

Technology transfer for the dry granulation process aiming at keeping identical ribbon properties

Petr Jan^{1,2}, Zámotný Petr¹, Stasiak Pawel²

¹University of Chemistry and Technology Prague, Faculty of Chemical Technology, Prague, the Czech Republic

²Zentiva, Pharma Development, Prague, the Czech Republic

Variability of the dry granulation (DG) systems design, compaction parameters, and input material properties make it difficult to understand the internal properties of the intermediate product (ribbon, granulate) and, as a result, the properties of the tablets. Therefore, it is not easy to unify the dry granulation technology for equipment from different manufacturers or of different size and to produce intermediate product of constant quality. Two compactors (Alexanderwerk WP200-PHARMA, Gerteis MINI-PACTOR) were used in research aiming at evaluation of how the process parameters are reflected in the compaction process of the powder. The ribbon stiffness has been selected as the indicator of the degree of ribbon compaction. This parameter has been calculated from ribbon texture analysis data recording the ribbon resistance to structural breaks due to the penetrating needle probe (force/penetration depth) – ribbon stiffness. Since the parameter is locally specific, the stiffness profile was recorded across the ribbon width and the mean integral value was used as the ribbon property. Regression models based on conversion of the compression parameters such as hydraulic pressure, and specific compaction force (SCF) have been performed to match targeted properties of the ribbon (i.e., mean ribbon stiffness; fraction mass yield of the compacted particles with a particle size larger than of the feed powder; bulk density and tapped density of the granulate). The output of these models are regression equations describing technology transfer. Experiments have been carried out on two formulations manufactured using same technology and others experiments are also being carried out.