



The Interregional Public Institution
“Institute of Engineering Physics”
(scientific, educational and industrial one)



THE **TAMERON** SERIES INNOVATIVE DRUGS

PHARMACEUTICAL MANUFACTURING



Has the following advantages:

- high-tech manufacturing facilities;
- annual inspection of all engineering systems (the entire list of qualification and validation works);
- highly qualified staff;
- effective pharmaceutical quality system;
- collecting prototypes for research;
- technological development to expand production;
- distribution of finished pharmaceutical lyophilized products that do not require special separation;
- long-term mutually beneficial partnership.

The license for drug manufacturing was issued to the interregional public institution "Institute of Engineering Physics" by the Ministry of Industry and Trade of the Russian Federation on January, 27, 2016, №00168-LS, for unlimited time.



ACTIVE PHARMACEUTICAL SUBSTANCE (APS),

manufactured in accordance with Russian technology (patent № 2673452, dated 11/27/2018. "Method of obtaining active pharmaceutical substance, presenting aminodihydrophthalazinedione of sodium")

TECHNOLOGY BENEFITS:

- **substance production in accordance with the Good manufacturing practice (GMP)** requirements, using the patented sterile filtration technological process;
- **complete suppression of the formation** of resinous substances, linear oligo- and polyimides, isomeric phthalimides;
- production of an APS in the form of **stable crystals** with precise fixation of the amount of water in the substance, which **guarantees quality and a high degree of reproducibility** during the production;
- it is characterised by **the exclusion of the use of toxic hydrazine hydrate** and other raw materials, high conversion, increased ergonomics and environmental friendliness;
- the use of the patented Russian technology for the production of the APS aminodihydrophthalazinedione sodium **guarantees high quality and reproducibility of the result in the complete absence** of mechanical, chemical and biological impurities;
- this method of producing the APS in the form of a lyophilized allows to achieve **better absorption of the drug** and, thus, increases its bioavailability;
- **one-step process** for obtaining the APS and the possibility of using inexpensive commercial reagents allows achieving low cost price.



Developer: Institute of Engineering Physics, The Interregional Public Institution
Entry number in the Russian State Register of Medicines: №FS-002112
dated 18.11.2020
Producer: BION LLC

THE MEDICINAL PRODUCT TAMERON

LYOPHILIZATE FOR SOLUTION FOR INTRAMUSCULAR INJECTION



МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
РОССИЙСКОЙ ФЕДЕРАЦИИ

**Регистрационное удостоверение
лекарственного препарата для медицинского применения**

(номер регистрационного удостоверения лекарственного препарата)

№П-006597

Наименование держателя (бальзаля) регистрационного удостоверения лекарственного препарата	Межрегиональное общественное учреждение "Институт инженерной физики" (МФУ "Институт инженерной физики"), Россия
Адрес местонахождения держателя (бальзаля) регистрационного удостоверения лекарственного препарата	142210, Московская обл., г. Серпухов, Большой Ударный пер., д. 1а
Дата государственной регистрации лекарственного препарата	24.11.2020
Срок действия регистрационного удостоверения лекарственного препарата	со срока действия 5 лет
Дата внесения изменений в регистрационное удостоверение лекарственного препарата (дата замены регистрационного удостоверения лекарственного препарата)	выдано впервые

Информация о зарегистрированном лекарственном препарате:

Торговое наименование	TAMERON®
Международное непатентованное, или группировочное, или химическое наименование	Аминодигидрофталазинидон натрия
Лекарственная форма	лиофилизат для приготовления раствора для внутримышечного введения
Дозировка	100 мг
Качественный состав и количественный состав действующих веществ и качественных состав вспомогательных веществ	аминодигидрофталазинидон натрия 100,0 мг
Форма выпуска (лекарственная форма, дозировка, первичная упаковка, количество лекарственной формы в первичной упаковке, количество первичных упаковок в потребительской упаковке, комплектность)	лиофилизат для приготовления раствора для внутримышечного введения, 100 мг (флакон) × 5 (глаза картонная)
Результаты нормативной документации	№П-006597-24.11.20

033315

Страница 2 регистрационного удостоверения № ПП-006597

Производственные площадки, участвующие в процессе производства лекарственного препарата, с указанием стадий производства, названий и фактических адресов местонахождения	<p><i>Производство основной лекарственной формы</i></p> <p>Межрегиональное общественное учреждение "Институт инженерной физики" (МФУ "Институт инженерной физики"), Россия</p> <p>Московская обл., г. Серпухов, Большой Ударный пер., д. 1а, стр. 1</p> <p><i>Первичная упаковка</i></p> <p>Межрегиональное общественное учреждение "Институт инженерной физики" (МФУ "Институт инженерной физики"), Россия</p> <p>Московская обл., г. Серпухов, Большой Ударный пер., д. 1а, стр. 1</p> <p><i>Вторичная потребительская упаковка</i></p> <p>Межрегиональное общественное учреждение "Институт инженерной физики" (МФУ "Институт инженерной физики"), Россия</p> <p>Московская обл., г. Серпухов, Большой Ударный пер., д. 1а, стр. 1</p> <p><i>Производство (Выпускной контроль качества)</i></p> <p>Межрегиональное общественное учреждение "Институт инженерной физики" (МФУ "Институт инженерной физики"), Россия</p> <p>Московская обл., г. Серпухов, Большой Ударный пер., д. 1а, стр. 1</p>
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Заместитель Министра  М.П. О.В. Гріднев

THE MEDICINAL PRODUCT
TAMERON
LYOPHILIZATE FOR SOLUTION FOR INTRAMUSCULAR INJECTION

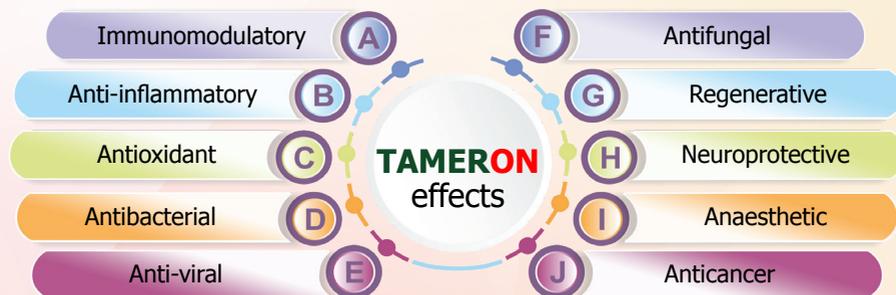


THE MEDICINAL PRODUCT **TAMERON**

LYOPHILIZATE FOR SOLUTION FOR INTRAMUSCULAR INJECTION



The use of **TAMERON** medicinal drug in the prevention and treatment of acute viral infections may reduce oxidative stress in cells and tissues, and thus inhibits the cytokine storm and the overreaction of the immune system. It prevents viral replication, promotes alveolar and other cells preservation, including the immune ones (in particular monocytes and T-cells). It also activates the immune response at the level of T-cells, which destroy cells infected with the virus. **TAMERON** shows its high efficiency in the treatment of neurogenic pathological processes caused by coronavirus infection. It's worth to note that **TAMERON** can also be used in the comprehensive treatment with other immunomodulators and specific anti-viral medications.



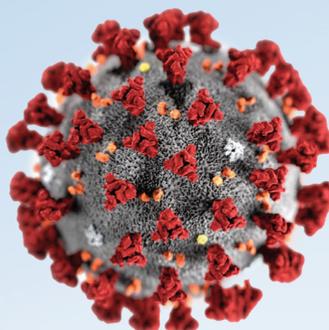
Developer: Institute of Engineering Physics, The Interregional Public Institution.

Entry number in the Russian State Register of Medicines: №LP-006597 dated 24.11.2020.

Producer: Institute of Engineering Physics, The Interregional Public Institution.

THE MEDICINAL PRODUCT TAMERON AND CORONAVIRUS SARS-COV-2

Coronavirus infects lung cells after its transmission from one person to another even if it goes without showing any symptoms. Coronavirus interacts with human cells receptors, particularly with the ACE2 receptor, which is extensively represented in the upper respiratory tract epithelial tissue and epithelial cells of the mucous tunic of the mouth. In the early stages of disease progression



COVID-19 leads to the hyperactivation of the immune response, known as cytokine storm or acute respiratory distress syndrome (ARDS), which damages multiple organs. Then in late stages this disease comes along with the immune suppression as a decrease in lymphocytes and in the type I interferon production. Nowadays there is no yet highly effective specific treatment for the coronavirus infection and that's why the use of well known drugs for non specific immunotherapy is still relevant. But **TAMERON** is likely to become such an effective drug.

TAMERON can affect two main virus pathogenicity factors as its replication in human cells and it also prevents the hyperactivation of the immune system and the cytokine storm progression. Coronavirus replication goes along with the oxidative stress in cells. **TAMERON** affecting the genetic apparatus of human cells suppresses reactive oxygen species generation.

THE USE OF TAMERON DRUG

in treatment of Coronavirus infection:

NORMALIZES

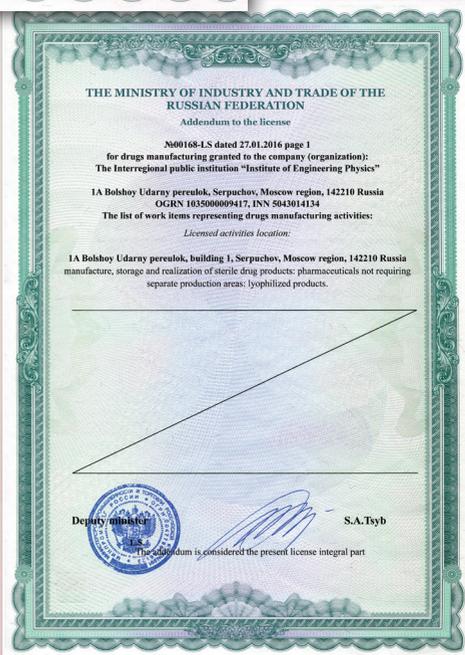
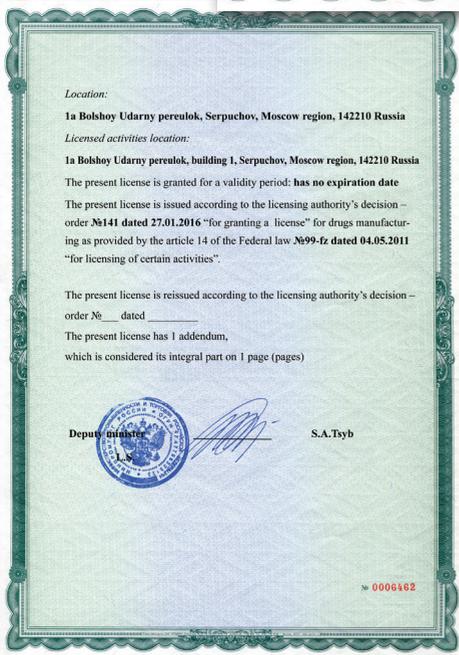
oxidation-reduction potential
of infected human cells.

PREVENTS

viral replication in cells.

RESULTS

in infected cells death.



RUSSIAN FEDERATION



PATENT FOR THE INVENTION

№ 2673452

METHOD OF OBTAINING ACTIVE PHARMACEUTICAL SUBSTANCE, PRESENTING AMINODIHYDROPHTHALAZINEDIONE OF SODIUM

Assignee: *Institute of Engineering Physics, The interregional public institution (RU)*

Authors: *Tsarkov Aleksey Nikolaevich (RU), Smurov Sergey Vladimirovich (RU), Prezent Michail Avramovich (RU), Volskiy Vladimir Stanislavovich (RU), Sedova Irina Vladimirovna (RU), Krasnova Yulia Valerjevna (RU), Chistyukova Anna Valerjevna (RU)*

Application number 2017129096
Invention priority date - THE 15TH OF AUGUST 2017
State registration date in the state registry of inventions of the Russian Federation - THE 27TH OF NOVEMBER 2018
Expiration date of the exclusive right to the invention - THE 15TH OF AUGUST 2037

Head of Federal service
for intellectual property

G.P. Ivliev G.P. Ivliev



Page 2 of the certificate of registration № LP-006597

THE MINISTRY OF INDUSTRY AND TRADE
OF THE RUSSIAN FEDERATION

Certificate of registration for the medicinal product

LP-006597
(registration number of the medicinal product)

Holder of the marketing authorization certificate for the medicinal product	The Interregional public institution "Institute of Engineering Physics", Russia
Location of the holder of the marketing authorization certificate for the medicinal product	1A Bolshoy Udayny pereulok, Serpukhov 142210, Moscow region, Russia
Date of the medicinal product state registration	24.11.2020
Validity period of the registration certificate for the medicinal product	Valid for 5 years
Date of changes to the certificate of registration for the medicinal product	Issued for the first time
Data on the registered medicinal product	
Trade name	TAMERON®
International nonproprietary or generic or chemical name	Aminodihydrophthalazinedione of sodium
Pharmaceutical form	Lyophilizate for solution for intramuscular injection
Dosage strength	100 mg
Qualitative and quantitative composition of active substances and qualitative composition of auxiliary substances	
Aminodihydrophthalazinedione of sodium 100.0 mg	
Release form (pharmaceutical form, dosage, primary packaging, pharmaceutical form quantity in the primary packaging, primary packaging quantity in the consumer packaging, product specification file)	Lyophilizate for solution for intramuscular injection, 100 mg (bottle) x 5 (cardboard pack)

083315

Industrial sites taking part in the drug production, specifying manufacturing stages, names and actual addresses	
Finished dosage form production	The Interregional public institution "Institute of Engineering Physics", Russia
1a Bolshoy Udayny pereulok, building 1, Serpukhov, Moscow region, 142210, Russia	
Finished dosage form production	The Interregional public institution "Institute of Engineering Physics", Russia
1a Bolshoy Udayny pereulok, building 1, Serpukhov, Moscow region, 142210, Russia	
Secondary consumer packaging	The Interregional public institution "Institute of Engineering Physics", Russia
1a Bolshoy Udayny pereulok, building 1, Serpukhov, Moscow region, 142210, Russia	
Producer (release quality control)	The Interregional public institution "Institute of Engineering Physics", Russia
1a Bolshoy Udayny pereulok, building 1, Serpukhov, Moscow region, 142210, Russia	

Deputy minister

I.S.
I.S.

Deputy minister

RUSSIAN FEDERATION



TRADEMARK CERTIFICATE

№ 598830

TAMERON

Owner: *Institute of Engineering Physics, The interregional public institution
1a Bolshoy Udamy pereulok, Serpuchov, Moscow region,
142210 Russia*

Application number 2015741327
Trademark priority date - the 16th of December 2025
Registered in the Public register of trademarks and service marks of the Russian Federation on the 14th of December 2016
Trademark registration valid until the 16th of December 2025

Head of Federal service
for intellectual property

Reliance G.P. Ivliev



RUSSIAN FEDERATION



PATENT
FOR THE INVENTION

№ 2744858

Method of obtaining lyophilizate of
aminodihydrophthalazinedione of sodium - Tameron,
medicinal product

Assignee: *Institute of Engineering Physics, The interregional public institution (RU)*

Authors: *Volskiy Vladimir Stanislavovich (RU), Ermakov Artem Michailovich (RU), Krasnova Yulita Valerievna (RU), Tsarkov Aleksey Nikolaevich (RU), Tsarkova Elena Aleksandrovna (RU)*

Application number 2020116296
Invention priority date - the 28th of April 2020
State registration date in the State registry of inventions of the Russian Federation - the 16th of March 2021
Expiration date of the exclusive right to the invention - the 28th of April 2040

Head of Federal service
for intellectual property

Reliance G.P. Ivliev





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For purchase issues



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