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A "QUALITY BY DESIGN" APPROACH FOR THE PHARMACEUTICAL DEVELOPMENT OF LIPOSOMAL DRUGS

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The creation of nanobiotechnological drugs is one of the promising areas of modern pharmacy, since it allows to develop products at a qualitatively new level. The "Quality by Design" approach implies a systematic approach to pharmaceutical development, based on understanding of the product characteristics and the technological process, which were confirmed by sound science [1].

The aim of the work is to analyze the pharmaceutical development of liposomal drugs. Based on the composition of liposomal drugs reported in the literature, the following main components can be identified: phospholipids, cholesterol, polyethylene glycol derivatives, stabilizers (cryoprotectants), buffer systems. All of them affect the structure of liposomal nanoparticles, their physicochemical and pharmacological properties.

One of the main issue of the creation of liposomal drugs is an optimal composition of lipid membrane, which is a critical for quality parameters of this pharmaceutical form. Phospholipids are the main membrane-forming components of liposomal nanoparticles. The presence of a hydrophilic and hydrophobic fragment in the phospholipid molecule and the diversity of their structure determines the leading role of phospholipids in a number of cellular processes. Nanobiotechnology uses natural and synthetic, neutral, cationic and anionic phospholipids, which differ in charge, saturation of fatty acids, properties of polar groups. The phospholipid composition of liposomes largely ensures the effectiveness of the encapsulation of active pharmaceutical ingredients in nanoparticles, the stability of the drug during production and during shelf life. When choosing a phospholipid component, it is necessary to take into account the phase transition temperature, which depends on the structure of the molecule [2, 3]. The use of cholesterol is a critical issue of the development of liposomal drugs, because it affects the fluidity and permeability of the lipid membrane. The inclusion of cholesterol increases the efficiency of encapsulation of hydrophilic active pharmaceutical ingredients, but can lead to heterogeneity of the liposomal emulsion [2].

In conclusion, the pharmaceutical development of liposomal forms requires studies to determine the optimal content of phospholipid and minor components, the study of the effectiveness of encapsulation of the active pharmaceutical ingredient and the stability of nanoparticles.

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