

THE STUDY OF THE TECHNOLOGICAL CHARACTERISTICS OF POWDER MIXTURES ON THE BASIS OF THE DERIVED CAMPHORIC ACID

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Natural carboxylic acids play a critical role in the biochemical processes that ensure the functioning of the body. On their basis a significant number of pharmacological agents and obtained biologically active substances (carbenoxolone, decamp).

In a State institution “V. Danilevsky Institute for Endocrine Pathology Problems National Academy of Medical Sciences of Ukraine” derived camphoric acid had been synthesized studied, which in experimental models of disturbed spermatogenesis improves its functions in the absence of hormonal and antihormonal action. Despite the widespread use and potential usefulness for the functioning of the reproductive system, there are medicines based on natural carboxylic acids that is designed for the treatment of its disorders in men.

A rational approach to the selection of the components of the dosage forms based on different technological tests provides a high level of therapeutic action and minimum unwanted side effects.

In this regard, the aim of our work was the rationale for the composition of the oral dosage form of the original drug derived on the basis of camphoric acid.

The objects of study were the substance derived camphoric acid, excipients, which are recommended for use by Ministry of health of Ukraine, and experimental powder mixture.

The definition of pharmaco-technological parameters of powders and powder compositions based on a derivative of camphoric acid (flow rate, angle of repose, coefficient Carr, bulk density, moisture content, moisture absorption) were performed according to standard techniques and tests the State Pharmacopoeia of Ukraine 1 edition.

Each formulation of the drug is necessary to choose a pharmaceutical factors based on their immediate effect on the activity and side effects of the drug. Selection and study of pharmaceutical factors is achieved by a complex pharmaco-technological tests at various stages of pharmaceutical drug development, registration, confirmation of the quality and the production technology.

Research for the purpose of selection of the composition of the oral dosage form of the original drug based on a derivative of camphor acid, primarily carried out

taking into account the physico-chemical and technological parameters of the powder substance, and a synthesis of literature data regarding the components of the most popular drugs in this pharmacological groups represented in the modern pharmaceutical market of Ukraine.

Testing of the active substance showed that derivative of camphor acid is a fine powder with crystals of irregular shape in the form of spheres, prisms and their fragments (predominant fraction with a particle size 6,01-12 micron), characterized by complete non-moisten, lack of moisture-absorbing properties and relates to free flowing materials. Also, it was determined that due to the complicated surface of the particles, the powder tends to accumulate statistics of electric charge, which can create potential difficulties at the stage of screening or mixing and heterogeneity in particle size can affect the time of the dissolution processes.

Thus, the technological characteristics of the substance of derivative of camphor acid allow to predict the use of conventional fillers, as well as their composition and quantity.

Bulk density of solids is an important factor that defines the parameters and constructive solutions to technological stages of production, namely the speed of loading, the use of special, standard or optional equipment. Powders differ in the bulk of the mass values from very heavy ($> 2.0 \text{ g/cm}^3$) to light ($< 0.6 \text{ g/cm}^3$).

The ability of the powder to leak out during overload or downloads characterized by means of such process parameters as fluidity (flowability) and the relative mass flow (angle of repose) and is described respectively from very good (8,6-12 g/sec; 25-30 degrees) to very bad (0.3 to 1 g/sec; >66 degrees).

Simple, fast and popular methods for predicting the flow properties of powders are the definition of the indicator of packing or coefficient of Hausner carried out by measuring the bulk volume and the volume of the powder after shrinkage.

Cellulose derivatives or copolymers of acrylic acid, varieties of starch, talc, salts of stearic acid, aerosil, sucrose, lactose, sugar alcohols (polyols) were requested as components of the dosage form. At first individual auxiliary substances in the experimental mixtures were studied with pharmaco-technological tests and then in various combinations for prediction of their behavior in dosage form. It was found that bulk density of the investigated powders was in the range of values of the middle class (of 1.1 to 0.6 g/cm^3). Parameters angle of repose allowed to take them to fluid materials 35-45 degrees. The value of pressing also meets satisfactory requirements of this technological indicator.

It can be concluded that the required ingredients allow to get technologically suitable mixture for the manufacture of oral dosage forms.