THE BIOEQUIVALENCE STUDY OF THE DRUG "PROSTANIK" (FERULEN) PRODUCED BY LLC "NIKA PHARM"

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Annotation: The active substance of the "prastanic" (ferulene) medicinal drug capsules produced by LLC "NIKA PHARM" is not differ from ferulene tablets produced by ICPS AS RUz The acute toxicity parameters of both compared drugs with the orally administered are not differ and are classified as low toxic substances; The "prastanic" produced by LLC "NIKA PHARM" and ferulen produced by the ICPS AS RUz equally reduces the mass of androgen-dependent organs, which indicates the bioequivalence of the compared drugs.

Key words: Ferula tenuisectae, ferulen, ferutinin, ferutin, teferin, tenufiridin, fertidin

The preparation is the sum of 5 esters of sesquiterpene alcohols, similar in chemical structure, obtained from the root part of the Ferula Tenuisecta plant of the following composition: ferutinin (basic), ferutin, teferin, tenufiridin and ferttidin and based on them the technology for obtaining the preparation of ferulen has been developed.

A decrease in the level of prostate-specific antigen in the blood serum, a significant decrease in the volume of the prostate gland, a decrease in the male sex hormones in the blood serum (testosterone and LH) in all patients are below normal. Based on the decision of the Presidium of the FC of the Ministry of Health of the Republic of Uzbekistan No. 16 dated July 21, 2015, Ferulen was approved as a medicine for use in medical practice in patients with benign hyperplasia (BPH) and prostate adenocarcinoma.

According to the content of the active substance and excipients, the compared preparations do not differ. In both cases, the content of ferulen in one tablet or capsule is 40 mg.

The study of the nature of the resorptive action and the acute toxicity parameters of the compared preparations was carried out in experiments on outbred white mice males weighing 24-26 grams. with the intragastric method of use. The drug was administered as a suspension

using an atraumatic metal probe in doses from 4000 mg / kg to 7000 mg / kg. Each dose of the drug was tested in 5 animals. Higher doses (5000 - 7000 mg / kg) were administered fractionally.

The control group of animals under similar experimental conditions was injected with distilled water. After drug administration, experimental animals were monitored for 14 days. The average lethal dose was determined by the Litchfield-Wilcoxon method [3].

A comparative study of the effect of Prostanik and Ferulen produced by "NIKA PHARM" LLCon androgen-dependent organs (ventral prostate, coagulating gland, seminal vesicles, testes) was evaluated in adult, intact male rats weighing 280-300 g.

Conducting experiments on normal animals is justified by the fact that adenoma and prostate cancer cells respond to androgen deprivation like normal cells (on which endrocrine therapy is based, on the other hand), and normal animals can be used for such an assessment, especially since the known experimental models of adenomas and cancer prostate gland are not identical to human prostate adenocarcinoma. The possibility of extrapolating the pharmacodynamic data obtained on the normal prostate gland of rats to patients with prostate adenocarcinoma and the adequacy of the results of preclinical studies of hormonal and antihormonal drugs in relation to their expected therapeutic efficacy in humans is confirmed by international experience in the experimental and clinical pharmacology of drugs for the treatment of prostate cancer [4].

In order to make a comparative assessment of the effect on androgen-dependent organs, the preparations were administered orally to male rats using an atraumatic metal probe at a dose of 10 mg / kg daily once a day for 14 days. Each dose of the drug was tested in 10 rats. The control group of animals under similar experimental conditions was injected with a solvent (dist. Water with the addition of apricot gum). After the end of the experiment, all experimental and control animals were decapitated, the mass of the ventral prostate, coagulating gland, seminal vesicles and testes were determined.

With a further increase in the dose of the drug, the above symptoms of poisoning intensified and the death of some experimental animals within 1-2 days after the administration of drugs. The completely lethal dose for mice was 7000 mg / kg. The results of comparative

studies to determine the parameters of acute toxicity during intragastric administration are presented.

A comparative study of ferulen on the mass of androgen-dependent organs in rats - male mg / 100g body weight in comparison with intact animals (n = 10)

Drug name	Dose mg / kg	Route of administration	Ventral prostate	Coagulating prostate	Seminal vesicles	Testis
Control	dist. water	into the stomach	90,5±5,9	63,6±4,2	198,6±10,2	1125,0±92,0
Outskirts of production of OOO "NIKA PHARM"	10,0	into the stomach	24,8±2,5*	22,8±2,2*	81,1±6,6*	585,2±45,0*
Ferulen production	10,0	into the stomach	23,5±2,4*	24,0±2,7*	77,4±6,3*	605,0±48,5*

* P <0.001 compared to control

Thus, the results of the studies showed that compared to the drug manufactured by LLC "NIKA PHARM" in terms of acute toxicity with the oral route of administration belong to the category of low-toxic substances. Both compared drugs according to the picture of poisoning, the onset of toxic effects practically do not differ from each other.

The results of studies on the evaluation of the effect on androgen-dependent organs showed that oral administration of the prostic drug produced by NIKA PHARM LLC at a dose of 10 mg / kg for 14 days reduces the mass of the ventral prostate, coagulating gland, seminal vesicles of the testes compared to the control group of rats by 72 6%; 64.2%, 59.2% and 48.0%, respectively, and with the introduction of ferulene produced by the mass of the ventral prostate decreased by 74%; coagulating gland by 62.3%; seminal vesicles by 61.1% and testes by 46.3% .

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