

INFLUENCE OF AUXILIARY AGENTS ON THE TECHNOLOGICAL PROPERTIES OF CAPSULE MASS

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Introduction. Development of domestic generic drugs of major pharmaceutical groups which have effective, safe and high quality, meet the objectives of the strategic import substitution program of Ukraine Government. Despite increased production in Ukraine, the major volume of pharmaceutical drug groups still needs of domestic health service in drugs with high quality and appropriate bioavailability, which is not satisfied fully yet.

Aim. Study of the effect of excipients on the quality of the capsule mass in solid dosage forms.

Materials and methods. Determination of physical and chemical parameters of the granulates in accordance with the requirements of the State Pharmacopoeia of Ukraine. The solution to this problem involves the use of an integrated approach to the creation of solid dosage forms by use of modern technological methods which based on systematic study of the properties, processing characteristics of substances and auxiliaries and their rational choice

Results and discussion. In the development of drugs the important role played by excipients, which are selected for each dosage form should be a reasonable estimate of the physical, chemical and technological characteristics, the study of their impact on the efficacy, safety and stability of drugs. It has been studied all characteristics of excipients for science-based selection of the composition and technology of encapsulated dosage forms; The choice of the proportion of auxiliaries was carried out taking into account the requirements to the quality of the mass for filling of capsules. In this case it was necessary to fulfill the following conditions: auxiliaries were mixed with the active substance with the greatest possible uniformity; the mass of granulation capsule should have sufficient fluidity to ensure the accuracy of the dosing process. As humectants solutions used alcohol plasdone K-29, polyvinylpyrrolidone (PVP), S-630 plasdone. The quality of resulting granules after moistening of the powder mass plasdone alcoholic solution of K-29 is significantly different from the latter, namely the granulate flowability sufficient for dispensing the formulation of an industrial production, which contributes to the homogeneity of dosing.

Conclusions. The results of these studies have shown the influence of excipients on the pharmaco-technological parameters of quality granulates. To ensure the homogeneity of dosing granulated mass is necessary to use a wet granulation method, and K-29 use as the humectant alcoholic solution of plasdone.