, Aflothenol®, film-coated tablet, 1000 mg, blister, 6x10 pcs, Caveda®, film-coated tablet, 2.5 mg, blister 30 pcs, Caveda®, film-coated tablet, 5 mg, blister, 30 pcs, Caveda®, film-coated tablet, 10 mg, blister, 4 pieces, Caveda®, film-coated tablet, 20 mg, blister, 2 pieces, Cholipam®, film-coated tablet, 10 mg, blister, 2x10 pcs, Cholipam®, film-coated tablet, 10 mg, blister, 3x10 pcs, Cholipam®, film-coated tablet, 20 mg, blister, 2x10 pcs, Cholipam®, film-coated tablet, 20 mg, blister, 3x 10 pcs, Clopidix, film-coated tablet, 75 mg, blister, 2x14, Cornelin, film-coated tablet, 10 mg, blister, 2x14 pcs.



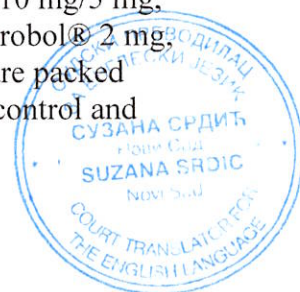
Cornelin, film-coated tablet, 20 mg, blister, 2x14 pcs, Cornelin, film-coated tablet, 10 mg, blister, 6x10 pcs, Cornelin, film-coated tablet, 20 mg, blister, 6x10 pcs, Cortiazem retard®, 90 mg, prolonged release tablet, blister, 3x10 pcs, Diklofenak Forte HF 100 mg, modified release tablet, blister, 2x10 pcs, Dilcoran 80 mg, prolonged release tablet, blister, 2x10 pcs, Elfonis®, film-coated tablet, 10x400 mg, Elfonis®, film-coated tablet 7x400 mg, Enzix®, tablet+film-coated tablet, 10mg+2.5mg, blister, 3x10 pcs, Enzix® duo, tablet+film-coated tablet, 10mg+2.5mg, blister, 3x15 pcs, Enzix® duo forte tablet+film-coated tablet, 20mg+2.5mg, blister, 3x15 pcs, Erynorm®, film-coated tablet, 50 mg, 3x10 pcs, Erynorm®, film-coated tablet, 100 mg, 3x10 pcs, Erynorm®, film-coated tablet, 50 mg, blister, 2x14 pcs, Erynorm®, film-coated tablet, 100 mg, blister, 2x14 pcs, Famotidin HF, film-coated tablet, 20 mg, blister, 3x10 pcs, Famotidin HF, film-coated tablet, 40 mg, blister, 3x10 pcs, Fiumin (sildenafil), film-coated tablet, 20 mg, blister, 90 film-coated tablets, Fluconal®, capsule hard, 50 mg, blister, 1x7 pcs, Fluconal®, capsule hard, 150 mg, blister, 1x1 pc, Flunisan®, tablet, 20 mg, blister, 3x10 pcs, Fomela, tablet, 500 mg, blister, 4x10 pcs, Fomela, tablet, 500 mg, blister, 2x10 pcs, Gluformin®, 1000 mg, film-coated tablet, 2x15 pcs, Gutana® (febuxostat), film-coated tablet, 80 mg, blister, 30 pcs, Gutana® (febuxostat), film-coated tablet, 120 mg, blister, 30 pcs, Hemopres®, tablet, 50mg+5mg, blister, 4x10 pcs, Hemokvin® (quinapril), film-coated tablet, 10 mg, blister, 2x10 pcs, Hemokvin® (quinapril), film-coated tablet, 20 mg, blister, 2x10 pcs, Hemokvin plus® (quinapril, hydrochlorotiazide), film-coated tablet, 20mg+12.5mg, blister, 2x10 pcs, Hypolip, film-coated tablet, 10 mg, blister, 3x10 pcs, Hypolip, film-coated tablet, 20 mg, blister, 3x10 pcs, Hypolip, film-coated tablet, 40 mg, blister, 3x10 pcs, Irbenida, film-coated tablet, 150 mg, blister, 3x10 pcs, Irbenida, film-coated tablet, 300 mg, blister, 3x10 pcs, Irbenida plus, film-coated tablet, 150 mg+12.5 mg, blister, 3x10 pcs, Irbenida plus, film-coated tablet, 300mg+12.5mg, blister, 3x10 pcs, Jaramera® (ezetimib), tablet, 10 mg, blister, 30 pcs, Midol®, gastro-resistant tablet, 30x100 mg, Midol®, gastro-resistant tablet, 75 mg, blister, 3x10 pcs, Milenol®, tablet, 12.5 mg, blister, 2x14 pcs, Milenol®, tablet, 25 mg, blister, 2x14 pcs, Milenol®, tablet, 12.5 mg, blister, 3x10 pcs, Milenol®, tablet, 25mg, blister, 3x10 pcs, Nystatin HF, coated tablet, 500 000 IU; blister, 1x10 pcs, Omnitus®, modified release film-coated tablet, 20 mg, blister, 1x10 pcs, Omnitus®, modified release film-coated tablet, 50 mg, blister, 1x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 5 mg, 3x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 10 mg, 3x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 20 mg, 3x10 pcs, Pressing®, tablet, 10 mg, blister, 1x10 pcs, Prilenap®, tablet, 5 mg, blister, 3x10 pcs, Prilenap®, tablet, 10 mg, blister, 2x10 pcs, Prilenap®, tablet, 10 mg, blister, 3x10 pcs, Prilenap®, tablet, 20 mg, blister, 2x10 pcs, Prilenap®, tablet, 20 mg, blister, 3x10 pcs, Prilenap H®, tablet, 10mg+25mg, blister, 3x10 pcs, Prilenap H®, tablet, 10mg+25mg, blister, 2x10 pcs, Prilenap® HL, tablet, 10mg+12.5mg, blister, 2x10 pcs, Prilenap® HL, tablet, 10mg+12.5mg, blister, 3x10 pcs, Prilinda® (Ramipril), tablet, 2.5 mg, blister, 4x7 pcs, Prilinda® (Ramipril), tablet, 5 mg, blister, 4x7 pcs, Prilinda® (Ramipril), tablet, 10 mg, blister, 4x7 pcs, Prilinda® plus, tablet, 2.5mg+12.5mg, 4x7 pcs, Prilinda® plus, tablet, 5mg+25mg, 4x7 pcs, Raptan Duo, modified release tablet, 75mg, blister, 1x10 pcs, Raptan Duo, modified release tablet, 75 mg, blister, 3x10 pcs, Rivaroxaban HF, 2.5 mg, film-coated tablet, 60 pcs, Rivaroxaban HF, 10 mg, film-coated tablet, 10 pcs, Rivaroxaban HF, 10 mg, film-coated tablet, 30 pcs, Rivaroxaban HF, 15 mg, film-coated tablet, 30 pcs, Rivaroxaban HF, 20mg, film-coated tablet, 30 pcs, Sidata®, film-coated tablet, 50 mg, blister, 2x14 pcs, Sidata®, film-coated tablet, 100 mg, blister, 2x14 pcs, Sildena, film-coated tablet, 25 mg, blister, 1x1 pcs, Sildena, film-coated tablet, 50 mg, blister, 1x1 pcs, Sildena®, film-coated tablet, 100 mg, blister, 1x1 pcs, Sildena®, film-coated tablet, 100 mg, 1x2 pcs, Sildena®, film-coated tablet, 100 mg, 2x2 pcs, Sildena®, film-coated tablet, 100 mg, 1x8 pcs, Ticagrex® (ticagrelor), film-coated tablet, 60 mg, blister, 4x15 pcs, Ticagrex® (ticagrelor)



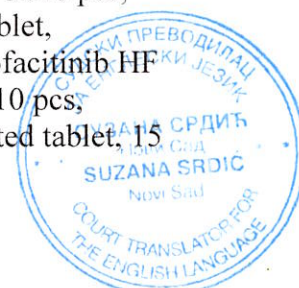
film-coated tablet, 90 mg, blister, 4x15 pcs, Treana®, film-coated tablet, 5 mg, blister, 3x10 pcs, Treana®, film-coated tablet, 10 mg, blister, 3x10 pcs, Trecar®, orodispersible tablet, 2.5 mg, blister, 3 pcs, Trecar®, orodispersible tablet, 5 mg, blister, 3 pcs, Trecar®, orodispersible tablet, 5 mg, blister, 6 pcs, Tregona®, film-coated tablet, 5 mg, blister, 2x14 pcs, Tregona®, film-coated tablet, 10 mg, blister, 2x14 pcs, Trefero® (aripiprazol), orodispersible tablet, 30x10 mg, Trefero® (aripiprazol), orodispersible tablet, 30x15 mg, Verapamil, film-coated tablet, 40 mg, blister, 3x10 pcs, Verapamil, film-coated tablet, 80 mg, blister, 5x10 pcs, Verapamil HF, film-coated tablet, 40 mg, blister, 3x10 pcs, Verapamil HF, film-coated tablet, 80 mg, blister, 5x10 pcs, Xepar® (Prasugrel), film-coated tablet, 5 mg, 2x15 pcs, Xepar® (Prasugrel), film-coated tablet, 10 mg, 2x15 pcs, Yanida, film-coated tablet, 28x80 mg, Yanida, film-coated tablet, 28x160 mg, Yanida® 80 mg, film-coated tablet, blister, 3x10 pcs, Yanida® 160 mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, film-coated tablet, 28x80 mg+12.5 mg, Yanida® plus, film-coated tablet, 28x160 mg+12.5mg, Yanida® plus, 80mg+12.5 mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, 160mg+12.5mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, 160mg+25mg, film-coated tablet, blister, 3x10 pcs, Yanida® trio, film-coated tablet, 5mg+160mg+12.5mg, 30 pcs, Yanida® trio, film-coated tablet, 5mg+160mg+25mg, 30 pcs, Yanida® trio, film-coated tablet, 10 mg+ 160mg+ 12.5 mg, 30 pcs, Yanida® combo, film-coated tablet, 5mg+80mg, blister, 2x15 pcs, Yanida® combo, film-coated tablet, 5mg+160mg, blister, 2x15 pcs, Yanida® combo, film-coated tablet, 10mg+160mg, blister, 2x15 pcs, Yurinx, tablet, 1 mg, blister, 2x10 pcs, Zenix®, film-coated tablet, 10x600 mg, Zolmitriptan, orodispersible tablet, 2.5 mg, blister, 1x3 pcs; Medicinal products which are manufactured at Hemofarm Banja Luka, with primary and secondary packaging site at the Packaging Centre, quality control, and batch release at Hemofarm Vršac: Aglikem 500 mg, film-coated tablet 30 pcs, Aglikem 500 mg, film-coated tablet 60 pcs, Aglikem 1000 mg, film-coated tablet 30 pcs, Barios®, tablet, 5mg, blister, 3x10 pcs, Belbien®, film-coated tablet, 10 mg, blister, 2x10 pcs, Criteo® (vildagliptin), 50 mg, tablet, 30 pcs, Criteo® (vildagliptin), 50 mg, tablet, 60 pcs, Criteo® duo, tablet, 50mg+ 850 mg, blister 60 pcs, Criteo® duo, tablet, 50mg+1000mg, blister 60 pcs, Diklofenak HF, gastro-resistant tablet, 50 mg, blister, 2x10 pcs, Gluformin®, gastro-resistant tablet, 500 mg, blister, 3x10 pcs, Hemomycin®, film-coated tablet, 500 mg, blister, 1x3 pcs, Ibumax®, film-coated tablet, 400 mg, blister, 1x10 pcs, Ibumax®, film-coated tablet, 400 mg, blister, 3x10 pcs, Ibumax® Rp, film-coated tablet, 400mg, blister, 3x10 pcs, Ibuprofen HF, film-coated tablet, 400 mg, blister, 3x10 pcs, Indivil 50 mg, tablet, 60 pcs, Indivil 50 mg, tablet, 30 pcs, Indivil Met, film-coated tablet, 50mg+850mg, blister, 60 pcs, Indivil Met, film-coated tablet, 50mg+ 1000 mg, blister, 60 pcs, Indapamid, 1.5mg, film-coated tablet, 3x10 pcs, Karbapin®, tablet, 200 mg, blister, 5x10 pcs, Methyldopa, film-coated tablet, 250 mg, blister, 2x10 pcs, Panlax®, gastro-resistant coated tablet, 5 mg, blister, 3x10 pcs, Panthenol, compressed lozenge, 120 mg, blister, 2x10 pcs, Paroxifen, 70 mg, blister, 1x4 pcs, Presolol®, film-coated tablet, 100 mg, blister 3x10 pcs, Presolol®, film-coated tablet, 50 mg, blister, 2x14 pcs, Presolol®, film-coated tablet, 50 mg, blister, 4x14 pcs, Rapten-K®, coated tablet, 50 mg, blister, 1x10 pcs, Risperidon, film-coated tablet, 1 mg, blister, 2x10 pcs, Risperidon, film-coated tablet, 2 mg, blister, 2x10 pcs, Risperidon, film-coated tablet; 3 mg; blister; 2x10 pcs, Risperidon, film-coated tablet, 4 mg, blister, 2x10 pcs, Risperidon, film-coated tablet, 1 mg, blister, 4x10 pcs, Risperidon, film-coated tablet, 2 mg, blister, 4x10 pcs, Vazotal® tablet, 5mg, blister, 3x10 pcs, Vazotal®, tablet, 10 mg, blister, 3x10 pcs, Verapamil, film-coated tablet, 40 mg, blister, 3x10 pcs, Verapamil, film-coated tablet, 80 mg, blister; 5x10 pcs, Verapamil HF, film-coated tablet, 40 mg, blister, 3x10 pcs, Verapamil HF, film-coated tablet, 80 mg, blister, 5x10 pcs, Erynorm plus, film-coated tablet, 50 mg+12.5mg, blister, 2x14 pcs, Erynorm plus, film-coated tablet, 50mg+12.5mg, 3x10 pcs; Medicines manufactured at Hemofarm Šabac, while primary and secondary packaging is performed at the Packaging



Centre, and quality control and batch release at Hemofarm Vršac: Alopurinol HF, tablet, 100 mg, blister, 2x20 pcs. Diprian, modified release tablet, 80 mg, blister 2x15 pcs, Doksiciklin HF, capsule, hard, 100 mg, blister, 1x5 pcs, Doxi-Hem®, capsule, hard, 500 mg, blister, 3x10 pcs, Eritromicin HF, film-coated tablet, 250 mg, blister, 2x10 pcs, Eritromicin HF, film-coated tablet, 500 mg, blister, 2x10 pcs, Haloperidol HF, tablet, 10 mg, blister, 2x15 pcs, Haloperidol HF, tablet, 2 mg, 25 tbl, Hemomycin, capsule hard, 250 mg, blister, 1x6 pcs, Ibumax® Cold, 200mg+5mg, film-coated tablet, blister, 1x10 pcs, Ibumax® Cold Forte, film-coated tablet, 400mg+10mg, blister, 1x10 pcs, Indapres®, film-coated tablet 2.5 mg, blister, 2x15 pcs, Indapres SR, modified release tablet, 1.5 mg, blister, 3x10 pcs, Klindamicin, capsule, hard, 150 mg, blister, 2x8 pcs, Marocen®, film-coated tablet, 250 mg, blister, 1x10 pcs, Marocen®, film-coated tablet, 500 mg, blister, 1x10 pcs, Monizol®, tablet, 20 mg, blister, 2x15 pcs, Monizol®, tablet, 40 mg, blister, 3x10 pcs, Mucodyne, capsule, hard, 375 mg, blister, 3x10 pcs, Naproksen HF, film-coated tablet, 375 mg, blister, 2x10 pcs, Pepticaid®, gastro-resistant tablet, 20 mg, blister, 1x14 pcs, Pepticaid®, gastro-resistant tablet, 40 mg, blister, 1x14 pcs, Pepticaid (pantoprazol), gastro-resistant tablet, 20 mg, blister, 1x14 pcs, Pepticaid (pantoprazol), gastro-resistant tablet, 40 mg, blister, 1x14 pcs, Pepticaid® control, gastro-resistant tablet, 20 mg, blister, 1x7 pcs, Pepticaid® 20 mg, gastro-resistant tablets, 28 gastro-resistant tablets, Pepticaid® 40 mg, gastro-resistant tablets, 28 gastro-resistant tablets, Propafen, film-coated tablet, 150 mg, blister, 5x10 pcs, Propafen, film-coated tablet, 300 mg, blister, 5x10 pcs, Rinasek® tablet, 60mg+2.5 mg, blister, 1x10 pcs, Taita®, gastro-resistant capsule, hard, 30 mg, 2x14 pcs, Taita®, gastro-resistant capsule, hard, 60 mg, 2x14 pcs, Yanida® 80 mg, film-coated tablet, blister, 3x10 pcs, Yanida® 160 mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, 80 mg+12.5 mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, 160 mg+12.5 mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, 160 mg+25 mg, film-coated tablet, blister, 3x10 pcs, Yanida® trio, film-coated tablet, 5 mg+160 mg+12.5 mg, 30 pcs, Yanida® trio, film-coated tablet, 5mg+160mg+25mg, 30 pcs, Yanida® trio, film-coated tablet, 10mg+160mg+12.5mg, Zodol®, film-coated tablet, 10 mg, blister, 1x10 pcs, Zorkaptil®, tablet, 25 mg, blister, 2x20 pcs, Zymbaktar®, film-coated tablet, 500 mg, blister, 2x7 pcs; **2.** Medicinal products which are packed into primary and secondary packaging material at the Packaging Centre, quality control and batch release (psychoactive substances) at Hemofarm Vršac, with an indicated place of manufacturing: Demetrin®, tablet, 10 mg, blister, 2x10 pcs - production Vršac, Diazepam HF, tablet, 10 mg, blister, 3x10 pcs - production Vršac, Diazepam HF, tablet, 2 mg, blister, 3x10 pcs - production Vršac, Diazepam HF, tablet, 5 mg, blister, 3x10 pcs - production Vršac, Phenobarbiton, tablet, 15 mg, blister, 3x10 pcs - production Vršac, Phenobarbiton, tablet, 100 mg, blister, 3x10 pcs - production Vršac, Bromazepam HF, tablet, 1.5 mg, blister, 2x15 pcs, production Šabac, Bromazepam HF, tablet, 3 mg, blister, 2x15 pcs - production Šabac, Bromazepam HF, tablet, 6 mg, blister, 1x20 pcs - production Šabac, Lorazepam HF, tablet, 1 mg, blister, 2x15 pcs - production Šabac, Lorazepam HF, tablet, 2.5 mg, blister, 2x10 pcs - production Šabac, Trodon, prolonged release tablet, 100 mg, blister, 1x10 pcs - production Šabac, Trodon, capsule, hard, 50 mg, blister, 2x10 pcs - production Šabac; **3.** Medicines which are packed into secondary packaging material at the Packaging Centre, quality control and batch release (psychoactive substances) at Hemofarm Vršac, - bulk is procured from a third party: Abiola (buprenorphine +naloxone), sublingual tablet, 2mg+0.5mg, 7 pcs, Abiola (buprenorphine +naloxone), sublingual tablet, 8mg+2mg, 7 pcs, Abiola (buprenorphine +naloxone), sublingual tablet, 16mg+4mg, 7 pcs, Oxydon® (Oxycodone/Naloxone), prolonged action tablet, 30x5mg/2.5mg, Oxydon® (Oxycodone/Naloxone), prolonged action tablets, 60x10 mg/5 mg, Oxydon® (Oxycodone/Naloxone), prolonged action tablet, 60x20mg/10mg, Buprobol® 2 mg, 7 sublingual tablets, Buprobol® 8 mg, 7 sublingual tablets; **4.** Medicines which are packed into primary and secondary packaging material at the Packaging Centre, quality control and



batch release at Hemofarm Vršac, - bulk is procured from a third party: Prilinda® duo, (ramipril/amlodipine), 5mg/5mg, capsule, hard, blister, 30 pcs, Prilinda® duo, (ramipril/amlodipine), 10mg/5mg, capsule, hard, blister, 30 pcs, Prilinda® duo, (ramipril/amlodipine), 5mg/ 10mg, capsule, hard, blister, 30 pcs, Prilinda® duo, (ramipril/amlodipine), 10mg/ 10mg, capsule, hard, blister, 30 pcs, Tadalafil RA Chem Pharma (tadalafil) 5 mg, film-coated tablet, 30x5mg, Tadalafil RA Chem Pharma (tadalafil) 10 mg, film-coated tablet, 4x10mg, Tadalafil RA Chem Pharma (tadalafil) 20 mg, film-coated tablet, 2x20mg, Vitopril 10 mg, 30 tablets, Gastroperidon, tablet, 10 mg, blister 3x10 pcs; **5.** Medicines which are packed into secondary packaging material at the Packaging Centre, quality control and batch release at Hemofarm Vršac, - bulk is procured from a third party: Alergofen® (Bilastine) 20 mg tablets, 10 pcs, Barios® Plus 5/12.5 mg 30 film-coated tbl. Barios® Plus 5/25 mg 30 film-coated tbl. Betamsal, modified release capsule, hard, 0.4 mg, blister, 3x10 pcs, Cefapan® (cefexime) 400 mg, 10 film-coated tbl. Cor Tensec® 1.25 mg 30 fct, Cor Tensec® 2.5 mg, 30 fct, Forteca, film-coated tablet; 250mg; blister; 2x5 pcs, Forteca, film-coated tablet; 500 mg; blister; 2x5 pcs, Datus duo, 0.5/0.4 mg, capsule, hard 30 pcs, Erynorm plus, film-coated tablet, 50 mg+ 12.5mg, blister, 3x10 pcs, Mateca (Colistin) 2000000 I.U. lyo inj. 10 vials, Daranda®, film-coated tablets 5 mg, blister, 30 pcs, Daranda®, film-coated tablets, 10 mg, blister, 30 pcs, Diklofenak HF 50 mg, 20 film-coated tablets, Dolista® (sitagliptin) 25 mg, film-coated tablet, blister, 30 pcs, Dolista® (sitagliptin) 50 mg, film-coated tablet, blister, 30 pcs, Dolista® (sitagliptin) 100 mg, film-coated tablet, blister, 30 pcs, Dolista® duo (sitagliptin, metformin) 50 mg+850 mg, film-coated tablet, blister, 60 pcs, Dolista® duo (sitagliptin, metformin) 50 mg+1000 mg, film-coated tablet, blister, 60 pcs, Gluformin XR® (Metformin) 500 mg, 30 prolonged release tablets, Gluformin XR® (Metformin) 750 mg, 30 prolonged release tablets, Gluformin XR® (Metformin) 1000 mg, 30 prolonged release tablets, Aglikem XR (Metformin), 500 mg, 30 prolonged release tablets, Aglikem XR (Metformin), 750g, 30 prolonged release tablets, Aglikem XR (Metformin) 1000 mg, 30 prolonged release tablets, Ibumax® rapid, capsule soft, 400 mg, 10 pcs, Infaxa®, film-coated tablet, 2.5 mg, blister, 60 pcs, Levetiracetam HF, 250 mg, film-coated tablet, 60 pcs, Levetiracetam HF, 500 mg, film-coated tablet, 60 pcs, Locamin/Metamizol 500 mg 10 tabl, LOTREKA® (Dabigatran) 75 mg, capsule, hard, 60 pcs, LOTREKA® (Dabigatran) 110 mg, capsule hard, 60 pcs, LOTREKA® (Dabigatran) 150 mg, capsule, hard, 60 pcs, Hoggar Night (doxylamine hydrogen succinate), orodispersible tablet, 25 mg, 10 pcs, Hoggar Night (doxylamine hydrogen succinate), orodispersible tablet, 25 mg, 20 pcs, Mentela®, film-coated tablet, 25 mg, blister, 28 pcs, Maysorb® 200 mg 112 film-coated tablet, Nersan®, 12.5 mg, 28 hard capsules, Nersan®, 25mg, 28 hard capsules, Nersan®, 37.5 mg, 28 hard capsules, Nersan®, 50 mg, 28 hard capsules, Pazopanib HF (Pazopanib) 200 mg, film-coated tablets, 30 pcs, Prilinda duo, (ramipril/amlodipine), 10mg/10mg, capsule, hard, blister, 30 pcs, Pirfenidon HF 267 mg 90 film-coated tablets, Paravano duo 10mg+10mg, film-coated tablets, 30 pcs, Paravano duo 10mg+20mg, film-coated tablets, 30 pcs, Paravano duo 10mg+40mg, film-coated tablets, 30 pcs, Prilinda® Duo 10+5 mg 30 caps, Prilinda® Duo 5 + 5 mg 30 caps, Robenan® BR, film-coated tablet, 5 mg, 1x10 pcs, Robenan® BR, film-coated tablet, 5 mg, 2x10 pcs, Robenan® BR, film-coated tablet, 5 mg, 3x10 pcs, Saurus® Combo (Solifenacin + tamsulosin) 6mg/0.4mg, 30 modified release tablets, Startina® 5mg+100 mg, capsule hard, 30 pcs, Startina® 10mg+100mg, capsule hard, 30 pcs, Startina® 20mg+100mg, capsule hard, 30 pcs, Saurus®, film-coated tablet, 5 mg, blister, 3x10 pcs, Saurus®, film-coated tablet, 10 mg, blister, 3x10 pcs, Tensec, film-coated tablet, 5 mg, blister, 3x10 pcs, Tensec, film-coated tablet, 10 mg, blister, 3x10 pcs, Tensec plus, film-coated tablet, 5mg+12.5mg, blister, 3x10 pcs, Tofacitinib HF 5 mg, 56 film-coated tablets, Tofacitinib HF 10 mg, 56 film-coated tablets, Trombocen®, film-coated tablet, 10 mg, blister, 10 pcs, Trombocen®, film-coated tablet, 10 mg, blister, 30 pcs, Trombocen®, film-coated tablet, 15



mg, blister, 30 pcs, Trombocen®, film-coated tablet, 20 mg, blister, 30 pcs, Trombocen®, film-coated tablet, 2.5 mg, blister, 60 pcs, Vazotal® Duo, tablet, blister, 4mg+5mg, 30 pcs, Vazotal® Duo, tablet, blister 4mg+10 mg, 30 pcs, Vazotal® Duo, tablet, blister, 8mg+5mg, 30 pcs, Vazotal® Duo, tablet, blister, 8mg+10mg, 30 pcs, Levetiracetam HF 100mg/ml or.sol. 150 ml/syringe 1ml, Levetiracetam HF 100mg/ml or.sol. 150ml/syringe 3 ml, Xofluza® (baloxavir marboxil), 20 mg film-coated tablet, 2 fct, Xofluza® (baloxavir marboxil), 40 mg film-coated tablets, 2 fct, Xofluza® (baloxavir marboxil), 40 mg film-coated tablets, 1 fct, Xofluza® (baloxavir marboxil), 80 mg film-coated tablets, 1 fct, Lapatinib STADA 250 mg, 70 film-coated tablets in a blister, YANIDA®S (Sacubitril/valsartan) 24/26 mg, 30 film-coated tablet, YANIDA®S (Sacubitril/valsartan) 49/51 mg, 60 film-coated tablets, YANIDA®S (Sacubitril/valsartan) 97/103 mg, 60 film-coated tablets, Lata, film-coated tablet, 10 mg, blister, 2x14 pcs; 6. Medicinal products which are packed into secondary packaging material at the Packaging Centre (quality control and batch release with the manufacturer of semi-finished product – third party): Allegra 120 mg, 10 film-coated tablets, Bisolvon 8 mg, 20 tablets, Buscopan 10 mg, 20 coated tablets, Dulcolax 5 mg, 20 gastro-resistant tablets, Telfast, 180 mg, 20 coated film tablets, Maalox maux destomac (400 mg + 400 mg), 40 chewing tablets, Magne B6 (470 mg + 5 mg), coated tablet 50 pcs; 7. Medicinal products which are packed in primary packaging material pursuant to the contract manufacturing agreement at the Packaging Centre: Acenokumarol UNION, tablet, 4 mg, blister, 1x10 pcs, Aminofilin retard, prolonged release tablet, 350 mg, blister, 1x10 pcs, Analgin UNION, tablet, 500 mg, blister, 1x10 pcs, Molikor, tablet, 2 mg, blister, 1x10 pcs.

In the period from 12/12 until 15/12/2023, the inspectors for medicines and medical devices conducted a direct 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 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 515-04-03786/2020-11 of 26/01/2024 was made. There were no objections to the factual status stated in the Protocol on the part of the manufacturer.

The subject of establishing compliance of pharmaceutical manufacturing with the Good Manufacturing Practice Guidelines referred to pharmaceutical production as Part of manufacturing procedure – primary and secondary packaging, and Part of the manufacturing procedure – secondary packaging of medicinal products, quality control and batch release, quality control and batch release for medicines 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 was concluded that the production of the above indicate medicines complies with the Good Manufacturing Practice Guidelines, about which a final report with a conclusion on compliance, number 515-04-03786-1/2020-11 of 14 February 2024, was prepared, and delivered to the manufacturer.

Based on the final report number 515-04-03786-1/2020-11 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 OF HEALTH

[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:	68
Date:	20 February 2024

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 - 15/12/2023
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.



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 515-04-03786-1/2020-11 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 205 of the Law on Medicines and Medical Devices ('Official Gazette of RS', number 30/10 and 107/12), and the final report numberof on the compliance of pharmaceutical manufacturing with the Good Manufacturing Practice Guidelines ('Official Gazette of RS', number 97/170),

☐ 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 OF HEALTH

[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

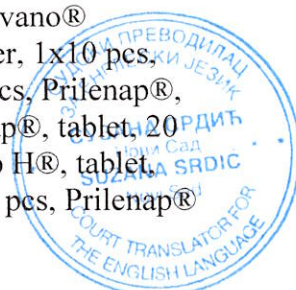
Approved pharmaceutical manufacturing processes, i.e. procedures	
☐ 1. Sterile production	☐ 1.1 Aseptic preparation ☐ 1.2 Final sterilization ☐ 1.3 Medicine batch release only
☒ 2. Production of non-sterile pharmaceutical products	☒ 2.1 Solid pharmaceutical forms ☐ 2.2 Semi-solid pharmaceutical forms ☐ 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 (<i>bulk products</i>)	☐ 6.1 Own manufacture ☐ 6.2 Market of the Republic of Serbia ☒ 6.3 Import



Annex 3

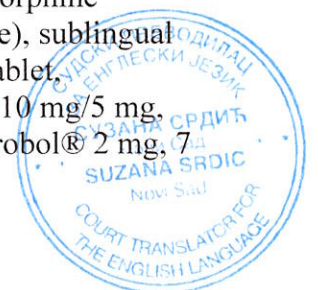
Notes, i.e. additional explanations concerning the contents of the certificate:

This certificate on compliance of pharmaceutical manufacture with the Good Manufacturing Practice Guidelines refers to: Part of the manufacturing procedure – primary and secondary packaging and Part of the manufacturing procedure – secondary packaging of medicinal products, quality control and batch release, specifically for: 1. Medicinal products which are manufactured in Hemofarm AD Vršac, with packaging site, quality control and batch release at Hemofarm Vršac: Aflothenol®, film-coated tablet, 250 mg, blister, 6x10 pcs, Aflothenol® film-coated tablet, 500 mg, blister, 6x10 pcs, Aflothenol®, film-coated tablet, 1000 mg, blister, 6x10 pcs, Caveda®, film-coated tablet, 2.5 mg, blister 30 pcs, Caveda®, film-coated tablet, 5 mg, blister, 30 pcs, Caveda®, film-coated tablet, 10 mg, blister, 4 pieces, Caveda®, film-coated tablet, 20 mg, blister, 2 pieces, Cholipam®, film-coated tablet, 10 mg, blister, 2x10 pcs, Cholipam®, film-coated tablet, 10 mg, blister, 3x10 pcs, Cholipam®, film-coated tablet, 20 mg, blister, 2x10 pcs, Cholipam®, film-coated tablet, 20 mg, blister, 3x 10 pcs, Clopidix, film-coated tablet, 75 mg, blister, 2x14, Cornelin, film-coated tablet, 10 mg, blister, 2x14 pcs, Cornelin, film-coated tablet, 20 mg, blister, 2x14 pcs, Cornelin, film-coated tablet, 10 mg, blister, 6x10 pcs, Cornelin, film-coated tablet, 20 mg, blister, 6x10 pcs, Cortiazem retard®, 90 mg, prolonged release tablet, blister, 3x10 pcs, Diklofenak Forte HF 100 mg, modified release tablet, blister, 2x10 pcs, Dilcoran 80 mg, prolonged release tablet, blister, 2x10 pcs, Elfonis®, film-coated tablet, 10x400 mg, Elfonis®, film-coated tablet 7x400 mg, Enzix®, tablet+film-coated tablet, 10mg+2.5mg, blister, 3x10 pcs, Enzix® duo, tablet+film-coated tablet, 10mg+2.5mg, blister, 3x15 pcs, Enzix® duo forte tablet+film-coated tablet, 20mg+2.5mg, blister, 3x15 pcs, Erynorm®, film-coated tablet, 50 mg, 3x10 pcs, Erynorm®, film-coated tablet, 100 mg, 3x10 pcs, Erynorm®, film-coated tablet, 50 mg, blister, 2x14 pcs, Erynorm®, film-coated tablet, 100 mg, blister, 2x14 pcs, Famotidin HF, film-coated tablet, 20 mg, blister, 3x10 pcs, Famotidin HF, film-coated tablet, 40 mg, blister, 3x10 pcs, Fiumin (sildenafil), film-coated tablet, 20 mg, blister, 90 film-coated tablets, Fluconal®, capsule hard, 50 mg, blister, 1x7 pcs, Fluconal®, capsule hard, 150 mg, blister, 1x1 pc, Flunisan®, tablet, 20 mg, blister, 3x10 pcs, Fomela, tablet, 500 mg, blister, 4x10 pcs, Fomela, tablet, 500 mg, blister, 2x10 pcs, Gluformin®, 1000 mg, film-coated tablet, 2x15 pcs, Gutana® (febuxostat), film-coated tablet, 80 mg, blister, 30 pcs, Gutana® (febuxostat), film-coated tablet, 120 mg, blister, 30 pcs, Hemopres®, tablet, 50mg+ 5mg, blister, 4x10 pcs, Hemokvin® (quinapril), film-coated tablet, 10 mg, blister, 2x10 pcs, Hemokvin® (quinapril), film-coated tablet, 20 mg, blister, 2x10 pcs, Hemokvin plus® (quinapril, hydrochlorotiazide), film-coated tablet, 20mg+12.5mg, blister, 2x10 pcs, Hypolip, film-coated tablet, 10 mg, blister, 3x10 pcs, Hypolip, film-coated tablet, 20 mg, blister, 3x10 pcs, Hypolip, film-coated tablet, 40 mg, blister, 3x10 pcs, Irbenida, film-coated tablet, 150 mg, blister, 3x10 pcs, Irbenida, film-coated tablet, 300 mg, blister, 3x10 pcs, Irbenida plus, film-coated tablet, 150 mg+12.5 mg, blister, 3x10 pcs, Irbenida plus, film-coated tablet, 300mg+ 12.5mg, blister, 3x10 pcs, Jaramera® (ezetimib), tablet, 10 mg, blister, 30 pcs, Midol®, gastro-resistant tablet, 30x100 mg, Midol®, gastro-resistant tablet, 75 mg, blister, 3x10 pcs, Milenol®, tablet, 12.5 mg, blister, 2x14 pcs, Milenol®, tablet, 25 mg, blister, 2x14 pcs, Milenol®, tablet, 12.5 mg, blister, 3x10 pcs, Milenol®, tablet, 25mg, blister, 3x10 pcs, Nystatin HF, coated tablet, 500 000 IU; blister, 1x10 pcs, Omnitus®, modified release film-coated tablet, 20 mg, blister, 1x10 pcs, Omnitus®, modified release film-coated tablet, 50 mg, blister, 1x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 5 mg, 3x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 10 mg, 3x10 pcs, Paravano® (rosuvastatin), film-coated tablet, 20 mg, 3x10 pcs, Pressing®, tablet, 10 mg, blister, 1x10 pcs, Prilenap®, tablet, 5 mg, blister, 3x10 pcs, Prilenap®, tablet, 10 mg, blister, 2x10 pcs, Prilenap®, tablet, 10 mg, blister, 3x10 pcs, Prilenap®, tablet, 20 mg, blister, 2x10 pcs, Prilenap®, tablet, 20 mg, blister, 3x10 pcs, Prilenap H®, tablet, 10mg+25mg, blister, 3x10 pcs, Prilenap H®, tablet, 10mg+25mg, blister, 2x10 pcs, Prilenap® HL, tablet, 10mg+12.5mg, blister, 2x10 pcs, Prilenap®

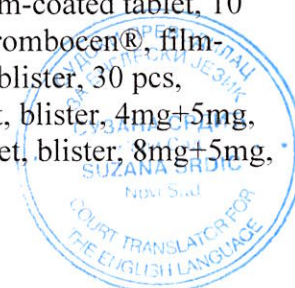


HL, tablet, 10mg+12.5mg, blister, 3x10 pcs, Prilinda® (Ramipril), tablet, 2.5 mg, blister, 4x7 pcs, Prilinda® (Ramipril), tablet, 5 mg, blister, 4x7 pcs, Prilinda® (Ramipril), tablet, 10 mg, blister, 4x7 pcs, Prilinda® plus, tablet, 2.5mg+ 12.5mg, 4x7 pcs, Prilinda® plus, tablet, 5mg+25mg, 4x7 pcs, Raptan Duo, modified release tablet, 75mg, blister, 1x10 pcs, Raptan Duo, modified release tablet, 75 mg, blister, 3x10 pcs, Rivaroxaban HF, 2.5 mg, film-coated tablet, 60 pcs, Rivaroxaban HF, 10 mg, film-coated tablet, 10 pcs, Rivaroxaban HF, 10 mg, film-coated tablet, 30 pcs, Rivaroxaban HF, 15 mg, film-coated tablet, 30 pcs, Rivaroxaban HF, 20mg, film-coated tablet, 30 pcs, Sidata®, film-coated tablet, 50 mg, blister, 2x14 pcs, Sidata®, film-coated tablet, 100 mg, blister, 2x14 pcs, Sildenafil, film-coated tablet, 25 mg, blister, 1x1 pcs, Sildenafil, film-coated tablet, 50 mg, blister, 1x1 pcs, Sildenafil®, film-coated tablet, 100 mg, blister, 1x1 pcs, Sildenafil®, film-coated tablet, 100 mg, 1x2 pcs, Sildenafil®, film-coated tablet, 100 mg, 2x2 pcs, Sildenafil®, film-coated tablet, 100 mg, 1x8 pcs, Ticagrex® (ticagrelor), film-coated tablet, 60 mg, blister, 4x15 pcs, Ticagrex® (ticagrelor), film-coated tablet, 90 mg, blister, 4x15 pcs, Treana®, film-coated tablet, 5 mg, blister, 3x10 pcs, Treana®, film-coated tablet, 10 mg, blister, 3x10 pcs, Trecar®, orodispersible tablet, 2.5 mg, blister, 3 pcs, Trecar®, orodispersible tablet, 5 mg, blister, 3 pcs, Trecar®, orodispersible tablet, 5 mg, blister, 6 pcs, Tregona®, fct, 5 mg, blister, 2x14 pcs, Tregona®, fct, 10 mg, blister, 2x14 pcs, Trefero® (aripiprazol), orodispersible tablet, 30x10 mg, Trefero® (aripiprazol), oro-dispersible tablet, 30x15 mg, Verapamil, film-coated tablet, 40 mg, blister, 3x10 pcs, Verapamil, film-coated tablet, 80 mg, blister, 5x10 pcs, Verapamil HF, film-coated tablet, 40 mg, blister, 3x10 pcs, Verapamil HF, film-coated tablet, 80 mg, blister, 5x10 pcs, Xepar® (Prasugrel), film-coated tablet, 5 mg, 2x15 pcs, Xepar® (Prasugrel), film-coated tablet, 10 mg, 2x15 pcs, Yanida, film-coated tablet, 28x80 mg, Yanida, film-coated tablet, 28x160 mg, Yanida® 80 mg, film-coated tablet, blister, 3x10 pcs, Yanida® 160 mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, film-coated tablet, 28x80 mg+12.5 mg, Yanida® plus, film-coated tablet, 28x160 mg + 12.5 mg, Yanida® plus, 80mg+12.5 mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, 160mg+12.5mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, 160mg+25mg, film-coated tablet, blister, 3x10 pcs, Yanida® trio, film-coated tablet, 5mg+160mg+12.5mg, 30 pcs, Yanida® trio, film-coated tablet, 5mg+160mg+25mg, 30 pcs, Yanida® trio, film-coated tablet, 10 mg+160mg+12.5mg, 30 pcs, Yanida® combo, film-coated tablet, 5mg+80mg, blister, 2x15 pcs, Yanida® combo, film-coated tablet, 5mg+160mg, blister, 2x15 pcs, Yanida® combo, film-coated tablet, 10mg+160mg, blister, 2x15 pcs, Yurinex, tablet, 1 mg, blister, 2x10 pcs, Zenix®, film-coated tablet, 10x600 mg, Zolmitriptan, orodispersible tablet, 2.5 mg, blister, 1x3 pcs; Medicinal products which are manufactured at Hemofarm Banja Luka, with primary and secondary packaging site at the Packaging Centre, quality control, and batch release at Hemofarm Vršac: Aglikem 500 mg, film-coated tablet 30 pcs, Aglikem 500 mg, film-coated tablet 60 pcs, Aglikem 1000 mg, film-coated tablet 30 pcs, Barios®, tablet, 5mg, blister, 3x10 pcs, Belbien®, film-coated tablet, 10 mg, blister, 2x10 pcs, Criteo® (vildagliptin), 50 mg, tablet, 30 pcs, Criteo® (vildagliptin), 50 mg, tablet, 60 pcs, Criteo® duo, tablet, 50mg+850mg, blister 60 pcs, Criteo® duo, tablet, 50mg+1000mg, blister 60 pcs, Diklofenak HF, gastro-resistant tablet, 50 mg, blister, 2x10 pcs, Gluformin®, gastro-resistant tablet, 500 mg, blister, 3x10 pcs, Hemomycin®, film-coated tablet, 500 mg, blister, 1x3 pcs, Ibumax®, film-coated tablet, 400 mg, blister, 1x10 pcs, Ibumax®, film-coated tablet, 400 mg, blister, 3x10 pcs, Ibumax® Rp, film-coated tablet, 400mg, blister, 3x10 pcs, Ibuprofen HF, film-coated tablet, 400 mg, blister, 3x10 pcs, Indivil 50 mg, tablet, 60 pcs, Indivil 50 mg, tablet, 30 pcs, Indivil Met, film-coated tablet, 50mg+850mg, blister, 60 pcs, Indivil Met, film-coated tablet, 50mg+1000 mg, blister, 60 pcs, Indapamid, 1.5mg, film-coated tablet, 3x10 pcs, Karbapin®, tablet, 200 mg, blister, 5x10 pcs, Methyldopa, film-coated tablet, 250 mg, blister, 2x10 pcs, Panlax®, gastro-resistant coated tablet, 5 mg, blister, 3x10 pcs, Panthenol, compressed lozenge, 120 mg, blister, 2x10 pcs, Paroxifen, 70 mg, blister, 1x4 pcs, Presolol®, film-coated tablet, 100 mg, blister, 3x10 pcs, Presolol®, film-coated tablet, 50 mg, blister, 2x14 pcs, Presolol®, film-coated tablet, 50 mg, blister, 4x14 pcs, Raptan-K®, coated tablet, 50 mg, blister, 1x10 pcs, Risperidon, film-coated tablet, 1 mg, blister, 2x10 pcs, Risperidon, fct, 2 mg, blister, 2x10 pcs, Risperidon, film-coated tablet; 3 mg; blister; 2x10 pcs, Risperidon, fct, 4 mg, blister, 2x10 pcs, Risperidon, film-coated

tablet, 1 mg, blister, 4x10 pcs, Risperidon, film-coated tablet, 2 mg, blister, 4x10 pcs, Vazotal® tablet, 5mg, blister, 3x10 pcs, Vazotal®, tablet, 10 mg, blister, 3x10 pcs, Verapamil, film-coated tablet, 40 mg, blister, 3x10 pcs, Verapamil, film-coated tablet, 80 mg, blister; 5x10 pcs, Verapamil HF, film-coated tablet, 40 mg, blister, 3x10 pcs, Verapamil HF, film-coated tablet, 80 mg, blister, 5x10 pcs, Erynorm plus, film-coated tablet, 50 mg+12.5mg, blister, 2x14 pcs, Erynorm plus, film-coated tablet, 50mg+12.5mg, 3x10 pcs; Medicines manufactured at Hemofarm Šabac, while primary and secondary packaging is performed at the Packaging Centre, and quality control and batch release at Hemofarm Vršac: Alopurinol HF, tablet, 100 mg, blister, 2x20 pcs. Diprian, modified release tablet, 80 mg, blister 2x15 pcs, Doksiciklin HF, capsule, hard, 100 mg, blister, 1x5 pcs, Doxi-Hem®, capsule, hard, 500 mg, blister, 3x10 pcs, Eritromicin HF, film-coated tablet, 250 mg, blister, 2x10 pcs, Eritromicin HF, film-coated tablet, 500 mg, blister, 2x10 pcs, Haloperidol HF, tablet, 10 mg, blister, 2x15 pcs, Haloperidol HF, tablet, 2 mg, 25 tbl, Hemomycin, capsule hard, 250 mg, blister, 1x6 pcs, Ibumax® Cold, 200mg+5mg, film-coated tablet, blister, 1x10 pcs, Ibumax® Cold Forte, film-coated tablet, 400mg+10mg, blister, 1x10 pcs, Indapres®, fct 2.5 mg, blister, 2x15 pcs, Indapres SR, modified release tablet, 1.5 mg, blister, 3x10 pcs, Klindamicin, capsule, hard, 150 mg, blister, 2x8 pcs, Marocen®, film-coated tablet, 250 mg, blister, 1x10 pcs, Marocen®, film-coated tablet, 500 mg, blister, 1x10 pcs, Monizol®, tablet, 20 mg, blister, 2x15 pcs, Monizol®, tablet, 40 mg, blister, 3x10 pcs, Mucodyne, capsule, hard, 375 mg, blister, 3x10 pcs, Naproksen HF, film-coated tablet, 375 mg, blister, 2x10 pcs, Pepticaid®, gastro-resistant tablet, 20 mg, blister, 1x14 pcs, Pepticaid®, gastro-resistant tablet, 40 mg, blister, 1x14 pcs, Pepticaid (pantoprazol), gastro-resistant tablet, 20 mg, blister, 1x14 pcs, Pepticaid (pantoprazol), gastro-resistant tablet, 40 mg, blister, 1x14 pcs, Pepticaid® control, gastro-resistant tablet, 20 mg, blister, 1x7 pcs, Pepticaid® 20 mg, gastro-resistant tablets, 28 gastro-resistant tablets, Pepticaid® 40 mg, gastro-resistant tablets, 28 gastro-resistant tablets, Propafen, film-coated tablet, 150 mg, blister, 5x10 pcs, Propafen, film-coated tablet, 300 mg, blister, 5x10 pcs, Rinasek® tablet, 60mg+2.5 mg, blister, 1x10 pcs, Taita®, gastro-resistant capsule, hard, 30 mg, 2x14 pcs, Taita®, gastro-resistant capsule, hard, 60 mg, 2x14 pcs, Yanida® 80 mg, film-coated tablet, blister, 3x10 pcs, Yanida® 160 mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, 80 mg+12.5 mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, 160 mg+12.5 mg, film-coated tablet, blister, 3x10 pcs, Yanida® plus, 160 mg+25 mg, film-coated tablet, blister, 3x10 pcs, Yanida® trio, film-coated tablet, 5 mg+160 mg+12.5 mg, 30 pcs, Yanida® trio, film-coated tablet, 5mg+160mg+25mg, 30 pcs, Yanida® trio, film-coated tablet, 10mg+160mg+12.5mg, Zodol®, film-coated tablet, 10 mg, blister, 1x10 pcs, Zorkaptil®, tablet, 25 mg, blister, 2x20 pcs, Zymbaktar®, film-coated tablet, 500 mg, blister, 2x7 pcs; 2. Medicinal products which are packed into primary and secondary packaging material at the Packaging Centre, quality control and batch release (psychoactive substances) at Hemofarm Vršac, with an indicated place of manufacturing: Demetrin®, tablet, 10 mg, blister, 2x10 pcs — production Vršac, Diazepam HF, tablet, 10 mg, blister, 3x10 pcs — production Vršac, Diazepam HF, tablet, 2 mg, blister, 3x10 pcs— production Vršac, Diazepam HF, tablet, 5 mg, blister, 3x10 pcs — production Vršac, Phenobarbiton, tablet, 15 mg, blister, 3+10 pcs — production Vršac, Phenobarbiton, tablet, 100 mg, blister, 3x10 pcs — production Vršac, Bromazepam HF, tablet, 1.5 mg, blister, 2x15 pcs, production Šabac, Bromazepam HF, tablet, 3 mg, blister, 2x15 pcs — production Šabac, Bromazepam HF, tablet, 6 mg, blister, 1x20 pcs — production Šabac, Lorazepam HF, tablet, 1 mg, blister, 2x15 pcs — production Šabac, Lorazepam HF, tablet, 2.5 mg, blister, 2x10 pcs — production Šabac, Trodon, prolonged release tablet, 100 mg, blister, 1x10 pcs — production Šabac, Trodon, capsule, hard, 50 mg, blister, 2x10 pcs — production Šabac; 3. Medicines which are packed into secondary packaging material at the Packaging Centre, quality control and batch release (psychoactive substances) at Hemofarm Vršac, - bulk is procured from a third party: Abiola (buprenorphine +naloxone), sublingual tablet, 2mg+0.5mg, 7 pcs, Abiola (buprenorphine +naloxone), sublingual tablet, 8mg+2mg, 7 pcs, Abiola (buprenorphine +naloxone), sublingual tablet, 16mg+4mg, 7 pcs, Oxydon® (Oxycodone/ Naloxone), prolonged action tablet, 30x5mg/2.5mg, Oxydon® (Oxycodone/ Naloxone), prolonged action tablets, 60x10 mg/5 mg, Oxydon® (Oxycodone/Naloxone), prolonged action tablet, 60x20mg/10mg, Buprobol® 2 mg, 7



sublingual tablets, Buprobol® 8 mg, 7 sublingual tablets; 4. Medicines which are packed into primary and secondary packaging material at the Packaging Centre, quality control and batch release at Hemofarm Vršac, - bulk is procured from a third party: Prilinda® duo, (ramipril/amlodipine), 5mg/5mg, capsule, hard, blister, 30 pcs, Prilinda® duo, (ramipril/amlodipine), 10mg/5mg, capsule, hard, blister, 30 pcs, Prilinda® duo, (ramipril/amlodipine), 5mg/10mg, capsule, hard, blister, 30 pcs, Prilinda® duo, (ramipril/amlodipine), 10mg/10mg, capsule, hard, blister, 30 pcs, Tadalafil RA Chem Pharma (tadalafil) 5 mg, film-coated tablet, 30x5mg, Tadalafil RA Chem Pharma (tadalafil) 10 mg, film-coated tablet, 4x10mg, Tadalafil RA Chem Pharma (tadalafil) 20 mg, film-coated tablet, 2x20mg, Vitopril 10 mg, 30 tablets, Gastroperidon, tablet, 10 mg, blister 3x10 pcs; 5. Medicines which are packed into secondary packaging material at the Packaging Centre, quality control and batch release at Hemofarm Vršac, - bulk is procured from a third party: Alergofen® (Bilastine) 20 mg tablets, 10 pcs, Barios® Plus 5/12.5 mg 30 film-coated tbl. Barios® Plus 5/25 mg 30 film-coated tbl. Betamsal, modified release capsule, hard, 0.4 mg, blister, 3x10 pcs, Cefapan® (cefixime) 400 mg, 10 film-coated tbl. Cor Tensec® 1.25 mg 30 fct, Cor Tensec® 2.5 mg, 30 fct, Forteca, film-coated tablet; 250mg; blister; 2x5 pcs, Forteca, film-coated tablet; 500 mg; blister; 2x5 pcs, Datus duo, 0.5/0.4 mg, capsule, hard 30 pcs, Erynorm plus, film-coated tablet, 50 mg+ 12.5mg, blister, 3x10 pcs, Mateca (Colistin) 2000000 I.U. lyo inj. 10 vials, Daranda®, film-coated tablets 5 mg, blister, 30 pcs, Daranda®, film-coated tablets, 10 mg, blister, 30 pcs, Diklofenak HF 50 mg, 20 film-coated tablets, Dolista® (sitagliptin) 25 mg, film-coated tablet, blister, 30 pcs, Dolista® (sitagliptin) 50 mg, film-coated tablet, blister, 30 pcs, Dolista® (sitagliptin) 100 mg, film-coated tablet, blister, 30 pcs, Dolista® duo (sitagliptin, metformin) 50 mg+850 mg, film-coated tablet, blister, 60 pcs, Dolista® duo (sitagliptin, metformin) 50 mg+1000 mg, film-coated tablet, blister, 60 pcs, Gluformin XR® (Metformin) 500 mg, 30 prolonged release tablets, Gluformin XR® (Metformin) 750 mg, 30 prolonged release tablets, Gluformin XR® (Metformin) 1000 mg, 30 prolonged release tablets, Aglikem XR (Metformin), 500 mg, 30 prolonged release tablets, Aglikem XR (Metformin), 750g, 30 prolonged release tablets, Aglikem XR (Metformin) 1000 mg, 30 prolonged release tablets, Ibumax® rapid, capsule soft, 400 mg, 10 pcs, Infaxa®, film-coated tablet, 2.5 mg, blister, 60 pcs, Levetiracetam HF, 250 mg, film-coated tablet, 60 pcs, Levetiracetam HF, 500 mg, film-coated tablet, 60 pcs, Locamin/Metamizol 500 mg 10 tabl, LOTREKA® (Dabigatran) 75 mg, capsule, hard, 60 pcs, LOTREKA® (Dabigatran) 110 mg, capsule hard, 60 pcs, LOTREKA® (Dabigatran) 150 mg, capsule, hard, 60 pcs, Hoggar Night (doxylamine hydrogen succinate), orodispersible tablet, 25 mg, 10 pcs, Hoggar Night (doxylamine hydrogen succinate), orodispersible tablet, 25 mg, 20 pcs, Mentela®, film-coated tablet, 25 mg, blister, 28 pcs, Maysorb® 200 mg 112 film-coated tablet, Nersan®, 12.5 mg, 28 hard capsules, Nersan®, 25mg, 28 hard capsules, Nersan®, 37.5 mg, 28 hard capsules, Nersan®, 50 mg, 28 hard capsules, Pazopanib HF (Pazopanib) 200 mg, film-coated tablets, 30 pcs, Prilinda duo, (ramipril/ amlodipine), 10mg/10mg, capsule, hard, blister, 30 pcs, Pirfenidon HF 267 mg 90 film-coated tablets, Paravano duo 10mg+10mg, film-coated tablets, 30 pcs, Paravano duo 10mg+20mg, film-coated tablets, 30 pcs, Paravano duo 10mg+40mg, film-coated tablets, 30 pcs, Prilinda® Duo 10+5 mg 30 caps, Prilinda® Duo 5 + 5 mg 30 caps, Robenan® BR, film-coated tablet, 5 mg, 1x10 pcs, Robenan® BR, film-coated tablet, 5 mg, 2x10 pcs, Robenan® BR, film-coated tablet, 5 mg, 3x10 pcs, Saurus® Combo (Solifenacin + tamsulosin) 6mg/0.4mg, 30 modified release tablets, Startina® 5mg+100 mg, capsule hard, 30 pcs, Startina® 10mg+100mg, capsule hard, 30 pcs, Startina® 20mg+100mg, capsule hard, 30 pcs, Saurus®, film-coated tablet, 5 mg, blister, 3x10 pcs, Saurus®, film-coated tablet, 10 mg, blister, 3x10 pcs, Tensec, film-coated tablet, 5 mg, blister, 3x10 pcs, Tensec, film-coated tablet, 10 mg, blister, 3x10 pcs, Tensec plus, film-coated tablet, 5mg+12.5mg, blister, 3x10 pcs, Tofacitinib HF 5 mg, 56 film-coated tablets, Tofacitinib HF 10 mg, 56 film-coated tablets, Trombocen®, film-coated tablet, 10 mg, blister, 10 pcs, Trombocen®, film-coated tablet, 10 mg, blister, 30 pcs, Trombocen®, film-coated tablet, 15 mg, blister, 30 pcs, Trombocen®, film-coated tablet, 20 mg, blister, 30 pcs, Trombocen®, film-coated tablet, 2.5 mg, blister, 60 pcs, Vazotal® Duo, tablet, blister, 4mg+5mg, 30 pcs, Vazotal® Duo, tablet, blister 4mg+10 mg, 30 pcs, Vazotal® Duo, tablet, blister, 8mg+5mg,



30 pcs, Vazotal® Duo, tablet, blister, 8mg+10mg, 30 pcs, Levetiracetam HF 100mg/ml or. sol. 150 ml/syringe 1ml, Levetiracetam HF 100mg/ml or.sol. 150ml/syringe 3 ml, Xofluza® (baloxavir marboxil), 20 mg film-coated tablet, 2 fct, Xofluza® (baloxavir marboxil), 40 mg film-coated tablets, 2 fct, Xofluza® (baloxavir marboxil), 40 mg film-coated tablets, 1 fct, Xofluza® (baloxavir marboxil), 80 mg film-coated tablets, 1 fct, Lapatinib STADA 250 mg, 70 film-coated tablets in a blister, YANIDA®S (Sacubitril/valsartan) 24/26 mg, 30 film-coated tablet, YANIDA®S (Sacubitril/valsartan) 49/51 mg, 60 film-coated tablets, YANIDA®S (Sacubitril/ valsartan) 97/103 mg, 60 film-coated tablets, Lata, film-coated tablet, 10 mg, blister, 2x14 pcs; 6. Medicinal products which are packed into secondary packaging material at the Packaging Centre (quality control and batch release with the manufacturer of semi-finished product – third party): Allegra 120 mg, 10 film-coated tablets, Bisolvon 8 mg, 20 tablets, Buscopan 10 mg, 20 coated tablets, Dulcolax 5 mg, 20 gastro-resistant tablets, Telfast, 180 mg, 20 coated film tablets, Maalox maux destomac (400 mg + 400 mg), 40 chewing tablets, Magne B6 (470 mg + 5 mg), coated tablet 50 pcs; 7. Medicinal products which are packed in primary packaging material pursuant to the contract manufacturing agreement at the Packaging Centre: Acenokumarol UNION, tablet, 4 mg, blister, 1x10 pcs, Aminofilin retard, prolonged release tablet, 350 mg, blister, 1x10 pcs, Analgin UNION, tablet, 500 mg, blister, 1x10 pcs, Mollicor, tablet, 2 mg, blister, 1x10 pcs.

----- 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.

SUZANA SRDIĆ, Permanent Sworn-in Court Translator for the English language appointed by the Decision of the Provincial Secretariat for Education, Governance and National Communities of the Autonomous Province Vojvodina No. 128-74-96/2011 of 30/03/2012



Srdić