№ 001823

Ministry of Health
of the Republic of Uzbekistan

Agency on Development of
Pharmaceutical Industry

Center of good practices

GMP – GOOD MANUFACTURING PRACTICE

CERTIFICATE

№ GMP – 34:2024

Is issued on the basis of a completed pharmaceutical inspection conducted in accordance with the regulation on the procedure for conducting inspections for compliance with the requirements of good manufacturing practice (GMP). *These regulations are authentic with the requirements of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and European Commission guidelines EU GMP.*

STATE ENTITY
"CENTER OF GOOD PRACTICES" APPROVES

located at

Republic of Uzbekistan, Tashkent region, Almalyk city, Usmon Nosira street, 3

LLC JV "JURABEK LABORATORIES"

Compliance with the requirements
of O'zDSt 2766:2018 – "Good Manufacturing Practice - GMP"

The basis for pharmaceutical inspection was application No A-332 dated September **25, 2024** of the LLC JV "Jurabek Laboratories" in accordance with the requirements of O'zDSt 2766:2018 - "Good manufacturing practice - GMP".

Tel: +99871 203-30-32, E-mail: gxp.duk@ssv.uz

GOOD MANUFACTURING PRACTICE — GMP CERTIFICATE APPENDIX

I. Sterile Products

1. Aseptically prepared (list of dosage forms):

☐ large volume liquids

☐ small volume liquids

☐ dispersions

√ **lyophilisates (workshops for the production of vaccines and lyophilized, injectable and infusion medicines)**

☐ solids

☐ semi-solids

☐ **other aseptically prepared products:**

√ **powder for solution for injection, in glass vials. (workshop for the production of vaccines and lyophilized injection and infusion medicines)**

√ **powder for solution for injection of antibiotics of the beta-lactam series, in glass vials. (workshops No. 1 for dispensing dry sterile antibiotics of the cephalosporin group in bottles)**

_____.

(the type of medicine or the type of activity is shown).

2. Medicines subject to sterilization at the end of production:

√ **large volume liquids (workshop for the production of infusion solutions in polymer bottles No. 1, No. 2, No. 3 and workshop for the production of vaccines and lyophilized injectable and infusion drugs)**

√ **small volume liquids (workshop No. 1 for the production of injection solutions in glass ampoules, workshop No. 2 for the production of infusion solutions in polymer bottles, workshop No. 3 solutions for injections in polymer ampoules, medicines for oral administration, workshop No. 2 for the production of infusion solutions in polymer bottles and workshop for the production of vaccines and lyophilized injectable and infusion medicines)**

☐ solids and implants

☐ semi-solids

☐ other terminally sterilised prepared products:

_____.

(the type of medicine or the type of activity is shown).

GOOD MANUFACTURING PRACTICE — GMP CERTIFICATE APPENDIX

II. Non-sterile products

☐ capsules, hard shell
☐ capsules, soft shell
☐ chewing gums
☐ impregnated matrices
√ liquids for external use: solutions, syrups, suspensions and drops (workshop No. 2 for the production of infusion solutions in polymer bottles, workshop No. 3 solutions for injections in polymer ampoules, medicines for oral administration)
√ liquids for internal use (workshop No. 2 for the production of infusion solutions in polymer bottles, workshops No. 3 and No. 4 solutions for injections in polymer ampoules, medicines for oral administration)
☐ medicinal gases
☐ other solid dosage forms
☐ pressurised preparations
☐ radionuclide generators
☐ semi-solids
☐ suppositories
☐ tablets
☐ transdermal patches
☐ intraruminal devices
☐ other non-sterile medicinal product:

_____.

(the type of medicine or the type of activity is shown).

III. Biological medicinal products

☐ blood products
√ immunological products (workshop for the production of vaccines and lyophilized injectable and infusion medicines)
☐ cell therapy products
☐ gene therapy products
☐ tissue engineered products
☐ biotechnology products
☐ human or animal extracted products
☐ other biological medicinal products:

_____.

(the type of medicine or the type of activity is shown).

GOOD MANUFACTURING PRACTICE — GMP CERTIFICATE APPENDIX

IV.Other products or manufacturing activity

☐ herbal products

☐ homoeopathic products

☐ other product

_____.

(the type of medicine or the type of activity is shown).

*Based on the information obtained during the pharmaceutical inspection conducted on **15-18.10.2024** and **31.10.2024**, the applicant complies with the requirements of the Good Manufacturing Practice - GMP. The certificate is valid if all its pages (both main pages and additional pages) are presented. The validity of this certificate can be checked from the database of the State entity "Center of Good Practices". If the certificate is not provided in the indicated database, it is necessary to contact the working body that issued it.*

The GMP – 34:2024 Good Manufacturing Practice - GMP certificate
validity period from ***05.11.2024*** to ***04.11.2027***

Director
of the SE "Center of Good Practices" _____ **Dusmatov A.F.**
(signature) (full name)

S.P.

Tel: +99871 203-30-32, E-mail: gxp.duk@ssv.uz

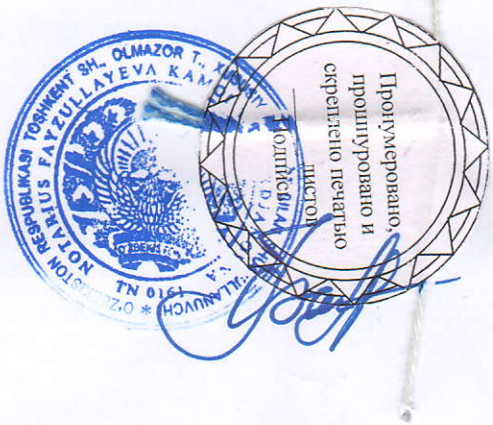
Вы можете проверить статус данного нотариального действия на электронном портале e-notarius.uz

Республика Узбекистан. Город Ташкент.
«12» ноября. Две тысячи двадцать четвертого года.

Я, **Файзуллаева Камола Тахирджановна,** Нотариус Алмазарского района города Ташкента, занимающаяся частной практикой «FAYZULLAYEVA KAMOLA TAXIRDJANOVNA» свидетельствую верность этой копии с подлинником документа, в последнем приписок, подчисток, зачёркнутых слов и иных, не оговорённых исправлений или, каких-либо особенностей не оказалось.

Зарегистрировано в АИС «Нотариус» за № 20240221602 5498
Взыскано государственной пошлины: 30000,00 сум

НОТАРИУС **Файзуллаева К.Т.**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O‘ZBEKISTON RESPUBLIKASI
SOG‘LIQNI SAQLASH
VAZIRLIGI

МИНИСТЕРСТВО
ЗДРАВООХРАНЕНИЯ
РЕСПУБЛИКИ УЗБЕКИСТАН

FARMASEVTIKA TARMOG'INI RIVOJLANTIRISH AGENTLIGI
AGENCY ON DEVELOPMENT OF PHARMACEUTICAL INDUSTRY
АГЕНТСТВО ПО РАЗВИТИЮ ФАРМАЦЕВТИЧЕСКОЙ ОТРАСЛИ

DORI VOSITALARI, TIBBIY BUYUMLAR VA TIBBIY TEXNIKA EXPERTIZASI VA STANDARTIZATSIYASI DAVLAT MARKAZI

STATE CENTRE OF EXPERTIZE AND STANDARDIZATION OF MEDICINES, MEDICAL DEVICES AND MEDICAL EQUIPMENT

ГОСУДАРСТВЕННЫЙ ЦЕНТР ЭКСПЕРТИЗЫ И СТАНДАРТИЗАЦИИ ЛЕКАРСТВЕННЫХ СРЕДСТВ, ИЗДЕЛИЙ МЕДИЦИНСКОГО НАЗНАЧЕНИЯ И МЕДИЦИНСКОЙ ТЕХНИКИ

RO‘YXATDAN O'TKAZILGANLIK TO‘G‘RISIDAGI GUVOHNOMA

REGISTRATION CERTIFICATE

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

Raqam / Number *(Номер)*	**DV/M 00457/11/15**
Dori vositasi yoki dori moddasi (substansiya) davlat ro‘yxatidan o`tkazilgan sana / Date of state registration of drug or API (substance) *Дата государственной регистрации лекарственного средства или лекарственного вещества(субстанции)*	**2020 yil 19 noyabr** *19 ноября 2020 года*
Amal qilish muddati/ Period of validity *Срок действия*	**5 yil (2025 yil 19 noyabrgacha)** *5 лет (до 19 ноября 2025 года)*
Dori vositasining savdo nomi yoki dori moddasini (substansiya) xalqaro patentlanmagan nomi yoki boshqa nomi / Trade name of the drug or International Nonproprietary Name (INN) of API (substance) or other name) / *Торговое название лекарственного средства или международное непатентованное наименование (МНН) лекарственного вещества (субстанции) или другое название*	**ATSESOL-JURABEK** *АЦЕСОЛЬ-JURABEK*
Dori shakli / Dosage form *Лекарственная форма*	**Infuziya uchun eritma 250 ml, 400 ml (flakonlar)** *Раствор для инфузий 250 мл, 400 мл (флаконы)*
Dori vositasining dastlabki ro’yxatdan o’tkazilgan sanasi va guvohnoma raqami / Date of primary registration of drug and number of registration certificate / *(Дата первичной регистрации лекарственного средства и номер регистрационного удостоверения)*	**DV/M 00457/11/15 27/11/15**

Ro‘yxatdan o‘tkazilganlik guvohnomasining egasi, davlati/ **Holder of the registration certificate, *country*** *Держатель регистрационного удостоверения, страна*	**"Jurabek Laboratories" MChJ QK O'zbekiston Respublikasi** *СП ООО " Jurabek Laboratories" Республика Узбекистан*
Ishlab chiqaruvchi (ishlab chiquvchi), korxona, davlati/ Manufacturer (developer) of drug, country / *Предприятие — производитель (разработчик), страна*	**"Jurabek Laboratories" MChJ QK O'zbekiston Respublikasi** *СП ООО " Jurabek Laboratories" Республика Узбекистан*
Dori modda (lar) yoki «in bulk» nomi, ishlab chiqaruvchi tashkilot, davlati*/ Name of API (substance) or «in bulk» drug, manufacturer (s), country(s)*/ *Наименование лекарственного (ых) вещества (в) или «ин балк» продукции, организация-производитель, страна)**	*натрия ацетата тригидрата-Масco Organiques s.r.o., Чехия; Натрия хлорид-Hebei Huachen Pharmaceutical Co., Ltd., Китай; Калия хлорид-Hebei Huachen Pharmaceutical Co., Ltd., Китай*

Ushbu guvohnoma mazkur dori vositasini tibbiyot amaliyotida qo‘llash huquqini beradi.
This certificate entitles using this drug in medical practice.
Настоящее удостоверение дает право на использование данного лекарственного средства в медицинской практике

“Dori vositalari, tibbiy buyumlar va tibbiy texnika ekspertizasi va standartlashtirish Davlat markazi” DUK direktori
Director of SUE “State Center of Expertise and Standardization of Drugs, Medical Products and Medical Equipment”
(Директор ГУП “Государственный центр экспертизы и стандартизации лекарственных средств, изделий медицинского назначения и медицинской техники”)

SH.X.ABDUGANIEV
Ш.Х.АБДУГАНИЕВ

M.O‘./ Stamp (M.П.)	Imzo/ Signature (подпись)	F.O.I./ Name (Ф.И.О.)

O‘ZBEKISTON RESPUBLIKASI
SOG‘LIQNI SAQLASH
VAZIRLIGI

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RO‘YXATDAN O‘TKAZILGANLIK TO‘G‘RISIDAGI GUVOHNOMA

REGISTRATION CERTIFICATE

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

Raqam / Number *(Номер)*	**DV/M 03757/03/21**
Dori vositasi yoki dori moddasi (substansiya) davlat ro‘yxatidan o`tkazilgan sana / Date of state registration of drug or API (substance) *Дата государственной регистрации лекарственного средства или лекарственного вещества(субстанции)*	**2021 yil 19 mart** *19 марта 2021 года*
Amal qilish muddati/ Period of validity *Срок действия*	**5 yil (2026 yil 19 martgacha)** *5 лет (до 19 марта 2026 года)*
Dori vositasining savdo nomi yoki dori moddasini (substansiya) xalqaro patentlanmagan nomi yoki boshqa nomi / Trade name of the drug or International Nonproprietary Name (INN) of API (substance) or other name) / *Торговое название лекарственного средства или международное непатентованное наименование (МНН) лекарственного вещества (субстанции) или другое название*	**Sermigolin®** ***Сермиголин®***
Dori shakli / Dosage form *Лекарственная форма*	**Inyeksion eritma tayyorlash uchun liofilizat 4 mg №1, №5, №10 (flakonlar) to'plamda erituvchisi bilan-0,9% natriy xlorid eritmasi 5ml (ampulalar)** *Лиофилизат для приготовления инъекционного раствора 4 мг №1, №5, №10 (флаконы) в комплекте с растворителем-0,9% раствор натрия хлорида 5 мл (ампулы)*
Ro‘yxatdan o‘tkazilganlik guvohnomasining egasi, davlati/ Holder of the registration certificate, *country* *Держатель регистрационного удостоверения, страна*	**"Jurabek Laboratories" MChJ QK O'zbekiston Respublikasi** *СП ООО " Jurabek Laboratories" Республика Узбекистан*

Ishlab chiqaruvchi (ishlab chiquvchi), korxona, davlati/
Manufacturer (developer) of drug, country /
Предприятие — производитель (разработчик), страна

"Jurabek Laboratories" MChJ QK
O'zbekiston Respublikasi
СП ООО " Jurabek Laboratories"
Республика Узбекистан

Dori modda (lar) yoki «in bulk» nomi, ishlab chiqaruvchi tashkilot, davlati*/
Name of API (substance) or «in bulk» drug, manufacturer (s), country(s)*/
*Наименование лекарственного (ых) вещества (в) или «ин балк» продукции, организация-производитель, страна)**

Ницерголин-Teva Czech Industries.S.R.O.
Чехия

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M.O./ Stamp (М.П.)

Imzo/ Signature (подпись)

M.M.QODIROV
M.M.КОДИРОВ
F.O.I./ Name (Ф.И.О.)