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SECTION 13.
PHARMACY AND PHARMACOTHERAPY

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JUSTIFICATION OF THE DEVELOPMENT OF SOLID DISPERSION SYSTEMS FOR IMPROVEMENT OF BIOAVAILABILITY OF DIFFICULTLY SOLUBLE API

At the current stage of industrial pharmacy development, in the pharmaceutical development of new drugs for predicting therapeutic efficacy, an important component is biopharmaceutical research and assessment of in vitro bioavailability of active pharmaceutical ingredients (APIs).

Complex studies of factors contributing to the dissolution or conversion of sparingly soluble APIs into dissolved states, based on innovative approaches to the management and design of pharmaceutical development, are necessary to substantiate and ensure bioavailability for oral pharmaceutical forms with sparingly soluble APIs [1-4].

In particular, studies of the effect of polymeric excipients on API solubility are gaining further relevance.

The degree of API solubility in the aqueous environment determines the possibility of effective introduction of the drug into the human body, and its solubility in non-polar solvents – the ability to pass through the lipid barrier of biological membranes. Thus, the factor of solubility in polar and non-polar media affects the processes of introduction, subsequent transmembrane transfer of API and its overall therapeutic effectiveness [5].

The development of solid dispersion systems of APIs and polymers is considered one of the promising achievements in the field of overcoming problems with limited solubility and permeability of drugs.

Solid dispersed systems consist of a hydrophobic or sparingly soluble API dispersed in a hydrophilic carrier medium. The role of the carrier is usually performed by pharmaceutically acceptable water-soluble or hydrophilic polymers (polyethylene glycol, polyvinylpyrrolidone, cellulose derivatives, and others). Optionally, surfactants can be included in these systems.

To obtain solid dispersed systems, the fluidized bed method is widely used, and the basis of which is the interaction of a flow of gas or liquid – a liquefying agent with a layer of a solid substance – AFI, solid particles suspended in the flow acquire a pulsating or vortex movement within the layer. The transition of a stationary layer into a fluidized one occurs at such a speed of the liquefying agent (the first critical speed) that ensures balance between the forces of weight and adhesion of solid particles and the aerodynamic force of the flow of the liquefying agent. Such a transition depends on certain conditions, since the limit of existence of the state depends on the size, shape and density of the solid particles, as well as on the properties of the liquefaction agent.

Application of the fluidized bed method in industrial pharmacy presupposes the use of appropriate pharmaceutical engineering: mechanical devices, process intensifiers, which allows obtaining high quality end products and creating acceptable conditions for pharmaceutical production. The equipment for applying the method of obtaining solid dispersed API systems with polymer auxiliary substances by the fluidized bed method is also used for drying granulates, and is divided into two groups: for loose and paste-like consistencies. Most often, the pharmaceutical industry uses devices of periodic action: batch-type dryers for drying granulates for obtaining tablet preparations and devices with a pulsating layer for obtaining granules for sachets and pellets.

However, the fluidized bed method has certain disadvantages: formation of agglomerates, sticking of API particles.

Therefore, as an alternative, Spray drying is also used - a method of obtaining solid dispersed systems - spray drying, a method of forming a dry powder from a liquid or suspension by rapid drying with hot gas. This is the preferred method of drying many temperature-sensitive APIs in the pharmaceutical manufacturing process, for which it is necessary to obtain a small particle size. The most common in application is the range of particle size diameters from 100 to 200 μm, which makes it possible to obtain dry powdered solid dispersion systems with acceptable flow ability.

Centrifugal formation of polymer fibers is also used as an alternative method for potential use as carriers of active pharmaceutical ingredients [3].

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