MEDELPHARM
the tableting instrument company

MATERIAL CHARACTERIZATION WITH A V-SHAPE COMPRESSION PROFILE ON STYL'ONE NANO

In the early stages of drug development, APIs are often available in limited amount. However, scientists have to foresee the impact of compaction parameters on tablet attributes. In fact, tablet quality such as its hardness depends on several process parameters including the compression speed, pressure and profile used.

Compaction simulators, such as the STYL'One Nano, can easily explore compression dynamics and allow researchers to deeply understand their powder with only few grams of material. This avant-garde technology is key for fundamental material characterization and deep understanding of their product.

The goal of this bulletin is to dive into the V-shape compression cycle available on STYL'One Nano and to demonstrate its usefulness in powder characterization with real speed sensitivity practical examples.

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Assess the compression speed sensitivity of your material with a V-shape profile

According to the Monograph 1062 from US Pharmacopeia, the V-shape profile is defined as a “linear compression and decompression phases that yield saw-tooth punch displacement–time profiles”.

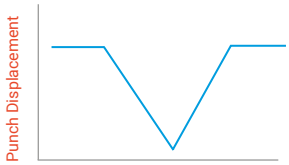

Figure 1
V-shape profile according to USP <1062>

This compression cycle is often used for powder characterization to ensure a constant punch speed during the compression and decompression events. Hence, it allows to study the compression speed impact on tablet characteristics. Speed in a range of 1 mm/s to 90 mm/s can be reached on the STYL’One Nano, allowing speed sensitivity assessment.

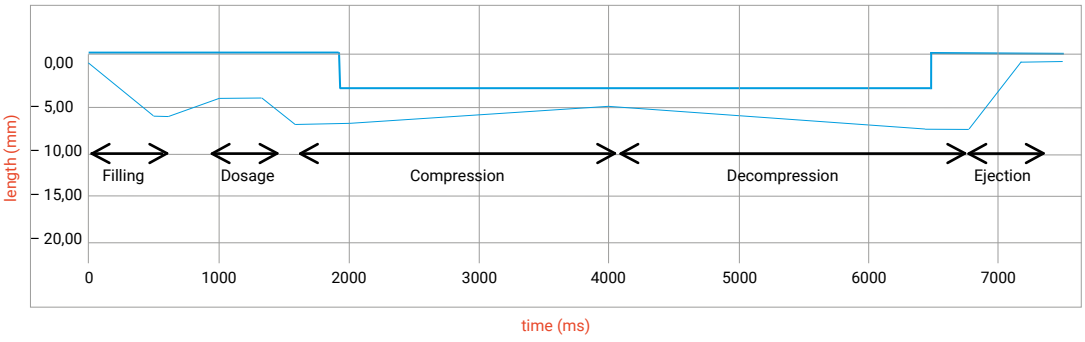

Figure 2
V-shape profile at a speed of 1 mm/s on STYL’One Nano

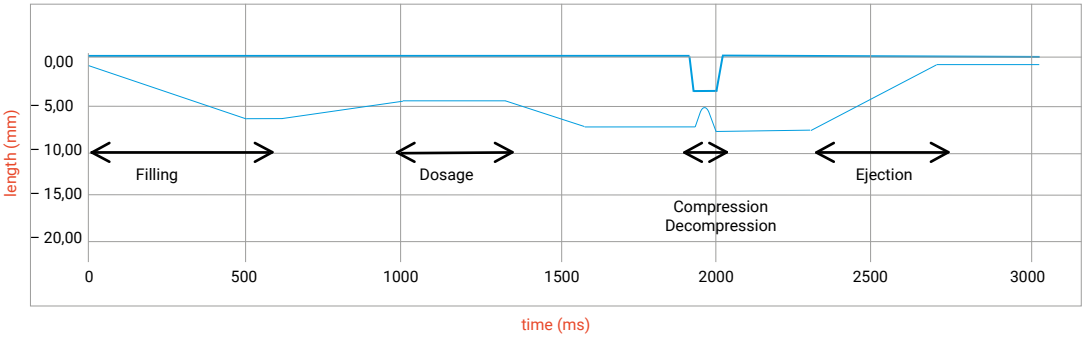

Figure 3
V-shape profile at a speed of 90 mm/s on STYL’One Nano

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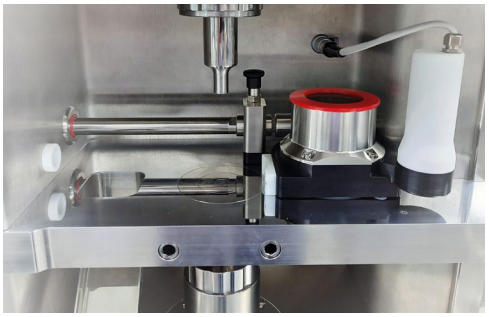
An experiment easy to implement for conclusive results

In this study, the speed sensitivity of a pregelatinized maize starch was assessed with the STYL'One Nano benchtop compaction simulator. A seven-point compression study was performed from 5 kN to 30 kN at two different compression speed using standard EU-B 16x8-mm oblong tooling and a V-shape compression profile. Tableting properties at high speed (90 mm/s) and low speed (1 mm/s) have been compared. Only 50 grams of powder were needed for this experiment.

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.



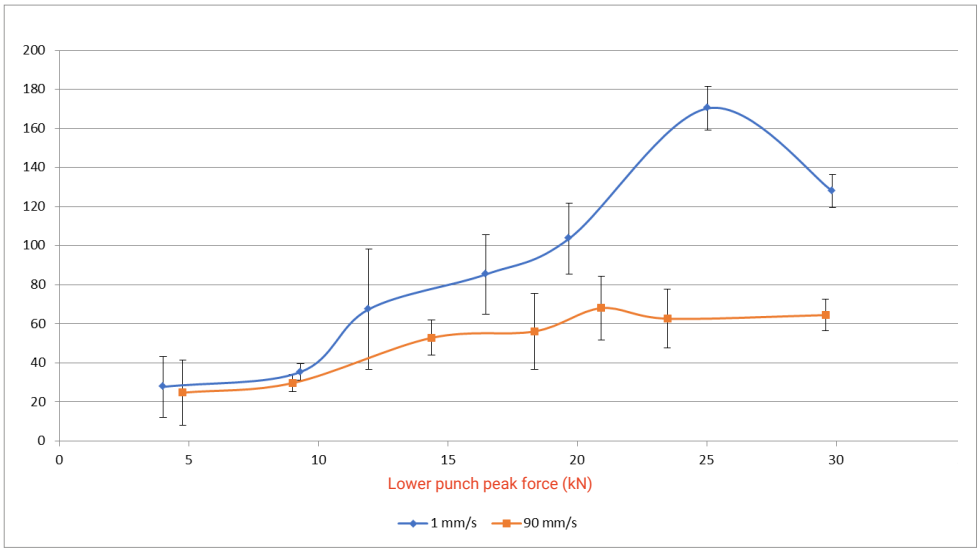


Figure 4

Manufacturability plots of pregelatinized maize starch at different compression speed

The manufacturability plot (hardness as a function of compression force) is highlighting a clear impact of the compression speed on the tablet hardness. The speed sensitivity of pregelatinized maize starch can be explained by its plastic/elastic deformation behavior. Product cohesion for such material is greater at low speed as increasing compression time would lead to stronger bonds between particles.

In practice, powders that show strain rate sensitivity might generate defects during manufacturing at high speed. Having this kind of information during early development stage will influence the choice of excipients and the manufacturing process.

Consider research compression profiles to characterize your powders

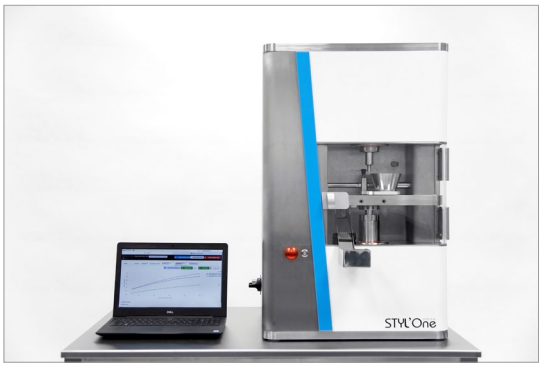
This case study demonstrated how the V-shape profile on the STYL'One Nano allows scientists to link compression speed to product cohesion. Different studies can be easily performed on the STYL'One Nano with neat APIs as well as final blends with only few grams of powders. For example:

- Characterize and compare different products at constant speed
- Study the impact of compression parameters on tablet properties
- Predict to what extent a formulation is strain rate sensitive

STYL'One Nano key benefits

The STYL'One Nano is a compaction simulator focused on API characterization and formulation development. This R&D tablet press is invaluable during the first steps of drug development. It allows researchers to:

- Get comprehensive product knowledge with only a small amount of material
- Screen formulation with a quick product changeover
- Explore process parameter influence on tablet properties
- Save time and money during development



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