ABSTRACT

Charles University, Faculty of Pharmacy in Hradec Králové

Department of:	Pharmaceutical Technology
Mentor:	doc. PharmDr. Jitka Mužíková, Ph.D.
Conzultant:	Mgr. Thao Tranová
Student:	Magdaléna Prejdová

Title of Thesis:	Study of tableting materials and tablets from spray-dried mixtures of the drug and excipients

This work deals with the influence of three different size fractions of spray dried powders (SDP) on flow properties and on the compressibility of tablets. The aim was to obtain orodispersible tablets with a poorly soluble drug aprepitant. Different particle sizes were obtained by different nitrogen flow rates during spray drying. The SDP were composed of aprepitant and hypromellose phthalate in a 1:2 ratio. The structure of the SDP was tested by scanning electron microscopy. SPD were part of directly compressible tabletting materials or tabletting materials made from granulates. All tablets contained the co-processed dry binder Prosolv® ODT G2, the sweetener sucralose and the lubricant magnesium stearate. The tested parameters of powders and tabletting materials were particle size and flow properties. The tablets were compressed by material testing machine the Zwick/Roell with a compression force of 2.5 kN. The compression process was evaluated by using the energy profile of the compression process. The tested properties of tablets were tensile strength, friability, disintegration time and the wetting time.

SDP were made up of spherical hollow particles. The SDP particles with the largest average particle size of d_{v50} 45,10 μm (AK) were easily deformable, while the SDP particles with the smallest average particle size of d_{v50} 24,20 μm (AJ) were more resistant to deformation. With increasing particle size and decreasing bulk density, the individual energies of the compression process increased, except for the energy

of elastic deformation (E_3), which was independent of these variables. The lowest measured energy values occurred in tablets with non-spray dried drugs. The tablets with SDP prepared by direct compression had the highest tensile strength and the longest disintegration time, which at the same time did not meet pharmacopoeia requirements for ODT. Tablets prepared from all granulates showed optimal disintegration time and wetting time, tablets with fraction AK had higher tensile strength and tablets with fraction AJ had friability value above the pharmacopoeia limit of 1 %. The most optimal tabletting material, for the production of orodispersible tablets, was a tabletting material made from granulate with a spray-dried powder of medium average particle size d_{v50} 31.80 μm (AC).