Brief information about the project

Name of the project	AP19679739 «Development of production technology for
	new immunomodulator based on monosaccharides combination for
	use in the complex cancer's treatment»
Relevance	This project is aimed at developing and implementing the
	production technology of a new generation immunomodulator with
	the working name "KM-1" based on a combination of
	pharmacopoeial monosaccharides in the form of a buffer system for
	oral use. The synthesis technique and formulation from the new
	immunomodulator with the working name "KM-1" were developed
	by us earlier. The drug was synthesized according to an original
	patentable technique and exhibits the ability to neutralize acidic
Dumoss	non-cellular pH, which is provided by the KM-1 buffer system.
Purpose	Creation of production technology for a new-generation
	immunomodulatory drug based on a combination of
	pharmacopoeial monosaccharides with citrate for use in the
	complex treatment and prevention of cancer, development of a set of documentation for registration of the drug as a bioactive
	of documentation for registration of the drug as a bioactive supplement.
Objectives	–Implementation of order and purchase of necessary
Objectives	materials, reagents and equipment. development under laboratory
	conditions of the main technological operations and processes of
	production of a new generation immunomodulator KM-1;
	–Development and testing of laboratory technological
	regulations for the production of KM-1;
	-Development of a package of medical and technical
	documentation, including the following documents:
	"Pharmaceutical development", "Risk management", technological
	instructions (TI). Development of laboratory technological
	regulations;
	-Execution and testing of semi-industrial technological
	procedure for production of KM-1; development of a trial batch of
	KM-1 drug;
	-Study under "in vivo" model conditions of regulation
	efficiency of acidic extracellular and alkaline intracellular pH in
	breast cancer tumors with buffered mixture of hexose sugars in
	combination with citrate (KM-1 preparation);
	-Study under "in vivo" model conditions of the effectiveness
	of anti-tumor activity of KM-1 preparate in combination with
	chemotherapy drug;
	-Preparation of the premises and registration dossier for KM-
	1 drug for its registration as a dietary supplement.
Expected and achieved	Main expected results:
results	- Necessary materials, reagents and equipment will be
	ordered and purchased. The main technological procedures and
	processes of obtaining a new generation immunomodulator KM-1
	will be developed in laboratory;
	- Laboratory technological regulations for KM-1 production
	will be developed and tested;
	- Medical and technical documentation will be developed,
	including the following documents: "Pharmaceutical

	development", "Risk management", technological instructions (TI).
	The laboratory technological procedures will be worked out;
	- Semi-industrial technological procedure for KM-1
	production will be executed and worked off; a pilot batch of KM-1
	preparation will be manufactured;
	- The efficacy of regulation of acidic extracellular and
	alkaline intracellular pH in breast cancer tumors with the use of
	buffered mixture of hexose sugars in combination with citrate (KM-
	1 preparation) will be studied under "in vivo" model conditions;
	- An in vivo study of KM-1 effectiveness in combination with
	chemotherapy drugs under model conditions will be performed;
	- A room and a registration dossier for KM-1 will be prepared
	for its registration as a dietary supplement.
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