ABSTRACT

Charles University, Faculty of Pharmacy in Hradec Králové

Department of: Pharmaceutical Technology

Consultant: PharmDr. Petra Svačinová, Ph.D.

Student: Hana Vondrušková

Title of Thesis: Evaluation of co-processed excipients

intended for orodispersible tablets

formulation

Co-processed excipients (CPE) can be defined as a combination of two or more substances, which are physically modified by an appropriate process (e.g. spray-drying). These excipients are currently increasingly used for production of tablets by direct compression. Due to the availability of a wide range of initial materials for their production, it is possible to obtain a large number of combinations with required characteristics and better properties than simple physical mixtures. Although the composition of these CPE may be similar, the small changes in the component's characteristics can make them behave differently after tableting.

The aim of this work was a comparison of compressibility (using *force-displacement* record) of CPE (Starlac®, Combilac®, Cellactose 80®, Disintequik™ ODT® containing lactose and Ludiflash®, SmartEx QD 50®, SmartEx QD 100® containing mannitol) and properties of obtained tablets (tensile strength, friability, disintegration and water absorption ratio) prepared using compression pressures of 78, 130, 182 MPa. CPE containing lactose had lower values of plasticity compared with CPE containing mannitol but higher values of released elastic energy. This observation is also reflected in values of tensile strength where the highest values were measured for Ludiflash® and lowest for Starlac®. CPE containing mannitol implied higher ejection force. All samples fulfil the requirements of Eur. Ph. for ODT tablets disintegration (3 minutes). The highest water absorption ratio was measured for Cellactose 80® while the lowest for Starlac®. Generally, it is not possible to select the best CPE, as their different properties fit different needs of manufacturers for final products.