Translated from Russian:

TESTING LABORATORY CENTER
Federal Medical Research Institute of
Physico-Chemical Medicine,
Certificate № ROSS KU.0001.21IMZZ
from September 27, 2007, recorded in
Unified register as of September 27, 2007,
valid until September 27, 2010

"APPROVED"
Head of Testing Laboratory Centre,
Research Institute of Physico-Chemical
Medicine
Member of RAMS, Professor V.I. Sergienko

(signature) 27th of February, 2008

Test results and the report are valid only for the samples submitted for testing

PROTOCOL № 651.008 dated February 27, 2008

Toxicological tests, local irritating effect and hemolytic activity of medical products (materials), establishing their biological safety.

Name of product (material):
Material hydrous biopolymer gel with silver ions Argiform, Technical Specification TU 9398-001-52820385-2005: surgical use – trademark ARGIFORM, urology – trademark DAM+, traumatology and orthopedics - NOLTREX

Manufacturer:
JSC "Research Center "Bioform", Russia

Material:
Materials are not listed by the manufacturer

Tested in accordance with:

Standards of GOST R ISO 10993 "Biological evaluation of medical devices"

"The collection of guidance papers for toxicological and hygienic studies of polymer materials and products based on medical purpose ", USSR Ministry of Health, 1987

GOST 51148-98 "Medical devices. Requirements for samples and documentation presented for toxicological tests, sanitary and chemical analyses, tests for sterility and pyrogenicity."

GN 2.3.3972-00 "MPC of chemicals released from materials contacting with food."

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Material hydrous biopolymer gel with silver ions Argiform, Technical Specification TU 9398-001-52820385-2005: surgical use – trademark ARGIFORM, urology – trademark DAM+, traumatology and orthopedics - NOLTREX

Manufacturer: JSC "Research Center "Bioform", Russia
The product is presented for testing by: JSC "Research Center "Bioform", Russia

Parameters tested and verification devices used:

№	Parameter	Verification devices and laboratory animals used in test
1.1	**Oxidizable impurities**	1 Electronic Scales "V-200", Acculab, USA 2. Stopwatch 3. Automatic buret OP-930/1 4. Measuring utensils 5 Reagents according to methodology
1.2	**Change in pH-extraction**	1. pH-meter H11131B/T "HANNA instruments", Portugal
1.3	**Ultraviolet absorption**	1. Spectrophotmeter DU-65 "Backman", Germany
1.4	**Toxicological characteristics** ***Irritating effect on the skin and mucous membrane of animals (in points)*** **Erythema** no erythema …….. (0) weak erythema …… (1) clear erythema …….. (2) moderate erythema …… (3) severe erythema (beetroot red) …….. (4) **Swelling** no swelling ……. (0) mild swelling …….. (1) marked swelling …… (2) moderate swelling (up to 1mm high)…(3) severe swelling (over 1mm high) …… (4) **Effect on conjunctiva of rabbit** no reaction ……..... (0) slight redness of the conjunctiva …….. (1) conjunctiva redness and sclera partially..(2) sudden redness of conjunctiva and a whole sclera, purulent ophthalmitis …….. (3)	1. Rabbits 2. White rats 3. White mice 4. Eyedroppers 5. Glass spreader 6. Syringe 1ml. 7. Electronic Scales "V-200", Acculab, USA
1.5	**Determination of acute toxicity in white mice**	
1.6	**Determination of hemolytic activity**	1. Rabbits 2. Centrifuge 3. Spectrophotmeter DU-65 "Backman", Germany 4. Measuring utensils 5. Reagents according to methodology
1.7	**Determination of metal contents (copper, lead, chromium, cadmium, barium, tin)**	1. atomic absorption spectrophotometer "Hitachi", 180-80, Japan

Testing results:

№	Parameter	Permissible values	Results	Conclusion
2.1	Oxidizable impurities	less than 1,0ml. (0,02 normal sodium thiosulfate solution)	0.31	complies
2.2	Change in pH-extraction	less than ± 1,0	0,2	complies
2.3	Ultraviolet absorption	less than 0,3 (range 230-260nm.)	0,12	complies
2.4	**Toxicological test results**			
2.4.1	***Irritating effect on the skin and mucous membrane of animals in points***			
	Skin	0	0	complies
	Conjunctiva of rabbit	0	0	complies
2.5	***Acute toxicity in white mice at intra-abdominal introduction***			
	Deaths	none	none	complies
	Clinical symptoms of intoxication	none	none	complies
	Macroscopic changes of organs and tissues	none	none	complies
	Weight coefficient of visceras (observed changes)	none	none	complies
2.6	**Hemolytic activity**	less than 2 %	0,42	complies
2.7	**Toxicity index**	70 - 120 %	84	complies
2.8	***Metal concentrations in the material extract***			
	Copper (Cu)	less than 1,0 mg/l	0,01	complies
	Lead (Pb)	less than 0,03 mg/l	0,01	complies
	Chromium (Cr)	less than 0,1 mg/l	0,01	complies
	Cadmium (Cd)	less than 0,001 mg/l	0,0001	complies
	Barium (Ba)	less than 0,1 mg/l	0,01	complies
	Tin (Sn)	less than 0,1 mg/l	0,01	complies
2.9	Formaline	less than 0, 1 mg/l	0	complies
2.10	***Sterility and pyrogenicity of samples***			
	Sterility	sterile	------	complies
	Pyrogenicity	non-pyrogenic	------	complies

CONCLUSION

Material hydrous biopolymer gel with silver ions Argiform, Technical Specification TU 9398-001-52820385-2005: surgical use – trademark ARGIFORM, urology – trademark DAM+, traumatology and orthopedics - NOLTREX

Manufaturer:

JSC "Research Center "Bioform", Russia

non-toxic, complies with the requirements of reference documentation.

Signed by:

Laboratory Chief	(signature)	A.K. Martynov
Junior Research Associate	(signature)	I.V. Artemkina