TRANSLATED FROM RUSSIAN

ACUTE TOXICITY TESTS OF THE MATERIAL

1. The acute toxicity of the material was studied in accordance with GOST R ISO 10993.11-99 “Medical devices. Studying of biological action of medical devices. Part 11. Research of general toxic action. Supplement B. Methods of studying of general toxic action. Supplement B1. Determination of acute toxicity on white mice”.

The experimental animals were kept in accordance with GOST R ISO 10993.2-99 “Medical devices. Studying of biological action of medical devices. Part 2. Regulations on protection of animals”.

Samples
The material is submitted in a sterile form. “ARGIFORM” is filled in disposable injection plastic syringes, which are tipped and vacuum-sealed in individual blister packaging. Each set consisting of a blister packaging with a syringe and an injection cannula which are packed into a separate branded carton box. The marking, description and the trademark are printed on the boxes.

2. Description and results

Acute toxicity was studied on white mice. The material was introduced intraperitoneally using a standard syringe in the amount of 50 ml/kg (of body mass) to 20 outbred male white mice with a body mass of 18-20 g.
The control animals received distilled water injection. The animals were kept in full correspondence with the sanitary norms.
During all the observation period (24 hours) there were neither deaths of the experimental animals, nor changes of their outward appearance, behavior, motion activity by comparison with the control animal group.
At the end of the experiment all of animals were withdrawn by decapitation.
The content of hemoglobin, leucocytes and red corpuscles in peripheral blood, the content of total protein and the ratio of protein fractions in blood serum were determined.
Results of examination of the animals are shown in table #1.

Table #1
Blood indices of mice during an acute experiment of an intraperitoneal injection of the material

Indices	Control	Test	R
White blood cells, 10^9/l	6.100±0.357	6.700±0.502	>0.05
Red blood cells, 10^{12}/l	8.400±0.218	8.100±0.107	>0.05
Hemoglobin, g/l	126.000±6.075	121.00±3.550	>0.05
Total serum protein, %	7.600±0.077	7.400±0.083	>0.05
Serum protein fractions of, %			
- Albumins	45.000±0.803	45.300±0.731	>0.05
- α1-globulins	7.100±0.640	5.400±0.792	>0.05
- α2-globulins	15.700±0.539	16.300±0.761	>0.05
- β-globulins	23.500±1.046	25.500±0.885	>0.05
- γ-globulins	8.700±0.667	7.500±0.563	>0.05

The weight coefficients of the internal organs were also calculated by the formula:

$$C = \frac{M_{organ},\ in\ mg}{M_{body},\ in\ g}$$

It follows from the data given in table #2 that the mass coefficients of the internal organs of the experimental animals have no statistically reliable differences from the similar indices of the control animals.

Table #2
Body mass and weigh coefficients of the internal organs of mice in an acute experiment of an intraperitoneal introduction of the material

Indices	Control	Test	R
Body mass, g	18. 458±0.453	19.813±0.232	>0.05
Internal organs, mg:			
– liver	50.188±1.204	47.804±1.804	>0.05
– spleen	3.535±0.233	3.164±0.359	>0.05
– kidneys	14.915±0.233	13.908±0.465	>0.05

3. Conclusions

After the prosection there were seen no macroscopic pathological changes of the internal organs or tissues at the experimental animals. The material is freely located into the abdominal cavity; there were found no symptoms of an inflammation of the peritoneum or intestines. A pathomorphological study didn't reveal any changes in the histological structure of the internal organs.

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