Mechanical and Physico-Chemical Characterization of Excipients in Order to Define their Applicability for Tableting

Katharina Maria Picker
Institute of Pharmaceutical Technology and Biopharmacy,
Martin-Luther-University Halle-Wittenberg, 06120 Halle/Saale, Germany

Aim of the process of tablet production always was to formulate tablets which are as robust and stable as possible. Therefore the main excipients, mainly the fillers, are expected to deform plastically.

However during the process of tablet production not only the excipients are deformed but the tableted product deforms also. This can lead to the total or partial damage of the product to be tableted: Biologically active proteins as enzymes can lose their activity, polymorphs can transform and change their solubility and the coating of pellets can lose its function. For such products the new concept "soft tableting" is necessary.

On the basis of thermodynamic equations [1], theoretical conditions were derived for which a tableting excipient should deform plastically and form stable tablets. Similar theoretical considerations were done to find the conditions for a tableting excipient for soft tableting.

For both applications traditional and soft tableting a precise definition and characterization of the process of tablet formation is necessary. The process of tablet formation can be defined as the sum of the tableting process and the final formation of the tablet after tableting.

The whole process was studied for several excipients, traditional ones as microcrystalline cellulose, dicalcium phosphate dihydrate and hydroxypropyl methyl-cellulose and new ones as carrageenans, chitosans and polyethylene oxides. For tableting an instrumented eccentric tableting machine (Korsch EK0) was used. The measured force, displacement, and time values were analyzed by three-dimensional mathematical modeling using the 3D-Model [2]. Elastic recovery (ER) up to the final expansion of the tablet was studied. Additionally, the physico-chemical properties of the materials were analyzed.

The results show that the mechanical properties of the tableting excipients influence directly the damage of the tableted product. Both traditional and soft tableting have special requirements.

[1] Freudenthal, A., Inelastisches Verhalten von Werkstoffen, VEB Verlag Technik Berlin, 1955.
[2] Picker, K.M., New Insights into the process of tablet formation – Ways to explore soft tableting. Habilitationsschrift, Universität Halle-Wittenberg, 2002