MEDELPHARM
the tableting instrument company

BULLETIN

MATERIAL CHARACTERIZATION ON STYL'ONE NANO

Particle morphology influence on tablet characteristics

Excipients, APIs or formulations can be processed in different ways, thus resulting in different properties. Research has been performed to improve powder properties including powder flow, powder density, particle size distribution and particle shape.

In the case of tableting, these improvements are crucial to guarantee optimal tablet properties, production yield and high production output.

This case study will illustrate how STYL'One Nano can be an efficient tool for scientists to demonstrate material properties, securing their formulation development and their product marketing.

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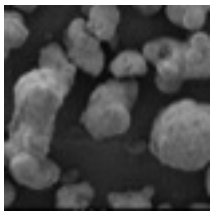
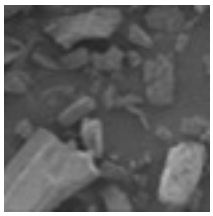
Crystalline versus spray-dried grades

Mannitol is a polyol widely used in formulations like chewable formulations but also as a filler or a bulk sweetener. It can also be used as replacement in lactose-free formulations. In this example, the effect of mannitol production processes and particle size distribution on tablet properties have been investigated. Two different processes can be used to produce mannitol:

- Spray dried mannitol has been developed to increase and control particle size and to improve the manufacturability while maintaining good flowability.



- Crystalline mannitol grades are typically milled or sieved to obtained different ranges of particle size.



Fast experiment set-up for comprehensive results

Tableting properties of two grades of spray dried mannitol (100SD and 200SD) and three grades of crystalline mannitol (25C, 50C and 160C) have been compared on a STYL'One Nano compaction simulator. Tablets were made at different forces ranging from 5 to 25 kN, using a standard EU-B 11.28-mm round flat tooling and a V-shape research compression profile. V shape profile is often used for material characterization to ensure constant speed of the punch during the compaction process.

Tablet physical properties including weight, dimension and hardness were measured on a Sotax® ST50 and automatically transferred to Alix, the piece of software that drives the STYL'One Nano and analyses the data generated. Alix then computes the data and generates standard and custom charts to accelerate the decision making during pharmaceutical development.

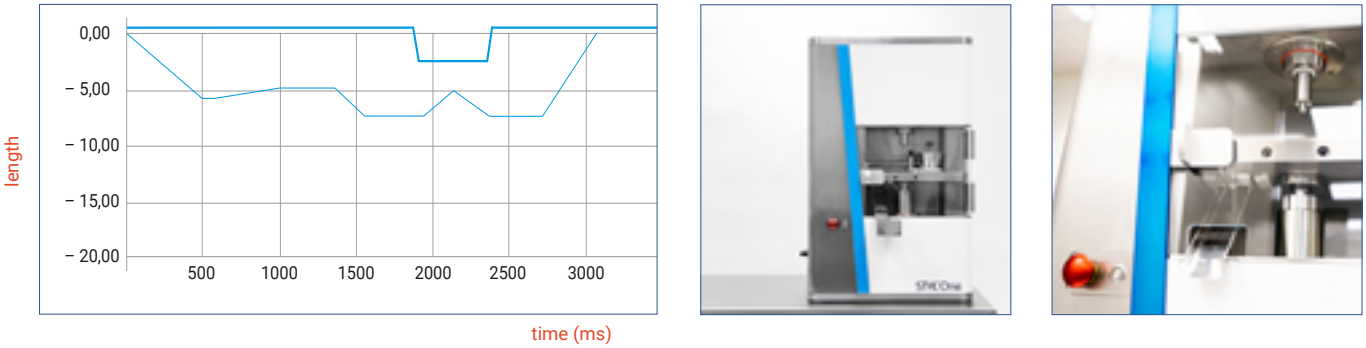


Figure 1
V-shape compression profile

Plastic energy: a driving factor for higher manufacturability

The manufacturability plot (hardness vs forces applied) is highlighting a clear difference between the two production processes.

The spray dried materials are providing higher tablet strength compared to crystalline grades. This phenomenon is not surprising as Spray drying has been developed to produce high functionality excipients to improve key properties such as flowability and manufacturability.

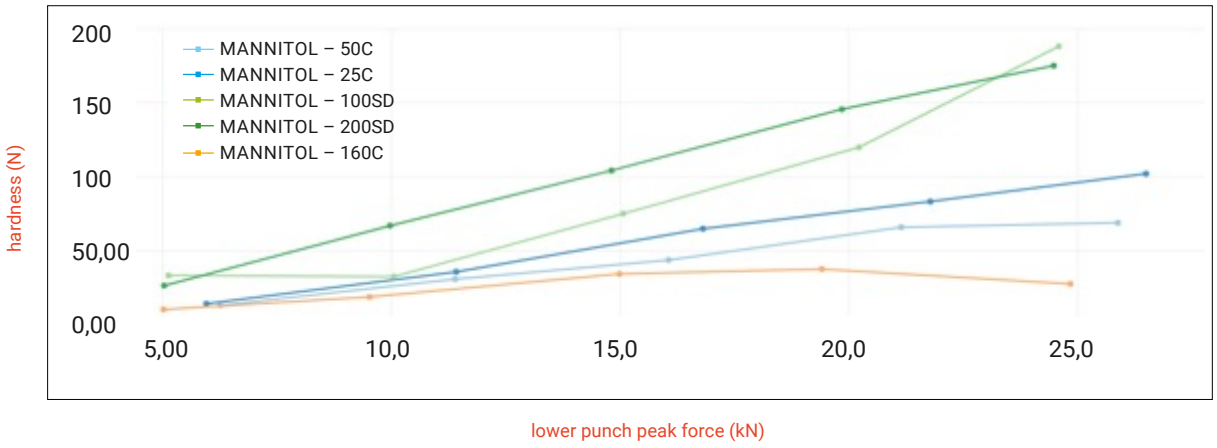


Figure 2
Manufacturability plots of different grades of Mannitol

Particle size of the crystalline grades also has an influence on manufacturability. Decreasing the particle size leads to increased surface area. This, combined with a higher plastic energy, results in an increase in tablet hardness due to higher cohesion between particles.

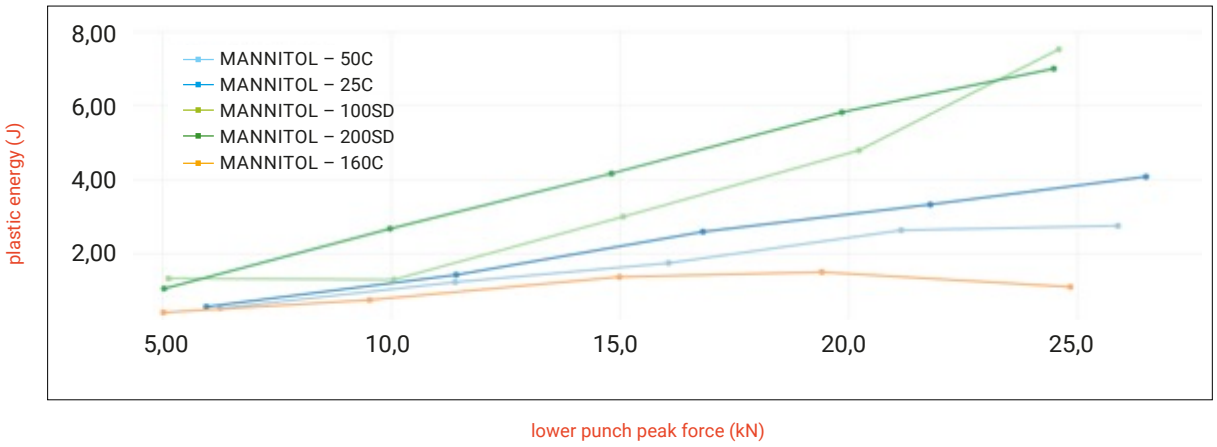


Figure 3
Plastic energy versus compression force

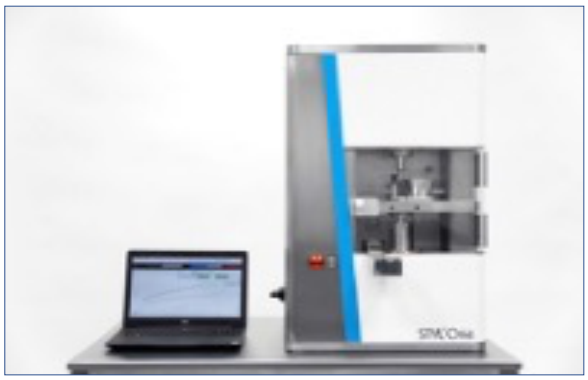
Imagine your own use of STYL'One Nano

This example showed how quickly different grades of excipient can be compared. Similar studies can be easily performed on a STYL'One Nano to assess the impact of a formulation process change with a small amount of material required (only a few grams). For example:

- Impact of granulation process parameters on tablet properties
- Influence of milling conditions on quality attributes
- Effect of mixing conditions on tablet properties
- Approval of a new excipient/API supplier

STYL'One Nano key benefits

- Compact & mobile
- Standard tooling
- Ideal for small amount of material
- Quick product or tooling changeover
- Easy to clean – easy to handle
- Intuitive HMI for fast experiment setup and results



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