EURASIAN ECONOMIC UNION
MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS

CERTIFICATE

COMPLIANCE WITH THE REQUIREMENTS OF THE RULES OF GOOD MANUFACTURING PRACTICE OF THE EURASIAN ECONOMIC UNION

№ GMP/EAEU/BY/0084-2021

Validity period from 25.08.2021 to 24.08.2024

Issued following the results of the pharmaceutical inspection in accordance with the Rules of Pharmaceutical inspections.

The Ministry of Health of the Republic of Belarus confirms the following: a pharmaceutical inspection has been carried out

JADRAN - GALENSKI LABORATORIJ d.d. / ЯДРАН - ГАЛЕНСКИ ЛАБОРАТОРИЙ a.o., Республика Хорватия

(full name of the manufacturer)

Svilno 20, 51000 Rijeka, Croatia / Свилно 20, 51000 Риека, Республика Хорватия

(address of the production site)

based on the order of the Ministry of Health of the Republic of Belarus No. 717 dated 18.06.2021.

Based on the information obtained during the pharmaceutical inspection, the last of which was carried out from 17/08/2021 to 25/08/2021, it is considered that this pharmaceutical manufacturer complies with the requirements of the Rules of Good Manufacturing Practice of the Eurasian Economic Union.

This certificate reflects the status of the production site on the date of the pharmaceutical inspection and after 3 years from the date of this pharmaceutical inspection should not be accepted as a document certifying the status of compliance. The validity period of the certificate can be shortened or extended by using the appropriate risk management principles, if there is a corresponding entry about it in the field "Restrictions or explanatory notes concerning the scope of this certificate".

The certificate is valid if all its pages (both main sheets and additional sheets) are submitted.

The authenticity (authenticity) of this certificate can be checked in the database of the Ministry of Health of the Republic of Belarus, located at: http://minzdrav.gov.by/dlya-spetsialistov/lekarstvennaya-politika/index.php (Register of GMP certificates of the EAEU).

If the certificate is not presented in the specified database, you should contact the authorized body that issued it.

☑ Medicinal products for human use
☐ Veterinary medicines
☐ Investigational New Drug

Production and quality control I. PRODUCTION OPERATIONS - MEDICINAL PRODUCTS

1. *Sterile products*

☑1. Products prepared aseptically (processing operations for the following dosage forms):
- ☐ large volume liquids
- ☑ small volume liquids
- ☐ dispersions
- ☐ lyophilisates
- ☐ solid forms and implants
- ☐ semi-solids
- ☐ other products

☐ 2. Products undergoing final sterilization (processing operations for the following dosage forms):
- ☐ large volume liquids
- ☐ small volume liquids
- ☐ solid forms and implants
- ☐ semi-solids
- ☐ other products, dosage forms

☑ 3. Release quality control

2. *Non-sterile products*

☑ 1. Non-sterile products (processing operations for the following dosage forms):
- ☐ hard-shelled capsules
- ☐ soft-shelled capsules
- ☐ chewable forms
- ☐ impregnated matrices
- ☑ liquids for external use
- ☑ liquids for internal use
- ☐ medical gases
- ☐ other solid dosage forms
- ☐ pressurized products
- ☐ radionuclide generators
- ☑ semi-solids: gels, creams, ointments
- ☐ suppositories
- ☑ tablets
- ☐ transdermal patches
- ☐ devices for intraruminal (intrauterine) administration
- ☐ other products

☑ 2. Release quality control

3. *Biological medicinal products*

☐ 1. Biological medicinal products:
- ☐ blood products
- ☐ immunological products
- ☐ somatic cell-based products
- ☐ gene therapy products
- ☐ tissue engineering products
- ☐ biotechnological products
- ☐ products extracted from animal sources or human organs (tissues)
- ☐ other products

☐ 2. Release quality control (list of product types):
- ☐ blood products
- ☐ immunological products
- ☐ somatic cell-based products
- ☐ gene therapy products
- ☐ tissue engineering products
- ☐ biotechnological products
- ☐ products extracted from animal sources or human organs (tissues)
- ☐ other products

4. *Other products or manufacturing activities*

☐ 1. Production:
- ☐ plant products
- ☐ homeopathic products
- ☐ other products: thick extracts, condensed extracts

☐ 2. Sterilization of active substances, excipients, finished products:
- ☐ filtering
- ☐ dry-heat sterilization
- ☐ steam sterilization
- ☐ chemical sterilization
- ☐ sterilization by gamma radiation
- ☐ electron beam sterilization.

☐ 3. Other

☑ 4. Primary (internal) packaging:
- ☐ hard-shelled capsules
- ☐ soft-shelled capsules
- ☐ chewable forms
- ☐ impregnated matrices
- ☑ liquids for external use
- ☑ liquids for internal use
- ☐ medical gases
- ☐ other solid dosage forms
- ☐ pressurized products
- ☐ radionuclide generators
- ☑ semi-solids: gels, creams, ointments
- ☐ suppositories
- ☑ tablets
- ☐ transdermal patches
- ☐ devices for intraruminal (intrauterine) administration

- ☐ other products, dosage forms

☑ 5. Secondary (consumer) packaging
☑ 6. Release quality control
☑ 7. Microbiological: sterility
☑ 8. Microbiological: non-sterility
☑ 9. Chemical (physical)
☑ 10. Biological

II. QUALITY CONTROL DURING IMPORT OF MEDICINAL PRODUCTS

☐ 1. Quality control of imported medicinal products:
- ☐ microbiological: sterility
- ☐ microbiological: non-sterility
- ☐ chemical (physical)
- ☐ biological.

☐ 2. Release control (batch certification) of imported products
☐ Sterile products:
- ☐ products prepared aseptically
- ☐ products undergoing final sterilization

☐ Non-sterile products
☐ Biological medicinal products:
- ☐ blood products
- ☐ immunological products
- ☐ somatic cell-based products
- ☐ gene therapy products
- ☐ tissue engineering products
- ☐ biotechnological products
- ☐ products extracted from animal sources or human organs (tissues)
- ☐ other products

☐ Other import activities:
- ☐ physical import site
- ☐ import of an intermediate product undergoing further processing
- ☐ other

Restrictions or explanatory notes regarding the scope of the certificate: no

Tarasenko A.A.
Deputy Minister - Chief State Sanitary
Doctor of the Republic of Belarus

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