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## SECTION 3. PHARMACY

### 3.1 The design of immunostimulants and adjuvants used for the treatment and prevention of animal diseases

The problem of stimulation of immunogenesis in veterinary practice is relevant and has attracted the attention of immunologists. Currently, the scientists of many countries carried out extensive work on the design of Immunostimulants and adjuvants used in conjunction with vaccines for the treatment and prevention of animal diseases. More than 100 years is the search for compounds that would affect the formation of antibodies and contributed to the emergence of immune responses. With this goal constantly develop new and more effective biological, chemical and physical adjuvants and adjuvants.

Currently, a large number of substances which are able to exert adjuvant effect on various antigens. As adjuvants are used killed microorganisms (mycobacteria, corynebacteria, Nocardia, etc.), organic substances (bacterial polysaccharides and lipopolysaccharides, lecithin, cholesterol, lanolin, agar, glycerin, gelatin, starch, pectin, protamines, etc.), inorganic substances (aluminium hydroxide, aluminum phosphate, calcium chloride, calcium phosphate, iron hydroxide, ammonialyase alum, mineral oil, etc.), synthetic substances (nucleotides, polyanion, etc.). In addition to simple adjuvants, use complex, representing a mixture of lipids with mineral sorbents, oil with lipopolysaccharides and emulsifiers, micro-organisms from oils and other substances. The following is a classification of adjuvants on physicochemical and biological properties (tabl. 1) [56, 57].

Table 1  
Classification of adjuvants

Adjuvant	Adjuvant Characteristics	Advantages / Disadvantages
----------	--------------------------	----------------------------

Group		
1	2	3
Mineral adjuvants	<p>The adjuvant properties of such inorganic substances as aluminum hydroxide gel (GOA), aluminum phosphate, calcium phosphate, silicon dioxide, and others have been widely studied [2]. Mineral adjuvants can provide a longer process for the receipt of antigens (depositing effect).</p>	<p>The disadvantage of these adjuvants is that aluminum salts, due to the formation of small granulomas in which the adsorbed antigen is retained, can trigger inflammatory reactions.</p>
Oil adjuvants	<p>Type of adjuvants based on mineral oils. Such preparations are droplets of water with an antigen dissolved in them, which are in the oil phase. This type of emulsion is called water in oil. The oil used is highly purified liquid paraffin. In addition to oil, an emulsifier must be present to stabilize the mixture. The opposite type of emulsion - "oil in water" is a microdroplet of oil in water, stabilized by hydrophilic emulsifiers. This type of emulsion provides a high level of antigen presentation and moderate antigen recognition, goes well with lipophilic immunomodulators [53].</p>	<p>The positive effect of vaccination is achieved by the fact that mineral oil is not metabolized, due to which drops of the emulsion with the antigen inside them are kept at the injection site for a long time [58].</p>

1	2	3
Natural adjuvants	<p>Many natural compounds of various origin have an adjuvant effect: proteins, glycoproteins, peptides, polysaccharides, etc. The peculiarity of this group of adjuvants is that they do not create an antigen depot in the body and directly stimulate the production of antibodies. In recent years, scientists from various countries conducted a series of studies on the use of chitosan and its derivatives as part of veterinary vaccines as an adjuvant. A number of works have been carried out by foreign scientists on the inclusion of chitosan modifiers as adjuvants in vaccines against listeriosis, pseudomonosis, brucellosis, foot and mouth disease, influenza and other infections</p>	<p>The use of chitosan as an adjuvant allows you to get an immune response to the introduced antigens at or above the immune response using known oil and mineral adjuvants, which indicates the promise of further research in this direction [55].</p>
Synthetic adjuvants	<p>Muramyl dipeptide derivatives (MDP) are most commonly used. Muramyl dipeptide promotes the production of antibodies to synthetic antigens. Due to its toxicity, the efforts of researchers</p>	<p>Its advantage is the relative non-toxicity and the manifestation of the adjuvant action in both oil and water solutions.</p>



	are aimed at obtaining synthetic analogues [2]. An example of such analogs is N-acetyl-muramyl-L-alanine-D-isoglutamine, which has similar efficacy.	
Surfactant Adjuvants and Searches	Saponin and Iskom are immunomodulators capable of stimulating Th 1 and Th 2 immune responses. The vaccine adjuvants mainly use partially purified or specific fractions of QS 21 or ISCOPREP saponin. Saponin causes tissue damage and thereby contributes to antigen retention at the injection site [54].	The resulting complexes have a higher immunogenicity than the original proteins. Since ISCOM are microparticles, they are easily absorbed by macrophages, where they are processed and presented [53].
Liposomes	Microscopic structures consisting of several concentric lipid bimembrane structures surrounded by water. They are vesicles that are able to encapsulate an antigen and act as a means of delivery [58].	Liposomes carry out directed transport of antigen to the cells of the reticuloendothelial system. Numerous studies have proved the ability to use liposomes not only as carriers, but also as an immunomodulator, having discovered the immunomodulating properties of liposomes themselves.

At present, special attention is paid to environmentally friendly drugs – immunostimulant. Feature of immunostimulating drugs is their high biological activity aimed at enhancing immunity and metabolic processes in animals, causing

the animal organism itself gets rid of parasites. In addition, Immunostimulants favorably to Anthelmintics those that do not have side effects, do not accumulate in organs and tissues of the animal and not cause addiction from the parasites and do not pollute the environment. Thus, the correct application of immunostimulatory drugs not only safe, but is aa highly effective method of prevention and treatment of animal diseases and maintenance of their resistance to highlevel.

Today, there is a large selection of new commercial ready-made adjuvant and immunostimulating products, which are also at the development and testing stage, designed for different types of animals, aimed at initiating various types of immune responses, combining different levels of efficacy and safety indicators. Therefore, studies on the inclusion of various types of adjuvants in the composition of inactivated vaccines, as well as on the use of immunostimulants, are very relevant, they are conducted by most European companies involved in the production of biological products for veterinary medicine.

### **3.2 Biopharmaceutical classification system as a tool for drug development**

With the growth of the pharmaceutical market and the level of drug consumption, the quality of medicines is an important aspect of effective care. Generics occupy a significant share in the growing market of medicines. Typically, generics have a lower cost. This is due to the lack of expenditure of companies of generic manufacturers to develop and study the original structure of the drug and conduct expensive clinical trials, as well as the much lower cost of bringing the replicated drug to market.

Biopharmaceutical studies are aimed at studying the relationship between medicine as a chemical system and macroorganism as a biological system. The aim of these studies is to find ways to increase the therapeutic activity of drugs and reduce their side effect, taking into account pharmaceutical factors. The term "pharmaceutical factors" was widely used when experimental data on the significant