Pilot production

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Branch of the Institute of Bioorganic Chemistry, Academy of Sciences of the Republic of Uzbekistan

The Institute of Bioorganic Chemistry (IBOKh) of the Academy of Sciences of Uzbekistan has launched an automated complex for the production of medicines. And also there is a production building and equipment for the production of drugs of the full technological cycle in tablet and capsule forms.
The buildings are designed in full compliance with applicable standards, rules and recommendations that ensure labor protection and safety.
Production capacity - 35.7 million tablets per year, 11.2 million capsules per year.
A separate area of the branch's activity is the provision of contract manufacturing services for pharmaceutical and food (BAA) full-cycle products.

Types of products:
- ordinary tablets and with a shell;
- encapsulation of powders: hard gelatin capsules (# 00, 0, 1, 2, 3, 4).

We also provide packaging services for tablets and capsules in the amount of 400.0 thousand in blisters (PVC / Alyu) per month.
There is a laboratory for quality control of solid medicines at OKK IBOKH AN RUz and is equipped with modern technology and equipment.

In the laboratory of quality control is carried out:

- input control of raw materials (medicinal substances (substances), auxiliary substances and materials, intermediate products);
- acceptance control of finished products;
- development of specifications for raw materials and supplies;
- control over storage of raw materials and finished products in warehouses;
- control over the sanitary condition of production and storage facilities, workplaces and equipment;
- sampling of raw materials and finished products;
- conducting stability tests;
- storage of arbitration samples of raw materials and finished medicines;
- development of measures to eliminate and prevent the release of marriage.
- microbiological purity is carried out in DVSIM LLC on the basis of an agreement.

The list of products being adjusted for the production of experimental-experimental production of IBOKh AN RUz:

1. Antiparkinsonian drug-dopaminomimetics Pramipexole Bio table. 0.25 mg No. 30.
2. Anti-Chlamydia drug Gozalidon caps. 100mg No. 20.
3. Antiviral agent Ragosin caps. 50 mg No. 10.
4. Immunosuppressive agent Mebavin caps. 100mg No. 20.
5. Antituberculous agent Biomeirin caps. 600 mg No. 20.
6. Antitumor agent Biocor table. 200mg No. 10.

At the end of 2018, certified drugs were produced for sale:

- antiviral agent - inducer of interferon Rutan table. 25 mg No. 20 in an amount of 12,460 packs;
- based on the services provided (processing of tolling raw materials) dietary supplement for food Caniferon C caps. No. 60 in the amount of 10,000 packages.

Permission for the production of dietary supplements for food (laxative) Ravonol caps. 0.55 g each

Pilot production is located at: Republic of Uzbekistan, Tashkent, Almazar district, st. Kichik hulk yuli, 1.

RUTAN

THE PRESCRIBING INFORMATION

Trade Name of preparation: Rutan®

Dosage Form: Tablets

The drug formula:

Active substance: Rutan - 25 mg.

Excipients: potato starch, calcium stearate, sucrose.

Description: Tablets from light beige to yellow.

Pharmacotherapeutic group: Antiviral agents- interferon inducer.

Pharmacological properties

Specific activity: Rutan has a pronounced antiviral effect against strains of influenza viruses A-H3N2 and H1N1, influenza B (01) and (03). It has a direct virucidal effect. Rutan is an inducer of endogenous interferon. In the human body, it triggers the formation of so-called late alpha-, beta- and gamma-interferons in almost all cell populations involved in the antiviral response.

Mechanism of action is executed intracellularly and based on the inhibitory effect on viral neuraminidase. This enzyme, a part of influenza virions, hydrolyzes the glycosidic bond connecting the keto group of N-acetylneuraminic acid with sugars. The suppression of viral neuraminidase disrupts the assembly of the virion, and thereby disrupts the reproduction of viruses. In addition, Rutan induces the production of interferon in blood cells in vitro and increases the content of interferon in the blood of patients.

The study of general toxicology showed that Rutan belongs to the V class of non-toxic compounds, does not accumulate. Under chronic administration, it does not have a toxic effect on peripheral blood indicators, renal and liver function, and pathomorphology of internal organs of experimental animals. There is a slight increase in total protein, an increased urine output and in the hemoglobin concentration, the number of red blood cells and reticulocytes (7-20%).

The study of specific toxicology showed that the drug does not have locally irritating, allergenic, mutagenic, immuno-toxic, teratogenic and embryo-toxic effects. Rutan has a pronounced stimulating effect on humoral immunity (a marked increase in the number of antibody producing cells), stimulates the nonspecific resistance of the body (increased phagocytic activity of neutrophils), and causes the tendency to increase the mass and cellularity of spleen, thymus, lymph nodes and bone marrow.

Rutan does not enhance the development of delayed hypersensitivity; on the contrary, under the influence of Rutan, there is a decrease in the index of inflammatory reactions, i.e. tendency to decrease the development of delayed hypersensitivity reations. Rutan also shows a moderate antimicrobial effect against gram-positive and gram-negative bacteria in vitro.

Rutan exhibits antiradical activity in regard to the stable DPPH free radical (1,1-diphenyl-2-picrylhydrazyl), prevents lipid and protein oxidation in biological membranes. The model of non-enzymatic Fe2 + / acorbate-induced lipid peroxidation on mitochondria shows a high antioxidant activity of the drug. This is due to both its ability to chelate various metal ions and to directly interact with reactive oxygen species: $O_2^{\bullet}$, OH radicals of singlet oxygen. Consequently, Rutan can be effective as an antitumor, anti-inflammatory agent.

Pharmacokinetics

Polyphenolic compounds, on the basis of which Rutan was created, belong to the class of tannins. The tannins in the human body break down into a number of metabolites that are difficult to study. Tannins are determined only in the form of metabolites in feces and urine in a range of 3-6%.

The main parts of ellagotannins are transformed into undetectable metabolites.

Indications for use

Rutan is administered for adults and children over 6 years of age as a preventive and therapeutic agent for influenza and other respiratory viral infections. For preventive purposes, the drug can be used any time, including immediately after contact with an infectious invader.

Dosage and administration

For the treatment of influenza and acute respiratory viral infections, Rutan is prescribed by 2 tablets 3 times a day during the first 2 days, 1 tablet 3 times a day for the next 2 days, and 1 tablet 2 times a day on the fifth day. The duration of treatment is 5 days.

Side effects

The development of allergic reactions could be observed.

Contraindications:

Increased individual sensitivity, pregnancy period and lactation, children under 6 years.

Drug interactions

Interactions with other drugs have not been studied.

Special instructions

It is recommended to stop breastfeeding, since the introduction of Rutan into breast milk has not been

studied in clinical trials.

The drug should be stored out of the reach of children and not be used after the expiration date.

Overdosing

There is no evidence of an overdose of the drug.

Drug form

25 mg tablets, on 10 tablets in a blister strip packaging from a film of polyvinyl chloride or import and aluminum foil printed varnished. Two contour cell packs, together with instructions for use, are placed in a pencil case from boxed cardboard.

Storage conditions

In a dry, dark place at a temperature not above 25^0C.

Period of validity

2 years.

Prescribing requirements from drug stores

With prescription.

Manufacturer

A.S. Sadykov Institute of Bioorganic Chemistry, Academy of Sciences of the Republic of Uzbekistan

1, Kichik Khalqa Yuli Str., Almazar district, Tashkent city, Uzbekistan