MEDELPHARM
the tableting instrument company

MATERIAL CHARACTERIZATION WITH AN EXTENDED DWELL TIME COMPRESSION PROFILE ON STYL'ONE NANO

During the development of a new drug, active materials are often available in small quantities for cost or process reasons. However, scientists have to understand their deformation behavior to design the best formulation possible and find suitable process parameters for production.

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 premium technology is key for fundamental material characterization and deep understanding of your powder.

The goal of this bulletin is to dive into the Extended Dwell Time cycle available on STYL'One Nano and to demonstrate its usefulness in powder characterization with real practical examples.

Evaluate your powder viscoelasticity/viscoplasticity with an Extended Dwell Time compression profile

According to the Monograph 1062 of the US Pharmacopeia, the Extended Dwell Time profile is defined as “square punch displacement–time profile”.

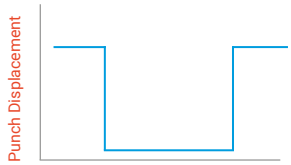

Figure 1

Extended Dwell Time profile according to USP <1062>

The dwell time is the period during which the punches are static throughout the compression cycle. Having the capability to modify this dwell time in the range of 1 ms to 3 000 ms with the Extended Dwell Time profile will allow scientists to define the viscoelasticity/viscoplasticity behavior of their powders.

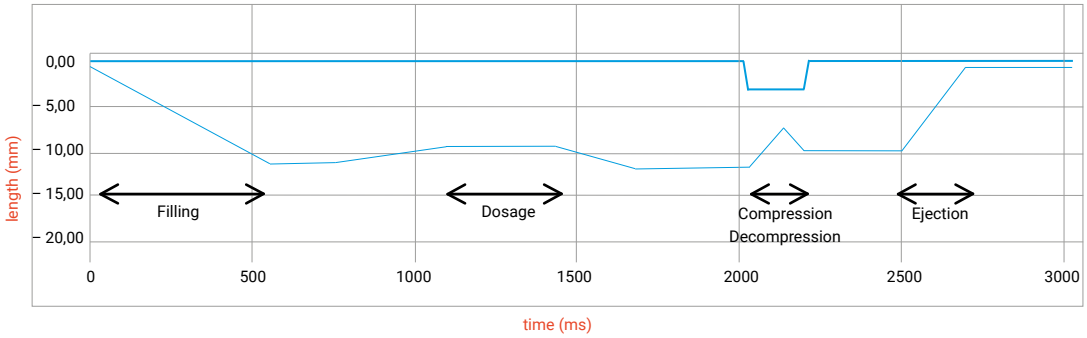

Figure 2

Extended Dwell time profile with a dwell time of 1 ms on STYL’One Nano

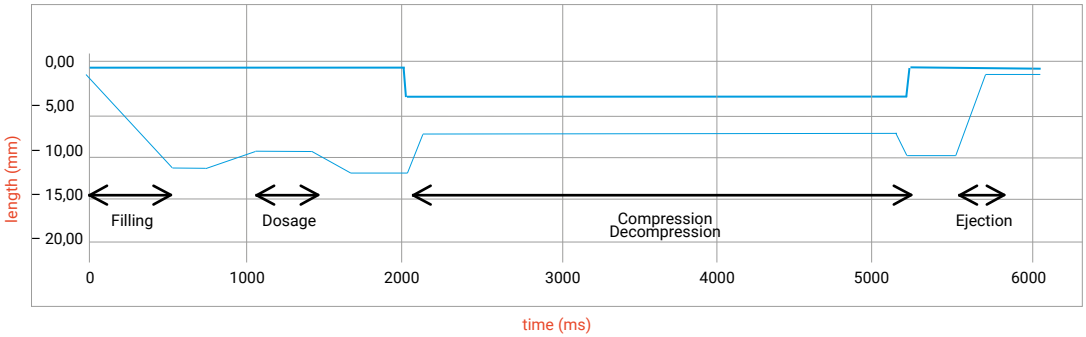

Figure 3

Extended Dwell time profile with a dwell time of 3000 ms on STYL’One Nano

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During compression, different deformation patterns can be observed: plastic, elastic, or brittle. Powder deformation can include a part of elastic, plastic, viscoplastic or viscoelastic deformation. Elastic deformation is a reversible deformation of particles in time function, whereas plastic deformation is irreversible and contributes to forming the tablet. Viscoplasticity or viscoelasticity means that the plastic or elastic deformation is time dependent. This can have a direct impact on tablets properties. At the contrary, brittle materials are not sensitive to speed.

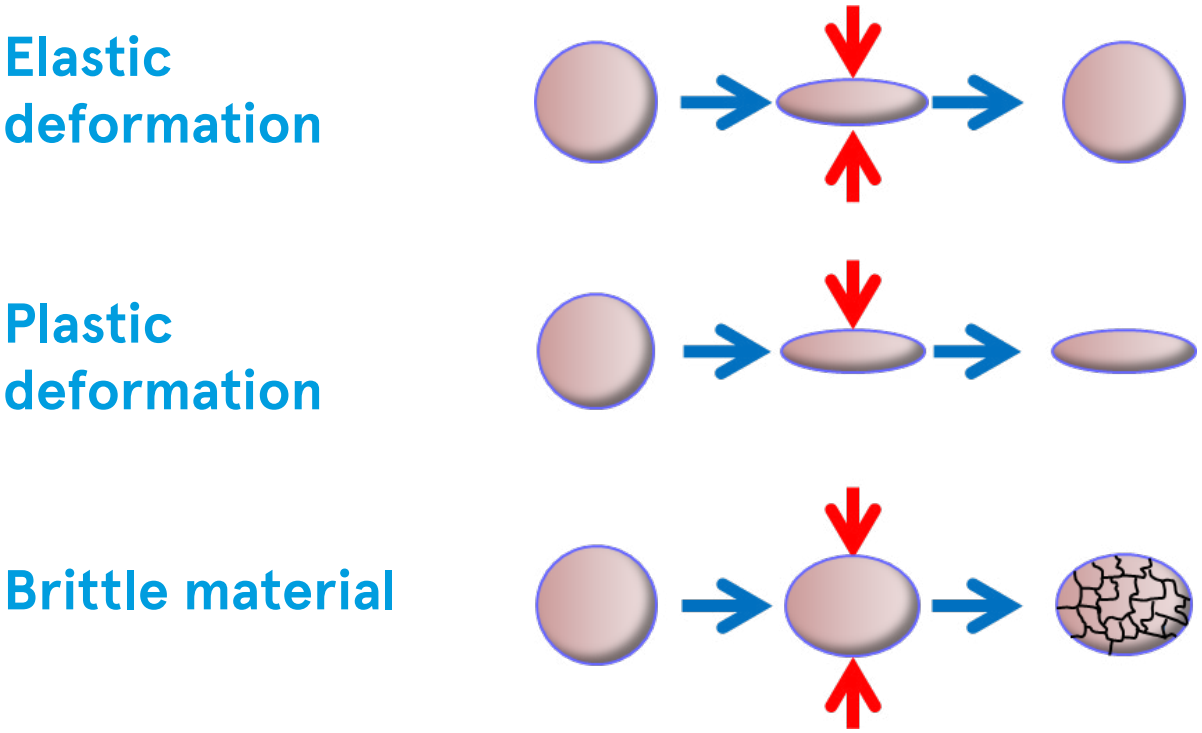


Figure 4
Different compression mechanisms

An easy-to-use compaction simulator for precise results

For this study, three well-known excipients were chosen based on their different deformation behaviour as described in the literature: microcrystalline cellulose grade 105 (MCC), partially pregelatinized starch (starch), di-calcium phosphate (DCP). Starch and MCC are known to be viscoplastic and viscoelastic, and to have high strain rate sensitivity while DCP is brittle and less sensitive to compression speed.

A one-point compression study was conducted at 200 MPa with the STYL'One Nano equipped with EU-D 11.28-mm round flat tooling. Dwell time was set to 3 000 ms thanks to the Extended Dwell Time profile. The MIST, a unique aerosol spray to manually disperse Magnesium Stearate, has been used to assess the tableting behavior of neat material and avoid high ejection stress.

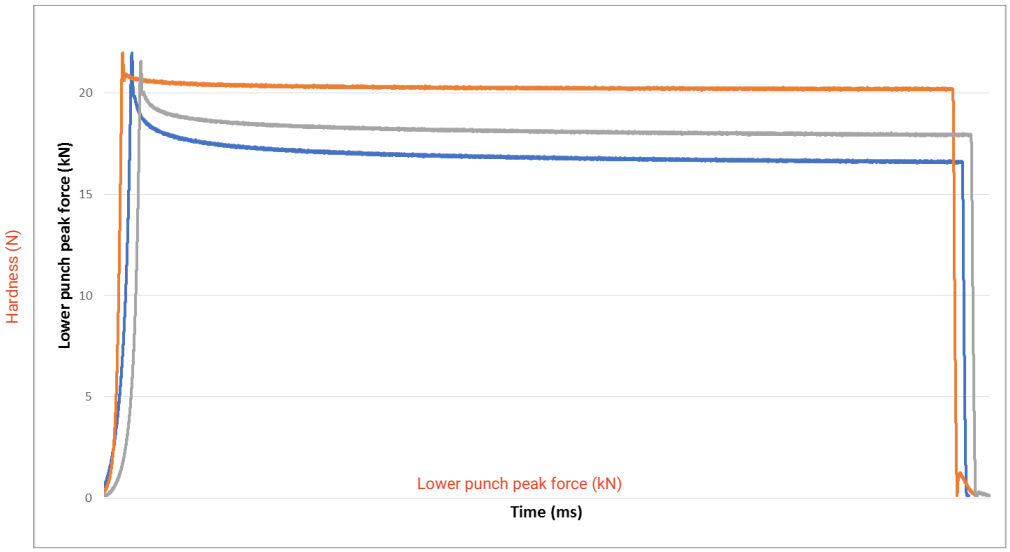


Figure 5

Graphic representation of lower punch peak force (kN) according to time (ms) for the three excipients

The graph shows different deformation behaviours between the three excipients. MCC, DCP and starch have different rearrangement behaviours as a function of time. Viscoplastic and viscoelastic materials like MCC or starch keep rearranging during the extended dwell-time. DCP is not exhibiting this trend.

By combining this result with energy calculation and manufacturability profile, formulation scientists have everything on hand to design the best formulation based on the behaviour of their APIs and excipients.

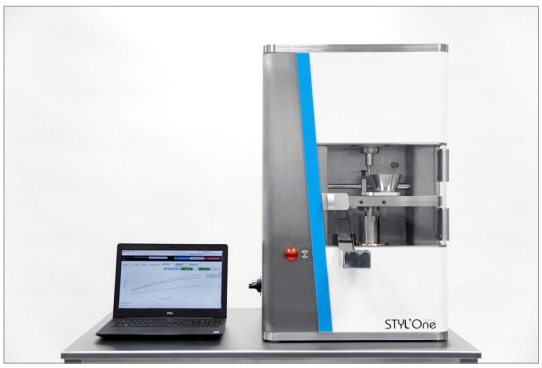
Think about using the extended dwell time profile to study the mechanical behavior of your powders

This study shows how the Extended Dwell Time profile allows scientists to identify different viscoplastic and viscoelastic behaviours between excipients. Different studies can be easily performed on the STYL'One Nano to optimize formulation for tableting.

STYL'One Nano key benefits

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

- Understand API/excipient compression behavior (plastic, elastic, brittle, etc.)
- Offer improved performances (tableting properties, lubrication effect, etc.)
- Find optimal formulation to meet tablet quality attributes (hardness, dissolution, disintegration, friability, etc.) and cost target
- Explore process parameters (dry granulation, wet granulation, drying, milling, compression, etc.) and their impact on tablet quality attributes
- Save time and money during development



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- USP Monograph 1062, current edition
- Léo Desbois et al., Characterization and modeling of the viscoelasticity of pharmaceutical tablets

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