

LLC «FORTIVA MED»

Philosophy of a healthy future



- ***Manufacture of medicines used in***
 - *pulmonology*
 - *allergology*
 - *otorhinolaryngology*
 - *pediatrics*
 - *dermatology*
- ***Manufacture of biologically active food supplements***



LLC Fortiva Med is a **Belarusian high-tech pharmaceutical company** engaged in the development, registration, production, and sale of medicines.

The main task of the enterprise is the innovative development and production of efficacious, high-quality drug products that fully comply with safety standards. The priority direction of development of the product portfolio of LLC Fortiva Med is **the development of pulmonological medicines.**

Thanks to innovative approaches to production technology and the established effective quality control system, the company creates and produces modern, effective, high-quality and affordable medicines.

The enterprise is located in a single building, and includes:

Industrial premises

- *sector of sterile forms (solutions, lyophilized preparations)*
- *sector of non-sterile forms (capsules, sprays, aerosols, solutions)*
- *purified water production sector*
- *air preparation sector*
- *laboratory*

Warehouse

Household premises



Control and quality



Incoming control
of raw materials



Control of
intermediate
products



Control
of the process
parameters



Finished product control +
Andersen cascade
impactor for aerosols

FORTIVA  MED

The production site of the company is equipped with a system for creating and maintaining a microclimate of clean rooms and system for producing purified water, water for injection and pure steam (BWT Pharma & Biotech GmbH, Germany). Environmental friendliness, cleanness and safety of production processes are provided by modern ventilation and air conditioning systems manufactured by NordVent Swiss Tech SA (Switzerland). The design of the production equipment provides convenience and the possibility of its cleaning, all parts of the process equipment in contact with the product are made of corrosion-resistant inert materials that do not react with the product.



All technological processes are carried out in accordance with international GMP standards

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ

СЕРТИФИКАТ
СООТВЕТСТВИЯ ПРОМЫШЛЕННОГО ПРОИЗВОДСТВА
ЛЕКАРСТВЕННЫХ СРЕДСТВ ТРЕБОВАНИЯМ
НАДЛЕЖАЩЕЙ ПРОИЗВОДСТВЕННОЙ ПРАКТИКИ (GMP)
№ 223/2023/GMP

выдан по итогам проведения инспектирования в соответствии с Положением о порядке и условиях инспектирования промышленного производства лекарственных средств на соответствие требованиям Надлежащей производственной практики, утвержденным постановлением Министерства здравоохранения Республики Беларусь от 18 ноября 2020 г. № 102.

Министерство здравоохранения Республики Беларусь подтверждает следующее:
проведено инспектирование общества с ограниченной ответственностью «Фортис Мед»

(наименование производителя, производственной(ых) площадки(ок))
223012, Минская обл., Минский район, г.п. Мачулищи, ул. Аэродромная, 4-1А
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Республика Беларусь; телефон: +375(44)7796277, e-mail: office@fortiva.by

на основании:
приказа Министерства здравоохранения Республики Беларусь от 20.09.2022 № 1258 «Об организации инспектирования» и приказа Министерства здравоохранения Республики Беларусь от 30.09.2022 № 1322 «Об организации инспектирования».

На основании сведений, полученных при проведении инспектирования, последнее из которых было проведено с 31.10.2022 по 03.11.2022, установлено, что данный производитель лекарственных средств соответствует требованиям Надлежащей производственной практики.

Настоящий сертификат отражает статус производственной(ых) площадки(ок) на момент проведения инспектирования и по истечении 3 лет от даты последнего дня последнего инспектирования не должен приниматься в качестве документа, свидетельствующего о статусе соответствия. При определении срока, на который выдается сертификат, учитываются принципы управления рисками в соответствии с документами системы качества фарминспектората и отражаются в поле «Ограничения или пояснительные замечки, касающиеся области применения настоящего сертификата». Сертификат является действительным в случае представления как основных, так и дополнительных листов.

Аутентичность (подлинность) настоящего сертификата можно проверить на официальном сайте Министерства здравоохранения Республики Беларусь в глобальной компьютерной сети Интернет.

Лист 1 из 2

GMP № 0000655

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ

СЕРТИФИКАТ
№ 223/2023/GMP

☒ Лекарственные препараты для медицинского применения
☐ Фармацевтические субстанции
☐ Ветеринарные лекарственные препараты
☐ Лекарственные препараты для клинических исследований (испытаний)

Код	Наименование
Наименование вида производства, лекарственной формы	
2	Промышленное производство нестерильных лекарственных средств и (или) фармацевтических субстанций и их оптовая реализация
2.1	Жидкие лекарственные формы для наружного и (или) местного применения
2.1.5	растворы
2.1.6	спреи
2.4	Жидкие лекарственные формы для приема внутрь
2.4.2	капли
2.5	Жидкие лекарственные формы для ингаляций или ингаляционного наркоза
2.5.2	растворы
2.8	Прочие лекарственные формы нестерильных лекарственных средств
2.8.1	аэрозоли
2.8.7	спреи
2.9	Выпускающий контроль
9	Промышленное производство лекарственных средств в части фасовки и (или) упаковки лекарственных средств и (или) фармацевтических субстанций и их оптовая реализация
9.1	вторичная упаковка лекарственных форм
9.9	Выпускающий контроль
11	Контроль качества
11.3	химические (физические) испытания

Ограничения или пояснительные замечки, касающиеся области применения сертификата: нет.

Заместитель Министра
здравоохранения
Республики Беларусь

Дата подписания
30 января 2023 г.

Д.В.Чердынченко

Лист 2 из 2

GMP № 0000656

Why Fortiva Med LLC is a high-potential partner?

- ✓ Modern and new pharmaceutical production – we work since 2019 on the latest equipment of the best world brands (Diosna, Ebseos, IMA, SP Scientific, Flexicon, Pamasol, etc.);
 - ✓ The first and only Belarusian enterprise performing a full-cycle manufacture of aerosols and inhalation solution (R&D→Manufacturing→Quality control→Package→Sales);
 - ✓ We manufacture products both on a full-cycle basis (aerosols and solutions), and perform the partial manufacture (individual stages of production);
 - ✓ Multi-stage quality control of released products;
 - ✓ We specialize in high-quality, modern and effective aerosols and inhalation solution;
 - ✓ Competitive price with high quality.
-
- ✓ **We offer the total and partial contract manufacturing (CMO/CDMO), In/Out Licensing, Co-branding and drop shipping.**
 - ✓ **We are open to any form of cooperation and are ready to consider individual proposals.**

IPRATEROL, IPRATEROL-AERO

Nebuliser solution (0,25+0,5) mg/ml, 20 ml

Pressurised inhalation solution (20+50) mcg/dose, 200 doses

INN: ipratropium bromide + fenoterol

Pharmacotherapeutic group: Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids

ATC code: R03AL01

Indications for use

- symptomatic treatment of chronic obstructive diseases of airways with reversible airway obstruction, such as bronchial asthma, chronic obstructive pulmonary disease (COPD), chronic obstructive bronchitis with or without emphysema



FENOTEROL, FENOTEROL-AERO

Nebuliser solution 1 mg/ml, 20 ml

Pressurised inhalation solution 100 mcg/dose, 200 doses

INN: Fenoterol

Pharmacotherapeutic group: Selective beta-2-adrenoreceptor Agonists

ATC code: R03AC04

Indications for use

- Attacks of bronchial asthma or other conditions with the occurrence of obstruction of the upper airways, chronic obstructive pulmonary disease (COPD)
- Prevention of attacks of bronchial asthma due to physical exertion





IPRATROPIUM

Nebuliser solution 0,25 mg/ml, 20 ml

INN: Ipratropium bromide

Pharmacotherapeutic group: Anticholinergics

ATC code: R03BB01

Indications for use

- maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease and, when used concomitantly with inhaled beta2-agonists
- treatment of acute and chronic asthma and acute bronchospasm associated with chronic obstructive pulmonary disease



FREELONG - Analogue of FOSTAIR (Chiesi Farmaceutici S.p.A., Italy)

Pressurised inhalation solution (100+6) mcg/dose, 200 doses

INN: Beclometasone + Formoterol

Pharmacotherapeutic group: Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics

ATC code: R03AK08

Indications for use

- The regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate
- Symptomatic treatment of patients with severe COPD and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.



PANTHENOL AERO

Aerosol for external use 2,5 g/58 g, 5 g/116 g

INN: Dexpanthenol

Pharmacotherapeutic group: Other cicatrizants

ATC code: D03AX03

Indications for use

- dry skin;
- wounds and burns (solar and thermal);
- dermatitis; bedsores; diaper rash; aseptic postoperative wounds; poorly engrafted skin grafts;
- prevention and treatment of cracks and inflammation of the nipples of the mammary glands during lactation;
- infant care; prevention and treatment of diaper rash in infants;
- activation of the healing process of the skin with minor injuries or erythema from diapers



EXOFORT

Solution for external use 10 mg/ml, 10 ml, 20 ml

Spray for external use 10 mg/ml, 30 ml, 60 ml

INN: Naftifine

Pharmacotherapeutic group: Other antifungals for topical use

ATC code: D01AE22

Indications for use

- fungal infections of the skin and skin folds (tinea corporis, tinea inguinalis);
- interdigital mycoses (tinea manum, tinea pedum);
- fungal nail infections (onychomycoses);
- skin candidiasis;
- tinea versicolor;
- dermatomycoses (with or without accompanying itching)



MINOXIFOR

Cutaneous solution 50 mg/ml, 60 ml

Cutaneous solution 20 mg/ml, 60 ml

INN: Minoxidil

Pharmacotherapeutic group: Other dermatologicals

ATC code: D11AX01

Indications for use

- Treatment of moderate androgenetic alopecia in women aged 18 – 65 years.



SEPTOFORT TOTAL

Oromucosal spray 30 ml

INN: benzydamine + cetylpyridinium chloride

Pharmacotherapeutic group: Other throat preparations

ATC code: R02AX03

Indications for use:

- symptomatic therapy of pain syndrome of inflammatory diseases of the oral cavity and ENT organs (of various etiologies), including tonsillitis, pharyngitis, as part of combined therapy



ORO-SPRAY

Oromucosal spray 30 мл

INN: Benzydamine

Pharmacotherapeutic group: Other agents for local oral treatment

ATC code: A01AD02

Indications for use:

- Symptomatic local treatment of inflammation and pain in inflammatory processes of the oral cavity and pharynx (gingivitis, stomatitis, pharyngitis), as well as after conservative treatment or extraction of teeth.



COMFORTIC

Oral drops 40 mg/ml, 100 mg/ml, 30 ml, 50 ml

INN: Simethicone (Silicones)

Pharmacotherapeutic group: Other drugs for functional gastrointestinal disorders

ATC code: A01AD02

Indications for use

- symptoms of intestinal colic in infants;
- symptoms of excessive formation and accumulation of gases in the gastrointestinal tract (including flatulence, increased gas formation in the postoperative period);
- symptoms of excessive gas formation caused by functional dyspepsia;
- preparation for diagnostic examination of the abdominal cavity and small pelvis (ultrasound, radiography, esophagogastroduodenoscopy, etc.), including as an additive to suspensions of contrast agents for obtaining an image using the double contrast method;
- acute poisoning with detergents containing foaming substances (surfactants), as a defoamer.





AQUAVIT D₃

Oral drops 15000 IE/ml, 10 ml, 15 ml

INN: Cholecalciferol

Pharmacotherapeutic group: Vitamin D and analogues

ATC code: A11CC05

Intended use:

- Prevention and treatment of vitamin D deficiency;
- Treatment of rickets;
- As an adjunct to specific therapy of osteoporosis
- in patients at risk of vitamin D deficiency.



MOMENEX

Nasal spray, suspension 50 mcg/dose, 140 doses

INN: Mometasone

Pharmacotherapeutic group: Corticosteroids

ATC code: R01AD09

Indications for use

- Seasonal and perennial allergic rhinitis in adults, adolescents, and children from 2 years of age.
- Acute sinusitis or aggravation of chronic sinusitis in adults (including the elderly ones) and adolescents from 12 years of age – as an auxiliary therapeutic agent in the course of treatment by antibiotics.
- Acute rhinosinusitis with mild and moderate symptoms without signs of severe bacterial infection in patients at the age of 12 or more.
- Preventive treatment of moderate or severe seasonal allergic rhinitis in adults and adolescents from 12 years of age (recommended 2 to 4 weeks before the expected beginning of a pollen season).
- Nasal polyposis accompanied by impaired nasal breathing and sense of smell, in adults (from 18 years of age).



FLUTINEX

Nasal spray, suspension 50 mcg/dose, 120 doses

INN: Fluticasone

Pharmacotherapeutic group: Corticosteroids

ATC code: R01AD08

Indications for use

- Inflammation of the mucous membrane of the nose (rhinitis) caused by seasonal allergies, such as hay fever.
- Inflammation of the nasal mucosa (rhinitis) caused by year-round allergies, such as animal allergies.
- Flutinex used in adults and children over 12 years of age





AZELINEX

Nasal spray, suspension 140 mcg/dose, 60 doses

INN: Azelastine

Pharmacotherapeutic group: Antiallergic agents, excl. corticosteroids

ATC code: R01AC03

Indications for use

- Symptomatic treatment of seasonal allergic rhinitis in adults
- Treatment of year-round allergic rhinitis in adults, adolescents and children from 6 years of age.



Analogue of TRIMBOW (Chiesi Farmaceutici S.p.A., Italy) — *under development*

Pressurised inhalation solution (87+5+9) mcg/dose, 120 doses

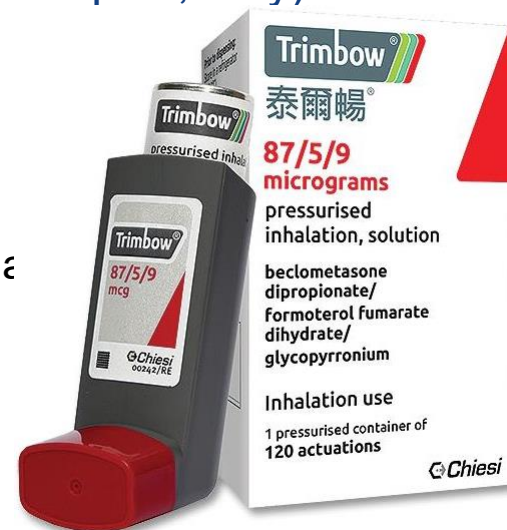
INN: Beclometasone + Formoterol + Glycopyrronium

Pharmacotherapeutic group: Adrenergics in combination with α combinations with corticosteroids

ATC code: R03AL09

Indications for use

- Asthma - Maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.
- COPD - Maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or a combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist



RINOMISTA (analogue of DYMISTA) – under development

Nasal spray, suspension (137+50) mcg/dose

INN: Azelastine + fluticasone

Pharmacotherapeutic group: Corticosteroids

ATC code: R01AD58

Indications for use

- Relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.



Contacts



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