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Investigation of the effect of specific pressing pressure on the pharmaco-technological parameters of tablets quality

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Abstract

The results of the specific pressing pressure influence on the parameters of friability, resistance to crushing, disintegration and height of tablets on the basis of *Scutellaria baicalensis* dry extract obtained by pressing with previous granulation are given. The choice of the rational mode of tableting to obtain tablets meeting the requirements of the State Pharmacopoeia of Ukraine has been substantiated.

Keywords: Compression pressure, pharmacotechnological indices, tablets, *Scutellaria baicalensis*

Introduction

Medicinal products based on medicinal plant raw materials are widely used in Ukraine. Their range is represented by a rather wide assortment. In addition, due to the diversity of biologically active compounds contained in the herbal raw material, phytopreparations remain relevant in the treatment of many diseases ^[1, 2].

In Ukraine, more than 45% of pharmaceuticals produced by the chemical and pharmaceutical industry are made from plant raw materials, and among the drugs used there is only a small amount of drugs with nootropic action ^[3-6]. Therefore, it is promising to create new solid dosage forms in the form of tablets based on the dry extract of *Scutellaria baicalensis*

In the manufacture of tablets in industrial conditions at optimal composition of the components, a significant impact on the compression process and the properties of the resulting tablets has compression pressure. The process of tablets compressing is determined by the free pressure on the punches, the lateral pressure on the walls of the matrix, the coefficient of external friction of the compressed tablet on the walls of the matrix, the temperature of the pressed material. Increasing the specific pressure can increase mechanical strength and affect the time of disintegration ^[7]. The pressure of pressing not only affects the quality of tablets, but also wearing and the duration of use of the press tool of the tablet machine.

In order to select the optimal pressing mode for obtaining high quality tablets based on the dry extract of the *Scutellaria baicalensis* we have investigated the effect of specific pressure of compression on the main pharmaco-technological parameters of the tablets under the conventional name "Skutex" - height, resistance to crushing, friability and disintegration.

Materials and Methods.

In the experiment we used a tablet mass that was compressed at 0.32 g on a hydraulic press with a diameter of punches 10 mm in the range of pressure 60-400 MPa. The resulting tablets were controlled by the following parameters: height and resistance to crushing, friability and disintegration. The tests were performed according to the procedures, given in the SPU ^[8] and plotted graphic dependencies.

Acknowledgment

We have found that physical and technological properties of the dry extract of *Scutellaria baicalensis* require the use of wet granulation method. At compression, high pressure can lead to an increase in the density of the granules adhesion in the tablet, which may affect solubility, disintegration and reduce bioavailability. It is believed that the optimal properties possess such tablet masses that can be pressed changing the pressure in wide ranges, while the resulting tablets meet the requirements of the SPU.

Initially, we studied the effect of compression pressure is increased in the range from 60 to 325 MPa, the height of the tablet decreases, and after 325 MPa the height becomes more stable and practically does not change. The height of the tablet at compression pressure from 120 to 325 MPa corresponds to the requirements of GOST 64-072-89 and is 3.2 ± 0.4 mm.

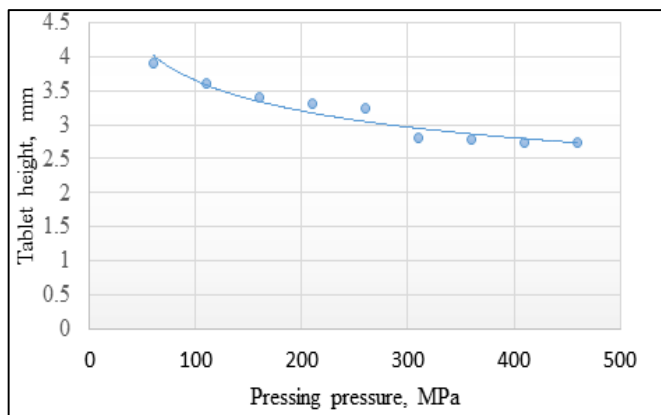


Fig 1: Effect of compression pressure on the height of tablets "Skutex"

The next step we studied the effect of pressing pressure on the resistance of tablets to crushing. The obtained results are shown in Fig. 2

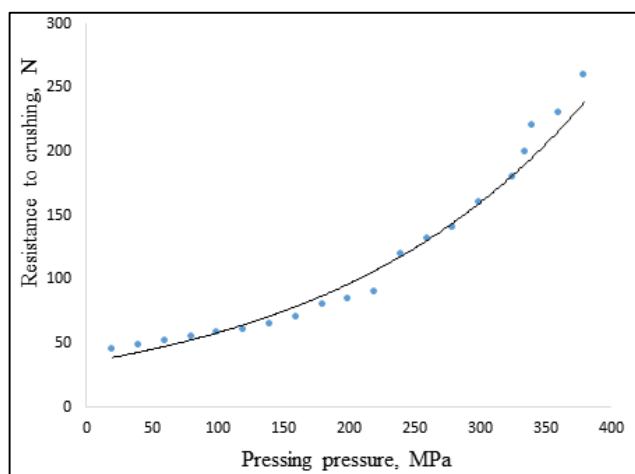


Fig 2: Effect of pressing pressure on the resistance of tablets to crushing

Data of Fig. 2 indicate that in the case of increasing compression pressure from 60 to 400 MPa there is an increase in the resistance of tablets to crushing. A significant increase occurs when pressure ranging from 120 to 240 MPa is used, when the stability of the tablets to the crushing increases from 60 to 140 N, further increase in pressure increases the resistance of the tablets to crushing within 30 -40 N. The resulting curve of the pressing process indicates a direct relationship between specific pressure and mechanical strength of the received dosage form, as well as the absence of plastic deformation of the powder mass.

The next step was to study the effect of pressing pressure on the tablets friability. The results of these studies are shown in Fig.3.

For the determination tablets compressed in the range from 60 to 400 MPa were used. When using the compression pressure of 60 MPa, the friability of the tablets was about 2%.

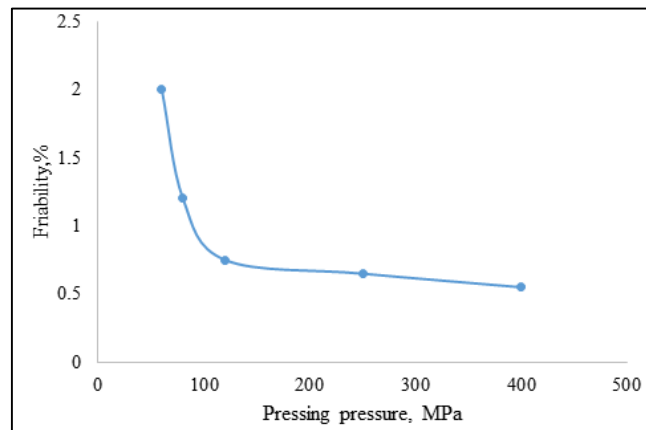


Fig 3: Effect of pressing pressure on friability.

With increasing compression pressure, a clear dependence was observed: an increase in pressure caused a decrease in the friability of the tablets. Studies have shown that only after applying a pressure above 100 MPa, the friability of tablets met the requirements of the SPU (less than 1%).

The effect of compression pressure on tablets disintegration is shown in Fig.4.

As it is seen in Fig. 4, tablets, compressed at the values of the specific compression pressure under 120 MPa, disintegrate within 3-4 minutes. Increasing the compression pressure from 120 to 250 MPa leads to an increase in disintegration time of up to 8 minutes. The further increase in the specific pressure of pressing above 250 MPa leads to an increase in the disintegration time of up to 17 minutes.

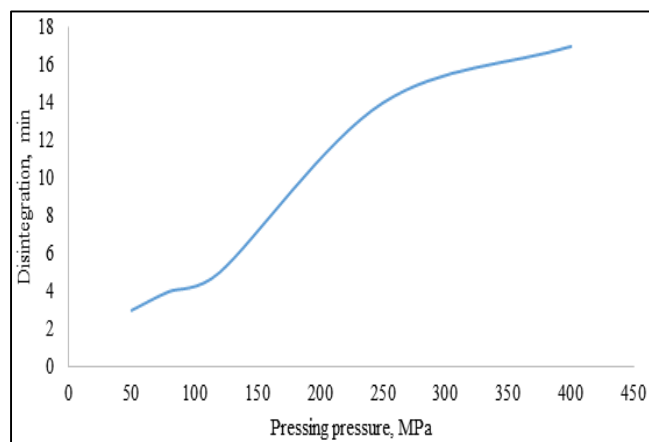


Fig. 4 Influence of compression pressure on disintegration.

Conclusions

The conducted studies allowed to establish a significant dependence of the studied tablets quality on the applied compression pressure and to choose the optimal tableting modes. According to the results of the research, it was determined that the specific compression pressure from 120 to 250 MPa provides obtaining of good quality tablets that meet the requirements of the SPU on indicators such as the height of the tablets, resistance to crushing, friability and disintegration.

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