

# STUDY OF PHYSICO-CHEMICAL AND TECHNOLOGICAL PROPERTIES OF ACTIVE SUBSTANCES IN THE COMPOSITION OF MEDICATED CHEWING GUM

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**Introduction.** Medicated chewing gum (MCG) - one of the modern pharmaceutical forms, which is widely used to treat a wide range of diseases. This formulation is especially effective for the treatment of dental diseases, which involves a number of advantages compared with other oral dosage forms: the length and location of action, the consistency of concentration of active substance, the rapid action and fewer side effects. As active ingredients for inclusion in the squad of MCG were selected proteolytic enzymes - lysozyme and papain, due to their combined effect on the oral tissue and a wide use in dentistry.

**Aim.** The aim of our work was the study of the physico-chemical and technological properties of active pharmaceutical ingredients (APIs), and their mixtures for the development of rational technology and composition of MCG.

**Materials and methods.** The objects of research were lysozyme and papain - protease of animal and vegetable origin, and their mixture as well. Were carried out following physicochemical (moisture content, shape and size of the crystals) and pharmaco-technology (bulk density before and after shrinkage, flowability, angle of repose) researches of samples of substances. Microscopic analysis of powders was performed using laboratory microscope «Konus Academy», equipped with a video camera ScopeTek. Images were processed by the software ScopePhoto (version 3.0.12.498). Moisture content of samples was studied using rapid moisture analyzer «Sartorius MA-150» (Germany). Fluidity defined on the device VP-12A by measuring the time of leakage of sample powder (100.0 g). Bulk density installed on the device for determining bulk volume type PT-TD1 (PharmaTest, Germany) (100.0 g).

**Results and discussion.** Lysozyme - animal enzyme from the class of hydrolases, has immunomodulatory, anti-inflammatory, antitoxic and antibacterial effect, and stimulates regeneration processes and erythropoiesis. It affects gram-positive and gram-negative bacteria and cell walls by hydrolysis.

Papain - enzyme of plant origin, which is obtained from the papaya fruit juice. It has anti-inflammatory, antibacterial, wound healing and an antioxidant action. In addition, it provides local cleaning of dental hard tissue by destroying microbial plaque and preventing its formation, thereby providing prophylactic and therapeutic effect on the teeth.

During the researches, for papain and lysozyme were studied following physico-chemical parameters - crystal size, their shape, character of surface, and moisture content. From the technological characteristics was determined the bulk density before and after shrinkage, the angle of repose and flowability.

According to the microscopic analysis, lysozyme particles are crystals of isodiametric (nearly spherical) shape, the size of 1.0-0.1 microns, with the presence of debris. Papain - flat, sometimes three-dimensional crystals with polygonal and uneven edges of anisodiametric type with a particle size of 2.0-0.1 microns, and with the presence of debris. The magnitude of the thickness and length of crystals both substances can be classified as fine. A mixture of papain and lysozyme crystal is polydisperse systems with particles of different shape and size.

The results of physicochemical and pharmaco-technological properties of the main components of MCG and their mixtures are shown in Table. 1.

**Table 1**

Physico-chemical and pharmaco-technological properties of the API  
and their mixture.

№	Properties	Papain	Lysozyme	Mixture of APIs
1.	Moisture, %	0.68±0.01	7.82±0.01	5.50±0.01
2.	Flowability, c/100 r sample	15.33±0.6	27.17±2.5	21.84±1.0
3.	Angle of repose, degree	29±1	31±2	30±1
4.	Bulk density before shrinkage, $\frac{m}{V_0}$ , g/ml	0.771±0.015	0.565±0.015	0.649±0.015
5.	Bulk density after shrinkage, $\frac{m}{V_{1250}}$ , g/ml	0.834±0.015	0.735±0.015	0.769±0.015

Note: n = 5, P = 95%.

The obtained data indicate that the API and their mixture have a good flowability, but during tests powders hung in the funnel, which required the use of vibration.

**Conclusions.** During the studies were identified physicochemical and pharmaco-technological properties of papain, lysozyme, and their mixtures, that will allow us to predict the including of rational auxiliaries of relevant groups to develop MCG.