

**Abstract format:** Poster

**Title:** The Role of Different Binary Binder Systems on Ibuprofen-Tablets by Dry Granulation (Roller Compaction)

**First and family names:** P. Müsse, Hochschule Fresenius University of Applied Sciences, 65510 Idstein, Germany / Dr. M. Yunis, BIOGRUND GmbH, 65510 Huenstetten, Germany

**Introduction:** Dry granulation (roller compaction) as a continuous process becomes more important for the pharmaceutical and related industries. That is the reason why the interest of different materials and their processing is growing. One negative aspect of the roller compaction is the work hardening effect. The term work hardening effect refers to the effect that granules often show a reduced tensile strength compared to direct compression. With CompactCel<sup>®</sup>, a dry binding agent, it is possible to improve the mechanical properties and lower the work hardening effect.

**Aims:** The present study investigates the suitability of CompactCel<sup>®</sup> based on Hydroxypropyl cellulose (HPC), CompactCel<sup>®</sup> based on low-substituted Hydroxypropyl cellulose (L-HPC) and a Reference, which is a binary binder system of Kollidon<sup>®</sup> (Vinylpyrrolidone-vinyl acetate copolymers) and microcrystalline cellulose (MCC), in the dry granulation.

**Methods:** Table 2: Used Devices/Methods

Methods / Device / Manufacturer

Dry granulation + milling / WP 120 / Pharma Alexanderwerk AG

Compression / Pressima / IMA Kilian GmbH & Co. KG

Particle size distribution / Camsizer XT / Retsch Technology GmbH

Angle of repose / BEP 2 / Copley Scientific Ltd.

Tablet hardness / TBH 325 / Erweka GmbH

Tablet friability / TAR 120 / Erweka GmbH

Disintegration time / ZTM 322 / Erweka GmbH

**Results:** The results of the comparison are shown in table 3 and figure 1–4.

The influence of the different binding agents on the granulation characteristics was determined by the resulting particle size of granules. The largest particle sizes and the lowest amount of fines resulted from formulations with CompactCel<sup>®</sup> based on HPC SSL SFP. Formulations granulated with CompactCel<sup>®</sup> based on L-HPC LH-31 or the Reference had a median particle size distribution of 44.5 µm and 93.3 µm respectively, whereas the formulation with CompactCel<sup>®</sup> based on HPC SSL SFP had a median particle size distribution of 158.4 µm

**Conclusions:** The study shows that the process of dry granulation needs a careful selection of the binder and disintegrant. The tablets with CompactCel<sup>®</sup> based on HPC SSL SFP as a binding agent are the most mechanically stable and are recommended for active pharmaceutical ingredients (API) which need a strong binder. The tablets with CompactCel<sup>®</sup> based on L-HPC LH-31 as a binding agent component have the lowest mechanical stability, whereas the two possible applications of L-HPC LH-31 are well-established during the trials. In addition to the use as a binder, L-HPC LH-31 is suitable as a swelling agent and the need of a disintegrant in the tablet is redundant. Depending on the API and desired dissolution, CompactCel<sup>®</sup> can be formulated with a disintegrant as well.

**Keywords:** #RollerCompaction, #Biogrunder, #DryGranulation, #CompactCel<sup>®</sup>, #BinaryBinderSystem, #Ibuprofen