taking place, resulting in disruption of protein synthesis. Interaction with phenolic groups of iodine tyrosine leads to breaking of hydrogen bonds in these amino acids. Affecting double carbon bonds of unsaturated fatty acids, iodine thereby changes the properties of lipids.

The ability of iodine to easily penetrate through cell membranes makes its application more valuable for those infections, the main development of which takes place in intracellular structures (brucellosis, clamidiosis, hepatitis, etc.).

There is a known drug *Yodomidol*, with bactericidal and virucidal activity, containing iodine, potassium or sodium iodide, synthetic water-soluble polymer, natural polymers such as polysaccharides and mono- and oligosaccharides, in the following ratio, g/L:

iodine	6-10
potassium iodide	9-15
synthetic water-soluble polymer	2-4
natural polymer (polysaccharides) and mono- and oligosaccharides	8-120
water	Balance

(KZ 6730B, 16.11.1998).

Disadvantage of this drug is its relatively high toxicity.

There is a known virulicidal pharmaceutical product (EP 0978289 A1, 02.09.2000), with antiviral activity, which contains iodine, potassium or sodium iodide, synthetic water-soluble polymer, a mixture of natural mono-, oligo- and polysaccharides and lithium chloride with the following components ratio, g/L:

iodine йод	0,8 – 25
potassium iodide	1,2 – 38
lithium chloride	0,1 – 20
synthetic water-soluble polymer	0,01 – 6
mono-, oligo- and polysaccharides	8– 400
water	Balance

There is a known bactericidal and virucidal pharmaceutical product for

In all of the above known patents, authors did not set the task of synthesizing complex compounds with a given structure and properties, or excreting complex compounds from solutions and determining their composition and physical-chemical properties, which makes it hard to use complex iodine compounds with carbohydrates and proteins with biocidal properties as medicinal products. Moreover, the development of appropriate dosage forms, without a specific set of properties and qualities of complex iodine compounds - antibacterial agents, characterized by physical and chemical properties and composition, is hindered.

In recent years, some works devoted to exploration of the structure of complex compounds of carbohydrates with salts of magnesium, calcium and other complexing agents have appeared in scientific literature (*O.Nimz, K.Geßler, I.Uson, W.Saenger // Carbohydrate Research 2001. V. 336. P.141–153.; M.Noltemeyer, W. Saenger // JACS 1980.V.102:8.9.P.2710.; M.Noltemeyer, W. Saenger // Nature.1976.V.259. 26.P.629).*

Crystalline structure of a whole number of enzymes with having in its composition ions of magnesium, potassium, calcium, lithium, in their composition, i.e., metal salts, has been established. (*Y.Goldgur, F.Dyda, A.B.Hickman, T.M.Jenkins, R.Craigie, D.R.Davies // Proc.Natl.Acid.Sci USA 1998. V.95. №16. P.9150-9154.; F.Dyda, A.B.Hickman, T.M.Jenkins, A. Engelman, R.Craigie, D.R.Davies // Science. 1994. V.266. P.1981-1986*).

At the same time there are no works involving a purposeful synthesis of iodine coordination compounds with a tailored nanoscale structure and, accordingly, tailored biocidal properties, suitable for implementation of a mechanism of action of these compounds.

Thus, the object of this invention is to create antibacterial agent (ABA) for the treatment of diseases of bacterial origin, including hospital acquired diseases and drug resistant TB.

Additional objectives of this invention are to develop a method for preparation of antibacterial agent and ABA based drug to treat infectious diseases

using an automated hematology analyzer Celly v 2.20, Hycel Diagnostics.

The recovery of bone marrow hematopoietic function was estimated using clonogenic test. [Bezirganyan K.B., Davtyan T.K., Galoyan A.A. Hypothalamic proline rich polypeptide regulates hematopoiesis / / Neurochem. Res. - 2010. - Vol. 35. - CL. 917-924], by determining the number of granulocyte-monocyte colony-forming (CFU-GM) progenitor bone marrow cells. For this purpose, bone marrow cells were cultured in a medium Methocult™ GF R3774, containing methylcellulose and growth factors, progenitor cells (stem cell factor, GM-CSF and IL-3), StemCell Technologies Inc (cat № 03774).

Example No. 1 FS-1.1

ABS synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. Temperature is maintained using thermostat "HUBER" - Ministat 230 CC2. 130g of carbohydrate is dissolved in 500 ml of water at 50°C. Further, 3.0g of sodium chloride and 1.98mg of calcium chloride dissolved in 100ml of water are added. The mixture is thoroughly stirred and cooled to 43°C (Product A).

5.0 g of albumin are dissolved in 150 ml of water and then 3.96g of lithium chloride, 8.4g magnesium chloride and 2.0g of sodium chloride added (Product B). 135 ml of the resulting solution is poured in the reactor. Reactor mixture is agitated for 20 minutes, and after that the solution temperature reduced to 25 °C.

0.82 g of I_2 and и 1.2 g of potassium iodide are dissolved in 100 ml of water (Product B). 70 ml of the resulting solution is poured in portions in the reactor. Iodine intercalation is performed for 2 hours at 25 ^{o}C, and after that the rest 15ml of Product B are added. After 1 hour, another 30 ml of Product B is added in portions into reactor, and iodine intercalation is completed within 2 hours.

Ionic strength of the solution is 13.6.

The resulting ionic nanostructured ABS complex is extracted from the reaction medium using a suitable method, for example, centrifugal chromatography method in "Kromaton" FCPC (Fast Centrifugal Chromatography), and dried (Fig.

10(a)).

Analysis results:

	Dextrin	Albumin	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fractions, %	**0.40**	**0.59**	**63.58**	**0.02**	**0.01**	**11.62**	**10.62**	**2.21**	**10.95**

$$[5280L_1 \cdot 1{,}5L_2 \cdot 33I_2] \cdot L_3$$

Example No. 2 FS-1.2

ABS synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 108.3g of dextran is dissolved in 500 ml of water at 45°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 2.5g of PVA dissolved in 150 ml of water, 4.0 g of sodium chloride and 1.65g of calcium chloride dissolved in 100ml of water, are added. The mixture is thoroughly stirred and cooled to 43°C (Product A).

4.17g of albumin is dissolved in 150 ml of water, and then 3.3g of lithium chloride, 7.0g of magnesium chloride and 0.17g of sodium chloride are added. The resulting solution is transferred to the reactor when the temperature of Product A specified above is reached. The mixture is stirred for 20 minutes, and after that the temperature of reaction zone is reduced to 25°C (Product B).

2.0g of I_2 and 3.0g of potassium iodide are dissolved in 100 ml of water. The resulting solution is poured in portions into the complex compound solution (Product B). Iodine intercalation is performed for 4 hours at 25°C.

Ionic strength of the solution is 13.2.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10 (b)).

Analysis results:

	Dextrin	Albumin	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fractions, %	**62.35**	**0.02**	**0.01**	**11.40**	**10.40**	**10.74**	**2.2**	**1.15**	**1.73**

$$[38L_1 \cdot 1{,}5L_2 \cdot 97I_2] \cdot L_3$$

Example No. 3 FS-1.3

ABS synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 72.0 g of carbohydrate is hydrolyzed in 600 ml of water at 60°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 1.7 g of PVA dissolved in 100 ml of water, 2.8g of sodium chloride and 1.1g of calcium chloride dissolved in 100ml of water are poured in. The mixture is thoroughly stirred and cooled to 43°C (Product A).

2.8 g of albumin is dissolved in 150 ml of water, and then 2.2 g of lithium chloride, 4.66 g of magnesium chloride and 0.8 g of sodium chloride are added. The resulting solution is transferred to the reactor when the temperature of Product A specified above is reached. The mixture is stirred for 20 minutes, and after that the temperature in reaction zone is reduced to 25°C (Product B).

Ionic strength of the solution is 10.8

4.1 g of I_2 and 6.0g of potassium iodide are dissolved in 100 ml of water. The resulting solution is poured in portions into the complex compound solution (Product B). Iodine intercalation is performed for 4 hours at 25°C.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10 (c)).

Analysis results:

	Dextrin	Albumin	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fractions, %	**0.96**	**0.04**	**0.03**	**24.38**	**22.46**	**22.95**	**4.65**	**7.57**	**16.96**

$$[611L_1 \cdot 24L_2 \cdot 294I_2] \cdot L_3$$

Example No. 4 FS-1.4

ABS synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 72.0 g of carbohydrate is hydrolyzed in 550 ml at 100°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 1.7 g of PVA dissolved in 250 ml of water is poured in (Product A). The mixture is thoroughly stirred during 20 min, after that the temperature in reaction zone is reduced to 25°C.

4.1 g of I_2 and 6.0g of potassium iodide are dissolved in 200 ml of water. The resulting solution is poured in portions into the complex compound solution (Product B). Iodine intercalation is performed for 4 hours at 25°C.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10 (d)).

Ionic strength of the solution is 3.02.

Analysis results:

	Carbohydrate	PVA	I_2	KI
Mole fractions, %	**29.67**	**66.45**	**3.78**	**0.10**

$$[37L_1 \cdot 294I_2] \cdot L_3$$

Example No. 5 FS-1

ABS synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 130 g of mixture of amylase and amylopectin in the ratio of 1:4 is dissolved in 500 ml of water at 43°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 3.0 g of PVA dissolved in 150 ml of water, 4.5 g of sodium chloride, and 2.0 g of calcium chloride dissolved in 100 ml of water are poured in (Product A).

5.0 g of albumin is dissolved in 150 ml of water, and then 4.0 g of lithium chloride, 8.4 g of magnesium chloride and 0.5 g of sodium chloride are added. The resulting solution is transferred to the reactor. The mixture is stirred for 20 minutes, and after that the temperature of reaction zone is reduced to 25°C (Product B).

8.2 g of I_2 and 12.1 g of potassium iodide are dissolved in 100 ml of water. The resulting solution is poured in portions into the complex compound solution (Product B). Intercalation of iodine is carried out in two stages, as described in the previous examples.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 11).

Ionic strength of the solution is 20.60.

Analysis results:

	Amylum	Albumin	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fracture, %	**0.94**	**0.04**	**0.02**	**23.90**	**21.62**	**22.31**	**4.56**	**8.17**	**18.44**

$$\left[38L_1 \cdot 2L_2 \cdot 333I_2\right] \cdot L_3$$

Example No. 6 FS-1.5

ABS synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 24.1 g of carbohydrate is hydrolized in 500 ml of water at 80°C until a certain molar weight is reached. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 2.8 g of PVA dissolved in 150 ml of water is poured in. The mixture is thoroughly stirred and cooled to 43°C (Product A).

34.0 g of I_2 and 50.5 g of potassium iodide are dissolved in 100 ml of water. The resulting solution is poured in portions into the complex compound solution (Product C). Intercalation of iodine is carried out in two stages, during 4 hours at 25°C.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10 (d)).

Ionic strength of the solution is 25.3.

Analysis results:

	Carbohydrate	PVA	I_2	KI
Mole fractures, %	**0.16**	**0.02**	**30.50**	**69.32**

$$[8L_1 \cdot 1488I_2] \cdot L_3$$

Example No. 7 FS-1.6

ABS synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 24.1 g of carbohydrate is hydrolized in 500 ml of water at 100°C until a certain molar weight is reached. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 2.8 g of PVA dissolved in 150 ml of water, 0.8 g of sodium chloride, and 0.37 g of calcium chloride dissolved in 100 ml are poured in. The mixture is thoroughly stirred and cooled to 43°C (Product A).

0.93g of albumin is dissolved in 150 ml of water, and then 0.73g of lithium chloride, 1.55g of magnesium chloride and 0.13g of sodium chloride are added. The resulting solution is transferred to the reactor after the required Product A temperature specified above is reached. The mixture is stirred for 20 minutes

(Product B) and after that the temperature of reaction zone is reduced to 25 °C.

34.0 g of I_2 and 50.5 g of potassium iodide are dissolved in 100 ml of water. The resulting solution is poured in portions in the complex compound solution (Product C). Intercalation of iodine is carried out in two stages, during 4 hours at 25°C.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10(e)).

Ionic strength of the solution is 27.9.

Analysis results:

	Carbohydrate	Albumin	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fractures, %	**0.14**	**0.006**	**0.02**	**3.51**	**3.23**	**3.31**	**0.68**	**27.23**	**61.70**

$$[26L_1 \cdot L_2 \cdot 4970I_2] \cdot 3L_3$$

Example No. 8 FS-1.7

ABS synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 130.0 g of dextrin and 3.0 g 0f PVA is dissolved in 500 ml of water at 50°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 4.0 g of sodium chloride and 2.0 g of calcium chloride dissolved in 100 ml of water are poured in. The mixture is thoroughly stirred and cooled to 43°C (Product A).

5.0 g of albumin is dissolved in 150 ml of water, and then 4.0 g of lithium chloride, 8.4 g of magnesium chloride and 1.0g of sodium chloride are added. The resulting solution is transferred to the reactor after the required Product A temperature specified above is reached. The mixture is stirred for 20 minutes (Product B), and after that the temperature of reaction zone is reduced to 25°C.

8.2 g of I_2 and 12.1g of potassium iodide are dissolved in 100ml of water. 70

ml of the resulting solution is poured in portions in the complex compound solution (Product B). Iodine intercalation is carried out in two stages during 4 hours at 25°C.

0.6g of IL-2 is dissolved in 150 ml of water and slowly added to the reactor. 30 minutes after the charge of IL-2, 20 ml of Product B is added to the reactor. The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10(f)).

Ionic strength of the solution is 20.60.

Analysis results:

	Dextrin	Albumin	IL-2	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole percent, %	**0.94**	**0.04**	**0.01**	**0.02**	**23.9**	**21.62**	**22.30**	**4.56**	**8.17**	**18.44**

$$\left[79L_1 \cdot 3L_2 \cdot Il - 2 \cdot 684I_2\right] \cdot 2L_3$$

Example No. 9 FS-1.8

ABS synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 13.1 g of carbohydrate is hydrolyzed in 100 ml at 130°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 3.0 g of PVA dissolved in 150 ml of water, 0.3 g of sodium chloride and 0.2 g of calcium chloride dissolved in 100 ml of water are poured in (Product A). The mixture is thoroughly stirred and cooled to 43°C. Синтез АБА проводят в лабораторном реакторе фирмы «QVF ENGINEERING» GMBH D-55122 Mainz тип RührgefäB 2L при постоянном перемешивании.

0.51 g of albumin is dissolved in 150 ml of water, and then 0.4 g of lithium chloride, 0.84 g of magnesium chloride and 0.2 g of sodium chloride are added.

The resulting solution is transferred to the reactor after the required Product A temperature specified above is reached. The mixture is stirred for 20 minutes (Product B), and after that the temperature in reaction zone is reduced to 25°C.

74.5 g of I_2 and 110.0 g of potassium iodide are dissolved in 500 ml of water. The resulting solution is poured in portions in the complex compound solution (Product B). Intercalation of iodine is carried out in two stages, during 4 hours at 25°C.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10(g)).

Ionic strength of the solution is 56.3.

Analysis results:

	Carbohydrate	Albumin	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fractures, %	**0.04**	**0.002**	**0.01**	**0.96**	**0.87**	**0.9**	**0.18**	**29.8**	**67.31**

$$[25L_1 \cdot L_2 \cdot 19575I_2] \cdot 7L_3$$

In biological activity testing it was established that ABA FS-1 is active *in vitro* both against clinical isolates, and control strains of MRSA and MSSA. MIC of antimicrobial agent was varied from 0.938 mg/ml to 0.234 mg/ml.

Tests for synergy with oxacillin have shown a decrease in MIC of both drugs. The decline was from 256 to 64 μg/ml for oxacillin, and from 0.234 to 0.117 μg/ml for ALA FS-1. FIC index for this test was 0.75, which can be regarded as a partial synergy between the tested drugs.

Test for synergy with cefamandole has shown a decrease in MIC of both drugs. The reduction ranged from 64 to 8 μg/ml for cefamandole, and from 0.469 μg/ml to 0.234 μg/ml for ABA FS-1. FIC index for this test was 0.62, which determines the interaction of these antibiotics as a partial synergy.

Test for synergy with lincomycin has shown a decrease in MIC of both drugs. The reduction ranged from 64 μg/ml to 8 μg/ml for lincomycin, and from 0.234 mg/ml to 0.117 mg/ml for ABA FS-1. FIC index for this test was 0.625, which determines the interaction of these antibiotics as a partial synergy.

ABA in Examples 1-9 (FS-1.1 - FS-1.8) has a greater or lesser bactericidal activity against pathogenic microorganisms of different classes (Table 6). The most acceptable and effective one, as follows from Table 6, with respect to Mycobacterium tuberculosis, is ABA in Example 5 (FS-1).

As the result of studying FS-1 antimycobacterial action against *M.tuberculosis H37Rv, M.tuberculosis MS-115* with multidrug-resistance, and *M. bovis*, it was established that at the drug concentrations in dilutions of 1:12.5, 1:25 and 1:50 a complete suppression of reproduction of mycobacteria was observed throughout the entire registration period.

Bactericidal activity of FS-1 was evaluated *in vitro* using a microbiological method of double serial dilutions in Shkolnikova liquid medium, with subsequent passaging on Levenstein-Jensen medium. *In vitro* bactericidal activity of FS-1 at concentrations ranging from 1.750 to 0.0437 mg/ml in field strains of mycobacteria, drug-resistant clinical isolates and *M. tuberculosis N37Rv* has been established. Bacteriostatic effect of FS-1 is observed in concentrations from 0.0218 to 0.0109 mg/ml.

Bactericidal activity of FS-1 *in vitro* in concentration of 0.0437 mg/ml in combination with anti-TB drugs, Type I, with subsequent passaging on Levenstein-Jensen medium in relation to museum strain *M. tuberculosis N37Rv* and 8 multi-drug resistant strains, was evaluated. The research identified, with various concentrations of anti-TB drugs of Type I, museum sensitive and multidrug-resistant strains. The results are presented in Table 7.

As can be seen from Table 7, after the combined action of FS-1 with different concentrations of anti-TB drugs, the growth of multidrug resistant strains of *Mycobacterium tuberculosis* was not detected in experimental test tubes, i.e. strains were susceptible to all concentrations of anti-TB drugs of Type I, in comparison

Table 1 – ABA composition

Example No.	Compound	I_2, g/L	KI, g/L	Carbohydrate, g/L	Protein		PVA, g/L	LiCl, g/L	NaCl, g/L	$CaCl_2$, g/L	$MgCl_2$, g/L	Ionic strengh
					Albumin, g/L	IL-2 mg/L						
1	FS-1.1	0.82	1.2	130.0	5.0	—	3.0	3.96	5.0	1.98	8.4	13.6
2	FS-1.2	2.0	3.0	108.3	4.17	—	2.5	3.3	4.17	1.65	7.0	13.2
3	FS-1.3	4.1	6.0	72.0	2.8	—	1.7	2.2	2.8	1.1	4.66	10.8
4	FS-1.4	4.1	6.0	72.0	—	—	1.7	—	—	—	—	3.02
5	FS-1	8.2	12.1	130.0	5.0	—	3.0	4.0	5.0	2.0	8.4	20.60
6	FS-1.5	34.0	50.5	24.1	—	—	2.8	—	—	—	—	25.3
7	FS-1.6	34.0	50.5	24.1	0.93	—	2.8	0.73	0.93	0.37	1.55	27.9
8	FS-1.7	8.2	12.1	130.0	5.0	0.6	3.0	4.0	5.0	2.0	8.4	20.60
9	FS-1.8	74.5	110.0	13.1	0.51	—	3.0	0.4	0.5	0.2	0.84	56.3

Table 2 - Output of complex Mg2 + n4I3-n6 depending on I_2 excess compared to the stoichiometric content,%

Calculated	78	86	94
Experimental	74	82	93
I_2 excess from от	0	20	50

Table 3 - Output of complex $Ca^{2+}_{n5}I_3^-{}_{n7}$ depending on I_2 excess compared to the stoichiometric content, %

Calculated	71	82	89
Experimental	68	76	85
I_2 excess from от	0	20	50

Table 4 - Spatial (lengths of coordination bonds (Å)) and energy (stabilization energy ΔE, kcal/mol) characteristics of I-IV complexes.

	I	II	III	IV
Li - I	2.93	2.96	2.97	2.80
N(O)-I	2.46	2.40	2.76	2.18
I-I	2.76	2.82	2.72	3.03
-ΔE	16.60	14.26	6.25	24.25

Table 5 - CC 50 and MNC for different series of the substance FS-1 in MDCK cell culture after 72-hour incubation

Drug name	Drug dilutions	
	CC 50	**MNC**
FS-1	1:20	1:80
ABA-1	1:50	1:100
ABA-2	1:800	1:3200
ABA-3	1:100	1:200
ABA-4	1:50	1:6400
ABA-5	1:1460	1:3200
ABA-6	1:5063	1:6000
ABA-7	1:565	1:1500
ABA-8	1:3637	1:6400

Table 6 - Bactericidal activity against microorganisms of different pathogenicity groups

Microorganism name	Minimum inhibitory concentration of the complex compound after the Example, mg/ml								
	1	2	3	4	5	6	7	8	9
Escherichia coli INMIA 5002 (ATCC 11303)	2.5	1	1	1	1	2.5	1	1	2.5
Escherichia coli INMIA 5230	2.5	1	1	1	1	2.5	1	1	2.5
Staphylococcus aureus INMIA 5233	2.5	1	1	1	1	5	1	1	2.5
Serratia marcescens INMIA 5251 (ATCC 9986. Bu 211. IFO 3736)	2.5	1	1	1	2.5	5	1	1	2.5
Mycobacterium spp INMIA 5237 (штамм B-5)	7	1	1	1	0.0437	7	1	1	7
Pseudomonas fluorescens	2.5	1	1	1	0.5	2.5	1	1	2.5

	60	-	30	42
Group 3 Test animals infected with *M. tuberculosis* $H_{37}R_v$ and treated with TBD	39	7	17	18
	46	14	11	8
	53	21	9	7
	60	28	3	2
	67	35	-	-
Group 4 Test animals infected with *M. tuberculosis* $H_{37}R_v$ and treated with FS-1	39	7	11	13
	46	14	10	9
	53	21	4	7
	60	28	-	-
	65	33	-	-
Group 5 Test animals infected with *M. tuberculosis* $H_{37}R_v$ and treated with TBD and FS-1	39	7	16	7
	46	14	6	5
	53	21	-	-
	60	28	-	-
	67	35	-	-
Group 6 Test animals infected with multiresistant strains of mycobacteria and treated with TBD	39	7	11	14
	46	14	14	16
	53	21	21	24
	60	28	20	23
	67	35	35	27
Group 7 Test animals infected with multiresistant strains of mycobacteria and treated with FS-1	39	7	12	14
	46	14	10	9
	53	21	4	5
	60	28	2	-
	66	35	-	-
Group 8 Test animals infected with multiresistant strains of mycobacteria and treated with TBD and FS-1	39	7	13	17
	46	14	3	7
	53	21	-	-
	60	28	-	-
	67	35	-	-

Table 9 – Haemagglutinin titre of the residual influenza virus HAU

Substance name	Substance content, mg/ml	Virus dilutions								Titr.,HAU
		1/2	1/4	1/8	1/16	1/32	1/64	1/128	1/256	
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
FS-1	0.188	----	----	----	----	----	----	----	----	0
	0.094	++++	++++	----	----	----	----	----	----	4
	0.047	++++	++++	++++	----	----	----	----	----	8
ABA-1	5.0	++++	++++	++++	++--	----	----	----	----	12
	2.5	++++	++++	++++	++--	----	----	----	----	12

Substance name	Substance content, mg/ml	Virus dilutions								Titr.,HAU
		1/2	1/4	1/8	1/16	1/32	1/64	1/128	1/256	
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
	1.25	++++	++++	++++	++++	++--	----	----	----	24
ABA-2	0.31	++++	++++	++++	++++	++++	----	----	----	32
	0.16	++++	++++	++++	++++	++++	++--	----	----	48
	0.08	++++	++++	++++	++++	++++	++--	----	----	48
ABA-3	2.5	++++	++++	++++	++++	++++	----	----	----	32
	1.25	++++	++++	++++	++++	++++	----	----	----	32
	0.63	++++	++++	++++	++++	++++	++--	----	----	48
ABA-4	5.0	++++	++--	----	----	----	----	----	----	3
	2.5	++++	++--	----	----	----	----	----	----	3
	1.25	++++	++++	++++	++++	++++	++++	----	----	64
ABA-5	0.2	++++	++++	++++	++--	----	----	----	----	12
	0.1	++++	++++	++++	++--	----	----	----	----	12
	0.05	++++	++++	++++	++++	++++	++--	----	----	48
ABA-6	0.05	++++	++++	++++	++++	++--	----	----	----	24
	0.025	++++	++++	++++	++++	++++	++--	----	----	48
	0.01	++++	++++	++++	++++	++++	++--	----	----	48
ABA-7	0.4	----	----	----	----	----	----	----	----	0
	0.2	----	----	----	----	----	----	----	----	0
	0.1	----	----	----	----	----	----	----	----	0
ABA-8	0.06	++++	++++	++++	++++	----	----	----	----	8
	0.03	++++	++++	++++	++++	----	----	----	----	16
	0.015	++++	++++	++++	++++	++--	----	----	----	24
Virus control		++++	++++	++++	++++	++++	++++	++--	----	96

Note:
«++++» - 100% «umbrella» hemagglutination
«+++» - 75% hemagglutination
«++» - 50% hemagglutination
«++» - 25% hemagglutination
«-» - no hemagglutination

Table 10 – Determination of FS-1 antiviral activity against influenza virus A/FPV/Waybrige/78/H7N7 in MDCK cell culture after 72 hours

Well number	Active substance content, mg/ml					
	0.038	0.019	0.009	0.005	0 (Cells control)	0 (Virus Control)
1	----*	----	++--	+++-	----	++++
2	----	----	++--	+++-	----	++++
3	----	----	++--	+++-	----	++++
4	----	----	++--	+++-	----	++++

Notes:
1 «*» - CPE manifestation degree
2 «++++» - pronounced degradation of cell monolayer.
3 «----» – no cell degradation.

Table 17 – Acute toxicity characteristics (LD50 mg/kg)

Example	Mice	Rats
Enteral route of administration		
ABA	330	243
ABA	579,25	360,5
ABA (FS-1)	n.d.	n.d.
Parenteral route of administration		
ABA	65	48
ABA	106	75
ABA (FS-1)	213	100

N.d. – not detected

Table 18 – Results of studying FS-1 cumulative toxicity in mice

FS-1 dose (mg/kg)	**Number of animals that died**	**Total number of animals in the group**
9.51	0	10
14.27	0	10
21.40	2	10
32.06	6	10
48.13	8	10
72.24	9	10
108.40	10	10

Table 19 – Results of studying ABA FS-1 fetal toxicity

Experimental groups	Dose, mg/kg	Effect (death rate or premature labor)
intramuscularly	100	Prenature labor, unviable fetus
intramuscularly	25	0
intramuscularly	6.25	0

Примечание: * - p<0.025; ** - p<0.001

Table 31 – Comparative data of radiological pattern dynamics

Groups	1 month	2 months	3 months	4 months	5 months	Groups
Group 1	80*	100***	100***	92.9**	92.3**	85.7*
Group 2	92*	95.5***	100***	93.3**	100***	
Group 3 (control)	63.2*	52.4***	53.8***	70**	62.5**	71.4*

Note: * - p<0.05; ** - p<0.025; **** - p<0.005

Table 32 - Comparative average statistical indicators of body weight dynamics within 1 month of therapy

Groups and doses	FS-1, 0.1 ml/kg				FS-1, 0.125 ml/kg				Placebo			
	n	M	±	m	n	M	±	m	n	M	±	m
initial	28	59.04	±	11.23	26	59.40	±	9.95	26	57.85	±	10.37
1 month	21	59.57	±	12.15	19	61.83	±	10.51	19	57.96	±	11.28
2 months	20	61.77	±	11.29	17	57.34	±	11.15	17	57.34	±	11.15
3 months	16	63.1	±	12.05*	15	64.19	±	11.88*	14	54.56	±	8.79
4 months	11	59.89	±	9.33	8	63.57	±	10.72*	10	53.26	±	6.87
5 months	9	62.91	±	9.41		-	-	-	8	54.86	±	7.93

Note: * - P<0.05; ** - P<0.01; *** - P<0.001

Patent Claims

1. Antibacterial agent for treating bacterial infectious diseases including hospital infections and drug resistant TB, which represents ionic nanostructured complex formed by proteins and/or polypeptides. Carbohydrates, salts of alkali and alkaline-earth metals and iodine intercalated into them, characterized in that the proteins and/or polypeptides of ion nanostructured complex contain at least one chain-terminal amino acid with electron-donor functional groups.
2. Antibacterial agent according to claim 1, characterized in that interleukins are used as proteins, and chain-terminal amino acids are Phe, Ala, Val, Ala, Leu, Ile, etc.
3. Antibacterial agent according to claim 1 or claim 2, characterized in that the antimicrobial agent increases bacterial susceptibility to antibiotics, including antibiotic-resistant bacteria.
4. Antibacterial agent according to any one of claims 1 to 3, characterized in that it increases the efficiency of antibiotic treatment for bacterial infectious diseases, including hospital infections and drug-resistant TB.
5. Antibacterial agent according to any one of claims 1 to 4, characterized in that it has antiviral action.
6. Antibacterial agent according to any one of the preceding claims, characterized in that it has immunogenic activity, increasing the activity of monocyte-macrophages and cytotoxic T-lymphocytes.
7. Antibacterial agent according to any one of claims 1 to 5, characterized in that it stimulates the hematopoietic function of bone marrow.
8. Antibacterial agent according to any one of claims 1 to 5, characterized in that it possesses antineoplastic action.

9. Antibacterial agent under according to any one of claims 1 to 5, characterized in that it has radioprotective properties.
10. Antibacterial agent according to any one of claims 1 to 6, characterized in that INSC has the following formula: [{(Ln (MeI3) +) y [Me (Lm) I] + x} (Cl-) y + x + k] with M = 30-300 kDa.
11. Antibacterial agent according to any one of claims 1 to 5, characterized in that it is presented in a pharmaceutical form suitable for parenteral, oral, external or other application.
12. Antibacterial agent according to any one of claims 1 to 5, characterized in that in certain acceptable concentrations of components it is a non-medicinal agent.
13. Method of producing the antibacterial agent according to claim 1, comprising complexation reaction of carbohydrates and proteins with metal salts, and intercalation of iodine into complex at ionic strength from $5 \cdot 10^{-4}$ to 15, characterized in that introduction of immunotropic proteins is carried out as an individual stage after iodine intercalation of 5 - 95%.

taking place, resulting in disruption of protein synthesis. Interaction with phenolic groups of iodine tyrosine leads to breaking of hydrogen bonds in these amino acids. Affecting double carbon bonds of unsaturated fatty acids, iodine thereby changes the properties of lipids.

The ability of iodine to easily penetrate through cell membranes makes its application more valuable for those infections, the main development of which takes place in intracellular structures (brucellosis, clamidiosis, hepatitis, etc.).

There is a known drug *Yodomidol*, with bactericidal and virucidal activity, containing iodine, potassium or sodium iodide, synthetic water-soluble polymer, natural polymers such as polysaccharides and mono- and oligosaccharides, in the following ratio, g/L:

iodine	6-10
potassium iodide	9-15
synthetic water-soluble polymer	2-4
natural polymer (polysaccharides) and mono- and oligosaccharides	8-120
water	Balance

(KZ 6730B, 16.11.1998).

Disadvantage of this drug is its relatively high toxicity.

There is a known virulicidal pharmaceutical product (EP 0978289 A1, 02.09.2000), with antiviral activity, which contains iodine, potassium or sodium iodide, synthetic water-soluble polymer, a mixture of natural mono-, oligo- and polysaccharides and lithium chloride with the following components ratio, g/L:

iodine	0,8 – 25
potassium iodide	1,2 – 38
lithium chloride	0,1 – 20
synthetic water-soluble polymer	0,01 – 6
mono-, oligo- and polysaccharides	8– 400
water	Balance

There is a known bactericidal and virucidal pharmaceutical product for

In all of the above known patents, authors did not set the task of synthesizing complex compounds with a given structure and properties, or excreting complex compounds from solutions and determining their composition and physical-chemical properties, which makes it hard to use complex iodine compounds with carbohydrates and proteins with biocidal properties as medicinal products. Moreover, the development of appropriate dosage forms, without a specific set of properties and qualities of complex iodine compounds - antibacterial agents, characterized by physical and chemical properties and composition, is hindered.

In recent years, some works devoted to exploration of the structure of complex compounds of carbohydrates with salts of magnesium, calcium and other complexing agents have appeared in scientific literature (*O.Nimz, K.Geßler, I.Uson, W.Saenger // Carbohydrate Research 2001. V. 336. P.141–153.; M.Noltemeyer, W. Saenger // JACS 1980.V.102:8.9.P.2710.; M.Noltemeyer, W. Saenger // Nature.1976.V.259. 26.P.629).*

Crystalline structure of a whole number of enzymes with having in its composition ions of magnesium, potassium, calcium, lithium, in their composition, i.e., metal salts, has been established. (*Y.Goldgur, F.Dyda, A.B.Hickman, T.M.Jenkins, R.Craigie, D.R.Davies // Proc.Natl.Acid.Sci USA 1998. V.95. №16. P.9150-9154.; F.Dyda, A.B.Hickman, T.M.Jenkins, A. Engelman, R.Craigie, D.R.Davies // Science. 1994. V.266. P.1981-1986*).

At the same time there are no works involving a purposeful synthesis of iodine coordination compounds with a tailored nanoscale structure and, accordingly, tailored biocidal properties, suitable for implementation of a mechanism of action of these compounds.

Thus, the object of this invention is to create antibacterial agent (hereinafter ABA) for the treatment of diseases of bacterial origin, including hospital acquired diseases and drug resistant tuberculosis (hereinafter TB).

Additional objectives of this invention are to develop a method for preparation of antibacterial agent and ABA-based drug to treat infectious diseases

using an automated hematology analyzer Celly v 2.20, Hycel Diagnostics.

The recovery of bone marrow hematopoietic function was estimated using clonogenic test. [Bezirganyan K.B., Davtyan T.K., Galoyan A.A. Hypothalamic proline rich polypeptide regulates hematopoiesis / / Neurochem. Res. - 2010. - Vol. 35. - CL. 917-924], by determining the number of granulocyte-monocyte colony-forming (CFU-GM) progenitor bone marrow cells. For this purpose, bone marrow cells were cultured in a medium Methocult^{TM} GF R3774, containing methylcellulose and growth factors, progenitor cells (stem cell factor, GM-CSF and IL-3), StemCell Technologies Inc (cat № 03774).

Example No. 1 FS-1.1

ABA synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. Temperature is maintained using thermostat "HUBER" - Ministat 230 CC2. 130g of carbohydrate is dissolved in 500 ml of water at 50°C. Further, 3.0g of sodium chloride and 1.98mg of calcium chloride dissolved in 100ml of water are added. The mixture is thoroughly stirred and cooled to 43°C (Product A).

5.0 g of albumin are dissolved in 150 ml of water and then 3.96g of lithium chloride, 8.4g magnesium chloride and 2.0g of sodium chloride added (Product B). 135 ml of the resulting solution is poured in the reactor. Reactor mixture is agitated for 20 minutes, and after that the solution temperature reduced to 25 °C.

0.82 g of I_2 and 1.2 g of potassium iodide are dissolved in 100 ml of water (Product B). 70 ml of the resulting solution is poured in portions in the reactor. Iodine intercalation is performed for 2 hours at 25 ^{o}C, and after that the rest 15ml of Product B are added. After 1 hour, another 30 ml of Product B is added in portions into reactor, and iodine intercalation is completed within 2 hours.

Ionic strength of the solution is 13.6.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, for example, centrifugal chromatography method in "Kromaton" FCPC (Fast Centrifugal Chromatography), and dried (Fig.

10(a)).

Analysis results:

	Dextrin	Albumin	polyvinyl alcohol (PVA)	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fractions, %	**0.40**	**0.59**	**63.58**	**0.02**	**0.01**	**11.62**	**10.62**	**2.21**	**10.95**

$$[5280L_1 \cdot 1{,}5L_2 \cdot 33I_2] \cdot L_3$$

Example No. 2 FS-1.2

ABA synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 108.3g of dextran is dissolved in 500 ml of water at 45°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 2.5g of polyvinyl alcohol (hereinafter PVA) dissolved in 150 ml of water, 4.0 g of sodium chloride and 1.65g of calcium chloride dissolved in 100ml of water, are added. The mixture is thoroughly stirred and cooled to 43°C (Product A).

4.17g of albumin is dissolved in 150 ml of water, and then 3.3g of lithium chloride, 7.0g of magnesium chloride and 0.17g of sodium chloride are added. The resulting solution is transferred to the reactor when the temperature of Product A specified above is reached. The mixture is stirred for 20 minutes, and after that the temperature of reaction zone is reduced to 25°C (Product B).

2.0g of I_2 and 3.0g of potassium iodide are dissolved in 100 ml of water. The resulting solution is poured in portions into the complex compound solution (Product B). Iodine intercalation is performed for 4 hours at 25°C.

Ionic strength of the solution is 13.2.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10 (b)).

Analysis results:

	Dextrin	Albumin	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fractions, %	**62.35**	**0.02**	**0.01**	**11.40**	**10.40**	**10.74**	**2.2**	**1.15**	**1.73**

$$[38L_1 \cdot 1{,}5L_2 \cdot 97I_2] \cdot L_3$$

Example No. 3 FS-1.3

ABA synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 72.0 g of carbohydrate is hydrolyzed in 600 ml of water at 60°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 1.7 g of PVA dissolved in 100 ml of water; 2.8g of sodium chloride and 1.1g of calcium chloride dissolved in 100ml of water are poured in. The mixture is thoroughly stirred and cooled to 43°C (Product A).

2.8 g of albumin is dissolved in 150 ml of water, and then 2.2 g of lithium chloride, 4.66 g of magnesium chloride and 0.8 g of sodium chloride are added. The resulting solution is transferred to the reactor when the temperature of Product A specified above is reached. The mixture is stirred for 20 minutes, and after that the temperature in reaction zone is reduced to 25°C (Product B).

Ionic strength of the solution is 10.8.

4.1 g of I_2 and 6.0g of potassium iodide are dissolved in 100 ml of water. The resulting solution is poured in portions into the complex compound solution (Product B). Iodine intercalation is performed for 4 hours at 25°C.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10 (c)).

Analysis results:

	Dextrin	Albumin	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fractions, %	**0.96**	**0.04**	**0.03**	**24.38**	**22.46**	**22.95**	**4.65**	**7.57**	**16.96**

$$[611L_1 \cdot 24L_2 \cdot 294I_2] \cdot L_3$$

Example No. 4 FS-1.4

ABA synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 72.0 g of carbohydrate is hydrolyzed in 550 ml at 100°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 1.7 g of PVA dissolved in 250 ml of water is poured in (Product A). The mixture is thoroughly stirred during 20 min, after that the temperature in reaction zone is reduced to 25°C.

4.1 g of I_2 and 6.0g of potassium iodide are dissolved in 200 ml of water. The resulting solution is poured in portions into the complex compound solution (Product B). Iodine intercalation is performed for 4 hours at 25°C.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10 (d)).

Ionic strength of the solution is 3.02.

Analysis results:

	Carbohydrate	PVA	I_2	KI
Mole fractions, %	**29.67**	**66.45**	**3.78**	**0.10**

$$[37L_1 \cdot 294I_2] \cdot L_3$$

Example No. 5 FS-1

ABA synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 130 g of mixture of amylase and amylopectin in the ratio of 1:4 is dissolved in 500 ml of water at 43°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 3.0 g of PVA dissolved in 150 ml of water, 4.5 g of sodium chloride, and 2.0 g of calcium chloride dissolved in 100 ml of water are poured in (Product A).

5.0 g of albumin is dissolved in 150 ml of water, and then 4.0 g of lithium chloride, 8.4 g of magnesium chloride and 0.5 g of sodium chloride are added. The resulting solution is transferred to the reactor. The mixture is stirred for 20 minutes, and after that the temperature of reaction zone is reduced to 25°C (Product B).

8.2 g of I_2 and 12.1 g of potassium iodide are dissolved in 100 ml of water. The resulting solution is poured in portions into the complex compound solution (Product B). Intercalation of iodine is carried out in two stages, as described in the previous examples.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 11).

Ionic strength of the solution is 20.60.

Analysis results:

	Amylum	Albumin	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fracture, %	**0.94**	**0.04**	**0.02**	**23.90**	**21.62**	**22.31**	**4.56**	**8.17**	**18.44**

$$[38L_1 \cdot 2L_2 \cdot 333I_2] \cdot L_3$$

Example No. 6 FS-1.5

ABA synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 24.1 g of carbohydrate is hydrolized in 500 ml of water at 80°C until a certain molar weight is reached. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 2.8 g of PVA dissolved in 150 ml of water is poured in. The mixture is thoroughly stirred and cooled to 43°C (Product A).

34.0 g of I_2 and 50.5 g of potassium iodide are dissolved in 100 ml of water. The resulting solution is poured in portions into the complex compound solution (Product C). Intercalation of iodine is carried out in two stages, during 4 hours at 25°C.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10 (d)).

Ionic strength of the solution is 25.3.

Analysis results:

	Carbohydrate	PVA	I_2	KI
Mole fractures, %	**0.16**	**0.02**	**30.50**	**69.32**

$$[8L_1 \cdot 1488I_2] \cdot L_3$$

Example No. 7 FS-1.6

ABA synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 24.1 g of carbohydrate is hydrolized in 500 ml of water at 100°C until a certain molar weight is reached. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 2.8 g of PVA dissolved in 150 ml of water, 0.8 g of sodium chloride, and 0.37 g of calcium chloride dissolved in 100 ml, are poured in. The mixture is thoroughly stirred and cooled to 43°C (Product A).

0.93g of albumin is dissolved in 150 ml of water, and then 0.73g of lithium chloride, 1.55g of magnesium chloride and 0.13g of sodium chloride are added. The resulting solution is transferred to the reactor after the required Product A temperature specified above is reached. The mixture is stirred for 20 minutes

(Product B) and after that the temperature of reaction zone is reduced to 25 °C.

34.0 g of I_2 and 50.5 g of potassium iodide are dissolved in 100 ml of water. The resulting solution is poured in portions in the complex compound solution (Product C). Intercalation of iodine is carried out in two stages, during 4 hours at 25°C.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10(e)).

Ionic strength of the solution is 27.9.

Analysis results:

	Carbohydrate	Albumin	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fractures, %	**0.14**	**0.006**	**0.02**	**3.51**	**3.23**	**3.31**	**0.68**	**27.23**	**61.70**

$$[26L_1 \cdot L_2 \cdot 4970I_2] \cdot 3L_3$$

Example No. 8 FS-1.7

ABA synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, after the constant stirring. 130.0 g of dextrin and 3.0 g 0f PVA is dissolved in 500 ml of water at 50°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 4.0 g of sodium chloride and 2.0 g of calcium chloride dissolved in 100 ml of water are poured in. The mixture is thoroughly stirred and cooled to 43°C (Product A).

5.0 g of albumin is dissolved in 150 ml of water, and then 4.0 g of lithium chloride, 8.4 g of magnesium chloride and 1.0g of sodium chloride are added. The resulting solution is transferred to the reactor after the required Product A temperature specified above is reached. The mixture is stirred for 20 minutes (Product B), and after that the temperature of reaction zone is reduced to 25°C.

8.2 g of I_2 and 12.1g of potassium iodide are dissolved in 100ml of water. 70

ml of the resulting solution is poured in portions in the complex compound solution (Product B). Iodine intercalation is carried out in two stages during 4 hours at 25°C.

0.6g of IL-2 is dissolved in 150 ml of water and slowly added to the reactor. 30 minutes after the charge of IL-2, 20 ml of Product B is added to the reactor. The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10(f)).

Ionic strength of the solution is 20.60.

Analysis results:

	Dextrin	Albumin	IL-2	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole percent, %	**0.94**	**0.04**	**0.01**	**0.02**	**23.9**	**21.62**	**22.30**	**4.56**	**8.17**	**18.44**

$$\left[79L_1 \cdot 3L_2 \cdot Il - 2 \cdot 684I_2\right] \cdot 2L_3$$

Example No. 9 FS-1.8

ABA synthesis is conducted in the laboratory reactor D-55122 Mainz, type RührgefäB 2L, QVF ENGINEERING GMBH, under the constant stirring. 13.1 g of carbohydrate is hydrolyzed in 100 ml at 130°C. Temperature is maintained using a thermostat "HUBER" - Ministat 230 CC2. Further, 3.0 g of PVA dissolved in 150 ml of water, 0.3 g of sodium chloride and 0.2 g of calcium chloride dissolved in 100 ml of water are poured in (Product A). The mixture is thoroughly stirred and cooled to 43°C.

0.51 g of albumin is dissolved in 150 ml of water, and then 0.4 g of lithium chloride, 0.84 g of magnesium chloride and 0.2 g of sodium chloride are added.

The resulting solution is transferred to the reactor after the required Product A temperature specified above is reached. The mixture is stirred for 20 minutes (Product B), and after that the temperature in reaction zone is reduced to 25°C.

74.5 g of I_2 and 110.0 g of potassium iodide are dissolved in 500 ml of water. The resulting solution is poured in portions in the complex compound solution (Product B). Intercalation of iodine is carried out in two stages, during 4 hours at 25°C.

The resulting ionic nanostructured ABA complex is extracted from the reaction medium using a suitable method, and dried (Fig. 10(g)).

Ionic strength of the solution is 56.3.

Analysis results:

	Carbohydrate	Albumin	PVA	LiCl	NaCl	$MgCl_2$	$CaCl_2$	I_2	KI
Mole fractures, %	**0.04**	**0.002**	**0.01**	**0.96**	**0.87**	**0.9**	**0.18**	**29.8**	**67.31**

$$[25L_1 \cdot L_2 \cdot 19575I_2] \cdot 7L_3$$

In biological activity testing it was established that ABA FS-1 is active *in vitro* both against clinical isolates, and control strains of MRSA and MSSA. MIC of antimicrobial agent was varied from 0.938 mg/ml to 0.234 mg/ml.

Tests for synergy with oxacillin have shown a decrease in MIC of both drugs. The decline was from 256 to 64 μg/ml for oxacillin, and from 0.234 to 0.117 μg/ml for ABA FS-1. FIC index for this test was 0.75, which can be regarded as a partial synergy between the tested drugs.

Test for synergy with cefamandole has shown a decrease in MIC of both drugs. The reduction ranged from 64 to 8 μg/ml for cefamandole, and from 0.469 μg/ml to 0.234 μg/ml for ABA FS-1. FIC index for this test was 0.62, which determines the interaction of these antibiotics as a partial synergy.

Test for synergy with lincomycin has shown a decrease in MIC of both drugs. The reduction ranged from 64 μg/ml to 8 μg/ml for lincomycin, and from 0.234 mg/ml to 0.117 mg/ml for ABA FS-1. FIC index for this test was 0.625, which determines the interaction of these antibiotics as a partial synergy.

ABA in Examples 1-9 (FS-1.1 - FS-1.8) has a greater or lesser bactericidal activity against pathogenic microorganisms of different classes (Table 6). The most acceptable and effective one, as follows from Table 6, with respect to Mycobacterium tuberculosis, is ABA in Example 5 (FS-1).

As the result of studying FS-1 antimycobacterial action against *M.tuberculosis H37Rv, M.tuberculosis MS-115* with multidrug-resistance, and *M. bovis*, it was established that at the drug concentrations in dilutions of 1:12.5, 1:25 and 1:50 a complete suppression of reproduction of mycobacteria was observed throughout the entire registration period.

Bactericidal activity of FS-1 was evaluated *in vitro* using a microbiological method of double serial dilutions in Shkolnikova liquid medium, with subsequent passaging on Levenstein-Jensen medium. *In vitro* bactericidal activity of FS-1 at concentrations ranging from 1.750 to 0.0437 mg/ml in field strains of mycobacteria, drug-resistant clinical isolates and *M. tuberculosis N37Rv* has been established. Bacteriostatic effect of FS-1 is observed in concentrations from 0.0218 to 0.0109 mg/ml.

Bactericidal activity of FS-1 *in vitro* in concentration of 0.0437 mg/ml in combination with anti-antitubercular (hereinafter anti-TB) drugs, Type I, with subsequent passaging on Levenstein-Jensen medium in relation to museum strain *M. tuberculosis N37Rv* and 8 multi-drug resistant strains, was evaluated. The research identified, with various concentrations of anti-TB drugs of Type I, museum sensitive and multidrug-resistant strains. The results are presented in Table 7.

As can be seen from Table 7, after the combined action of FS-1 with different concentrations of anti-TB drugs, the growth of multidrug resistant strains of *Mycobacterium tuberculosis* was not detected in experimental test tubes, i.e. strains were susceptible to all concentrations of anti-TB drugs of Type I, in comparison

Table 1 – ABA composition

Example No.	Compound	I_2, g/L	KI, g/L	Carbohydrate, g/L	Protein		PVA, g/L	LiCl, g/L	NaCl, g/L	$CaCl_2$, g/L	$MgCl_2$, g/L	Ionic strengh
					Albumin, g/L	IL-2 mg/L						
1	FS-1.1	0.82	1.2	130.0	5.0	—	3.0	3.96	5.0	1.98	8.4	13.6
2	FS-1.2	2.0	3.0	108.3	4.17	—	2.5	3.3	4.17	1.65	7.0	13.2
3	FS-1.3	4.1	6.0	72.0	2.8	—	1.7	2.2	2.8	1.1	4.66	10.8
4	FS-1.4	4.1	6.0	72.0	—	—	1.7	—	—	—	—	3.02
5	FS-1	8.2	12.1	130.0	5.0	—	3.0	4.0	5.0	2.0	8.4	20.60
6	FS-1.5	34.0	50.5	24.1	—	—	2.8	—	—	—	—	25.3
7	FS-1.6	34.0	50.5	24.1	0.93	—	2.8	0.73	0.93	0.37	1.55	27.9
8	FS-1.7	8.2	12.1	130.0	5.0	0.6	3.0	4.0	5.0	2.0	8.4	20.60
9	FS-1.8	74.5	110.0	13.1	0.51	—	3.0	0.4	0.5	0.2	0.84	56.3

Table 2 - Output of complex Mg2 + n4I3-n6 depending on I_2 excess compared to the stoichiometric content,%

Calculated	78	86	94
Experimental	74	82	93
I_2 excess from	0	20	50

Table 3 - Output of complex $Ca^{2+}_{n5}I_3^-{}_{n7}$ depending on I_2 excess compared to the stoichiometric content, %

Calculated	71	82	89
Experimental	68	76	85
I_2 excess from	0	20	50

Table 4 - Spatial (lengths of coordination bonds (Å)) and energy (stabilization energy ΔE, kcal/mol) characteristics of I-IV complexes.

	I	II	III	IV
Li - I	2.93	2.96	2.97	2.80
N(O)-I	2.46	2.40	2.76	2.18
I-I	2.76	2.82	2.72	3.03
-ΔE	16.60	14.26	6.25	24.25

Table 5 - CC 50 and MNC for different series of the substance FS-1 in MDCK cell culture after 72-hour incubation

Example №	Compound	Drug dilutions	
		CC 50	**MNC**
1	ABA -1 (FS-1.1)	1:50	1:100
2	ABA -2 (FS-1.2)	1:800	1:3200
3	ABA -3 (FS-1.3)	1:100	1:200
4	ABA -4 (FS-1.4)	1:50	1:6400
5	FS-1	1:20	1:80
6	ABA -6 (FS-1.5)	1:1460	1:3200
7	ABA -7 (FS-1.6)	1:5063	1:6000
8	ABA -8 (FS-1.7)	1:565	1:1500
9	ABA -9 (FS-1.8)	1:3637	1:6400

Table 6 - Bactericidal activity against microorganisms of different pathogenicity groups

Microorganism name	Minimum inhibitory concentration of the complex compound after the Example, mg/ml								
	1	2	3	4	5	6	7	8	9
Escherichia coli INMIA 5002 (ATCC 11303)	2.5	1	1	1	1	2.5	1	1	2.5
Escherichia coli INMIA 5230	2.5	1	1	1	1	2.5	1	1	2.5
Staphylococcus aureus INMIA 5233	2.5	1	1	1	1	5	1	1	2.5
Serratia marcescens INMIA 5251 (ATCC 9986. Bu 211. IFO 3736)	2.5	1	1	1	2.5	5	1	1	2.5
Mycobacterium spp INMIA 5237 (B-5 strain)	7	1	1	1	0.0437	7	1	1	7
Pseudomonas fluorescens	2.5	1	1	1	0.5	2.5	1	1	2.5

	60	-	30	42
Group 3 Test animals infected with *M. tuberculosis* $H_{37}R_v$ and treated with TBD	39	7	17	18
	46	14	11	8
	53	21	9	7
	60	28	3	2
	67	35	-	-
Group 4 Test animals infected with *M. tuberculosis* $H_{37}R_v$ and treated with FS-1	39	7	11	13
	46	14	10	9
	53	21	4	7
	60	28	-	-
	65	33	-	-
Group 5 Test animals infected with *M. tuberculosis* $H_{37}R_v$ and treated with TBD and FS-1	39	7	16	7
	46	14	6	5
	53	21	-	-
	60	28	-	-
	67	35	-	-
Group 6 Test animals infected with multiresistant strains of mycobacteria and treated with TBD	39	7	11	14
	46	14	14	16
	53	21	21	24
	60	28	20	23
	67	35	35	27
Group 7 Test animals infected with multiresistant strains of mycobacteria and treated with FS-1	39	7	12	14
	46	14	10	9
	53	21	4	5
	60	28	2	-
	66	35	-	-
Group 8 Test animals infected with multiresistant strains of mycobacteria and treated with TBD and FS-1	39	7	13	17
	46	14	3	7
	53	21	-	-
	60	28	-	-
	67	35	-	-

Table 9 – Haemagglutinin titre of the residual influenza virus HAU

Example №	Compound	Substance content, mg/ml	Virus dilutions								Titr., HAU
			1/2	1/4	1/8	1/16	1/32	1/64	1/128	1/256	
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
1	ABA-1 (FS-1.1)	5.0	++++	++++	++++	++--	----	----	----	----	12
		2.5	++++	++++	++++	++--	----	----	----	----	12
		1.25	++++	++++	++++	++++	++--	----	----	----	24
2	ABA -2 (FS-1.2)	0.31	++++	++++	++++	++++	++++	----	----	----	32
		0.16	++++	++++	++++	++++	++++	++--	----	----	48

Example №	Compound	Substance content, mg/ml	Virus dilutions								Titr., HAU
			1/2	1/4	1/8	1/16	1/32	1/64	1/128	1/256	
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
		0.08	++++	++++	++++	++++	++++	++--	----	----	48
3	ABA -3 (FS-1.3)	2.5	++++	++++	++++	++++	++++	----	----	----	32
		1.25	++++	++++	++++	++++	++++	----	----	----	32
		0.63	++++	++++	++++	++++	++++	++--	----	----	48
4	ABA -4 (FS-1.4)	5.0	++++	++--	----	----	----	----	----	----	3
		2.5	++++	++--	----	----	----	----	----	----	3
		1.25	++++	++++	++++	++++	++++	+++ +	----	----	64
5	ABA FS-1	0,188	----	----	----	----	----	----	----	----	0
		0,094	++++	++++	----	----	----	----	----	----	4
		0,047	++++	++++	++++	----	----	----	----	----	8
6	ABA -6 (FS-1.5)	0.2	++++	++++	++++	++--	----	----	----	----	12
		0.1	++++	++++	++++	++--	----	----	----	----	12
		0.05	++++	++++	++++	++++	++++	++--	----	----	48
7	ABA -7 (FS-1.6)	0.05	++++	++++	++++	++++	++--	----	----	----	24
		0.025	++++	++++	++++	++++	++++	++--	----	----	48
		0.01	++++	++++	++++	++++	++++	++--	----	----	48
8	ABA -8 (FS-1.7)	0.4	----	----	----	----	----	----	----	----	0
		0.2	----	----	----	----	----	----	----	----	0
		0.1	----	----	----	----	----	----	----	----	0
9	ABA -9 (FS-1.8)	0.06	++++	++++	++++	++++	----	----	----	----	8
		0.03	++++	++++	++++	++++	----	----	----	----	16
		0.015	++++	++++	++++	++++	++--	----	----	----	24
	Virus control		++++	++++	++++	++++	++++	+++ +	++ --	----	96
	Note: **«++++» - 100% «umbrella» hemagglutination** **«+++» - 75% hemagglutination** **«++» - 50% hemagglutination** **«++» - 25% hemagglutination** **«-» - no hemagglutination**										

Table 10 – Determination of FS-1 antiviral activity against influenza virus A/FPV/Waybrige/78/H7N7 in MDCK cell culture after 72 hours

Well number	Active substance content, mg/ml					
	0.038	0.019	0.009	0.005	0 (Cells control)	0 (Virus Control)
1	----*	----	++--	+++-	----	++++
2	----	----	++--	+++-	----	++++
3	----	----	++--	+++-	----	++++
4	----	----	++--	+++-	----	++++
Notes: 1 «*» - CPE manifestation degree 2 «++++» - pronounced degradation of cell monolayer. 3 «----» – no cell degradation.						

Table 17 – Acute toxicity characteristics (LD50 mg/kg)

Example №	Example	Mice	Rats
	Enteral route of administration		
3	ABA -3 (FS-1.3)	330	243
1	ABA -1 (FS-1.1)	579,25	360,5
5	ABA (FS-1)	n.d.	n.d.
	Parenteral route of administration		
3	ABA -3 (FS-1.3)	65	48
1	ABA -1 (FS-1.1)	106	75
5	ABA (FS-1)	213	100

N.d. – not detected

Table 18 – Results of studying FS-1 cumulative toxicity in mice

FS-1 dose (mg/kg)	**Number of animals that died**	**Total number of animals in the group**
9.51	0	10
14.27	0	10
21.40	2	10
32.06	6	10
48.13	8	10
72.24	9	10
108.40	10	10

Table 19 – Results of studying ABA FS-1 fetal toxicity

Experimental groups	Dose, mg/kg	Effect (death rate or premature labor)
intramuscularly	100	Prenature labor, unviable fetus
intramuscularly	25	0
intramuscularly	6.25	0

Note: * - p<0.025; ** - p<0.001

Table 31 – Comparative data of radiological pattern dynamics

Groups	1 month	2 months	3 months	4 months	5 months	Groups
Group 1	80*	100***	100***	92.9**	92.3**	85.7*
Group 2	92*	95.5***	100***	93.3**	100***	
Group 3 (control)	63.2*	52.4***	53.8***	70**	62.5**	71.4*

Note: * - p<0.05; ** - p<0.025; **** - p<0.005

Table 32 - Comparative average statistical indicators of body weight dynamics within 1 month of therapy

Groups and doses	FS-1, 0.1 ml/kg			FS-1, 0.125 ml/kg			Placebo		
	n	M ± m		n	M ± m		n	M ± m	
initial	28	59.04 ± 11.23		26	59.40 ± 9.95		26	57.85 ± 10.37	
1 month	21	59.57 ± 12.15		19	61.83 ± 10.51		19	57.96 ± 11.28	
2 months	20	61.77 ± 11.29		17	57.34 ± 11.15		17	57.34 ± 11.15	
3 months	16	63.1 ± 12.05*		15	64.19 ± 11.88*		14	54.56 ± 8.79	
4 months	11	59.89 ± 9.33		8	63.57 ± 10.72*		10	53.26 ± 6.87	
5 months	9	62.91 ± 9.41			- - -		8	54.86 ± 7.93	

Note: * - P<0.05; ** - P<0.01; *** - P<0.001

Patent Claims

1. Antibacterial agent for treating bacterial infectious diseases including hospital infections and drug resistant tuberculosis (TB), which comprises an ionic nanostructured complex formed by proteins and/or polypeptides, carbohydrates, salts of alkali and alkaline-earth metals and iodine intercalated into them, characterized in that the proteins and/or polypeptides of the ionic nanostructured complex contain at least one free chain-terminal amino acid with electron-donor functional groups.
2. Antibacterial agent according to claim 1, characterized in that interleukins are used as proteins, and chain-terminal amino acids are Phe, Ala, Val, Ala, Leu, Ile, etc.
3. Antibacterial agent according to claim 1 or claim 2, characterized in that the antimicrobial agent increases bacterial susceptibility to antibiotics, including antibiotic-resistant bacteria.
4. Antibacterial agent according to any one of claims 1 to 3, characterized in that it increases the efficiency of antibiotic treatment for bacterial infectious diseases, including hospital infections and drug-resistant tuberculosis (TB).
5. Antibacterial agent according to any one of claims 1 to 4, characterized in that it has antiviral action.
6. Antibacterial agent according to any one of the preceding claims, characterized in that it has immunogenic activity, increasing the activity of monocyte-macrophages and cytotoxic T-lymphocytes.
7. Antibacterial agent according to any one of claims 1 to 5, characterized in that it stimulates the hematopoietic function of bone marrow.
8. Antibacterial agent according to any one of claims 1 to 5, characterized in that it possesses antineoplastic action.

9. Antibacterial agent according to any one of claims 1 to 5, characterized in that it has radioprotective properties.
10. Antibacterial agent according to any one of claims 1 to 6, characterized in that the ionic nanostructured complex (INSC) has the following formula: $[\{(L_n\ (MeI_3)^+)_y\ [Me\ (L_m)I]^+_x\}\ (Cl^-)_{y+x+k}]$ with M = 30-300 kDa.
11. Antibacterial agent according to any one of claims 1 to 5, characterized in that it is presented in a pharmaceutical form suitable for parenteral, oral, external or other application.
12. Antibacterial agent according to any one of claims 1 to 5, characterized in that in certain acceptable concentrations of components it is a non-medicinal agent.
13. Method of producing the antibacterial agent according to claim 1, comprising complexation reaction of carbohydrates and proteins with metal salts, and intercalation of iodine into complex at ionic strength from $5 \cdot 10^{-4}$ to 15 mol/L, characterized in that introduction of immunotropic proteins is carried out as an individual stage after iodine intercalation of 5 - 95%.