

STYL'One Evo

Advanced Compaction Simulator



Research and Development in Focus

With over 125 years of combined experience with small-scale, fully instrumented machines, KORSCH and MEDELPHARM have entered into a strategic partnership agreement focused on offering the most advanced line of R&D tablet compression technology in the world.

The combined R&D product line meets and exceeds every requirement, from early-stage powder characterization and formulation development, to scale-up and production support.

The new R&D line covers the full spectrum of tableting technology from single-layer to five-layer, as well as core coating. MEDELPHARM compaction simulators are the perfect complement to the KORSCH product line.

www.korsch.com

The Most Versatile Compaction Simulator

The STYL'One Evo is the most advanced compaction simulator and has the capability to produce virtually any tablet format. The machine features 50 kN compression force capability, which may be applied for both precompression and main compression. The machine permits the use of

standard EU/TSM B, D, and EU-441 tooling. Special tooling for larger formats, or multi-tip tools for mini-tablets can also be utilized.

The STYL'One Evo is an easy to use, easy to clean R&D press.



- Work with minimal material quantities
- Work with standard compression profiles
- Scale-up to a specific high-speed rotary press

Understand and formulate your product



- Single-layer
- Multi-layer
- Tab-in-Tab

Develop any Type of Tablet



- Replicate a high-speed production press
- Produce small batch of real prototypes
- Produce small clinical batches with GMP production module

Scale-Up to Production



- Replicate any roller compactor
- A minimum amount of powder needed
- Fast feasibility assessment

Study dry Granulation

STYL'One Evo is very flexible and can be equipped with a wide range of accessories and software modules to accommodate virtually any product development requirement. The powerful software is very intuitive and the machine permits tablet format changes in just minutes. Compression stud-

ies can be planned and executed in a simple and efficient manner, with the capability to create an experiment using standard profiles (saw tooth or square wave), or replicate a high-speed production press. The STYL'One Evo is offered in a medium and high containment execution.

Characterization of API and Excipients

The STYL'One Evo comes fully equipped to provide precise information on powders to evaluate the effect of Process Parameters (PP) and compare Quality Attributes (QA). Additional accessories enable you to measure die wall pressure and take-off force.

- With minimal material quantities
- Comparison of different sources of material
- Formulation development and optimization

Flexible Configuration

The STYL'One Evo permits the production of single-layer, bi-layer, tri-layer, four-layer, and five-layer tablets with three different products. A core feeding system permits automated positioning of cores onto the powder bed for core placement applications.

- Quick conversion between the different tablet formats
- Retrofittable at any time
- Multi-Layer and Tab-in-Tab software modules

Simulation of any Rotary Tablet Press

The STYL'One Evo can reproduce the high compression speed of large production rotary presses. A micro dispensing unit allows production using external lubrication. The machine can be connected to tablet testers for sampling and automatic data transfer for reporting.

- Comprehensive library of rotary press compression profiles
- External lubrication feasibility assessment
- Good and bad tablet sorting chute
- GMP production module with automatic weight regulation

Mimicking of any Roller Compactor

Lab-size roller compactors have identical roller diameters of those installed on production-scale machines, requiring a large amount of powder, whereas this unique tool can mimic roller compactors with a very limited amount of product.

- Roller compaction software module
- Specific roller compactor profiles
- Quickly target a specific solid fraction
- Dry granulation feasibility assessment

STYL'One Evo Advanced Compaction Simulator

Tableting has never been so easy to investigate, from pure API characterization and formulation development to scale-up at production speeds. The versatility of the STYL'One Evo covers all tablet formats from single to five-layer, including core placement for Tab-in-Tab.

The machine is equipped with a unique drive technology in a compact footprint which is ideal for the laboratory

environment. The simulator can operate in a displacement mode to replicate any rotary press, or in a compression force mode where the system will produce tablets at preset force targets.

The powerful and intuitive data acquisition and analysis software is integrated in the STYL'One Evo which supports advanced analysis of the data, including plot generation.



Benefits at a Glance

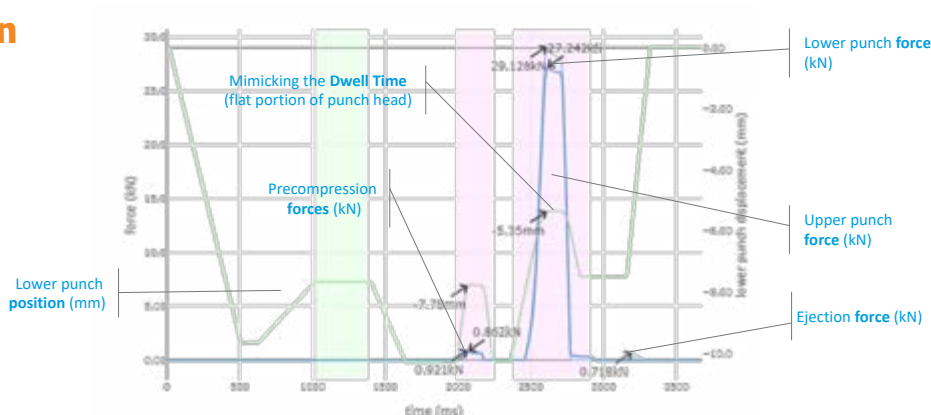
- Easy handling and cleaning
- Innovative drive technology
- Standard EU/TSM B&D Tooling
- Full Instrumentation (force & displacement)
- Ideal for minimal material quantities
- Simulation of any rotary tablet press
- Multi-layer & Tab-in-Tab modules
- Roller compactor simulation module
- Powerful data acquisition and analysis software
- Medium and high containment versions

Advanced Instrumentation

The STYL'One Evo is designed with the most advanced instrumentation to measure the upper and lower compression force and punch position. Mechanical deformation is measured and compensated by the software.

Standard Instrumentation

- Precompression Force
- Main Compression Force
- Ejection Force
- Upper Punch Displacement
- Lower Punch Displacement



Optional Instrumentation

- Die wall pressure
- Take-off force

Innovative Drive Technology

At the heart of the STYL'One Evo is a powerful drive system and a low-inertia brushless motor controlled by the Analis software which supports high punch acceleration and velocity required to mimic production rotary press kinetics. The base of the STYL'One Evo is a unique system to drive both the upper

and lower punches independently with planetary roller screws, a maintenance free technology used in the aeronautic industry. This technology is hydraulic-free. The die is stationary and the feeders move over the die to fill it. An innovative system allows feeding of one layer or multi-layer with up to three feeders.

Pre- and Main Compression

A powerful drive technology allows to replicate precompression and main compression of rotary tablet presses at high punch velocity.

Force and Position Control

Position control is the preferred choice to mimic compression dynamics and to study the effect of precompression level. Force control is the mode of choice for API characterization or to quickly plot tablet breaking force vs compression force.

Fast and Independent Upper and Lower Punch Dynamics

Compression displacement is performed by the upper and lower punches to mimic punch travel on a rotary tablet press. The upper punch penetration can be adjusted to assess the

criticality of this process parameter. Both asymmetric and symmetric compression can be easily achieved to evaluate tablet quality attributes.



Powerful Software Platform

The user-friendly Analis software is installed on a laptop or on a panel PC. Analis controls the STYL'One Evo, collects the data generated, and analyzes the data by plotting a wide range of parameters including manufacturability, tabletabil-

ity, compressibility and compactibility. Customized plots for any data parameter are easily developed to explore porosity, ejection stress, elastic recovery.

Control System

The STYL'One Evo is entirely controlled by software. Each process parameter is precisely entered through a Human Machine Interface (HMI):

- Filling and dosing height
- Force or punch distance for precompression and main compression
- Upper punch penetration depth
- Ejection height
- Feeder parameters
- Number of tablets

Data Acquisition and Analysis

The HMI interface simplifies the design and execution of experiments. Tablet tester data can be uploaded automatically to support subsequent reports and graphs.

- Get fast feedback on your experiment to drive your development
- No need to export the data for subsequent analysis
- Access data from any computer to simplify data analysis

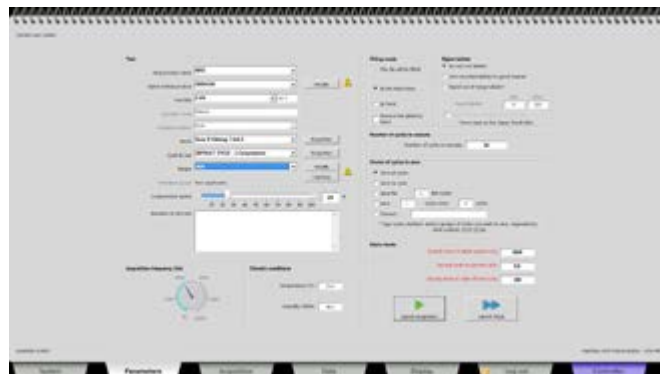
Efficient Analysis

The software has been designed with different modules to accommodate a wide range of tablet formats while keeping ease of use and ergonomics at the heart of the development. Pre-defined compression cycles are readily accessible for more than 200 production tablet presses. In addition, R&D

compression profiles are available and new profiles can be generated to evaluate compression time of precompression and main compression, relaxation time between pre- and main compression, time before ejection, ejection speed and filling time.

User Friendly Interface

The interface looks like a laboratory notebook which simplifies and streamlines experimental design and data analysis. The setup of experiments is done by specifying the tooling type and the compression dynamics (cycles and process parameters). After high frequency data collection, the system moves seamlessly to data analysis and graph generation.



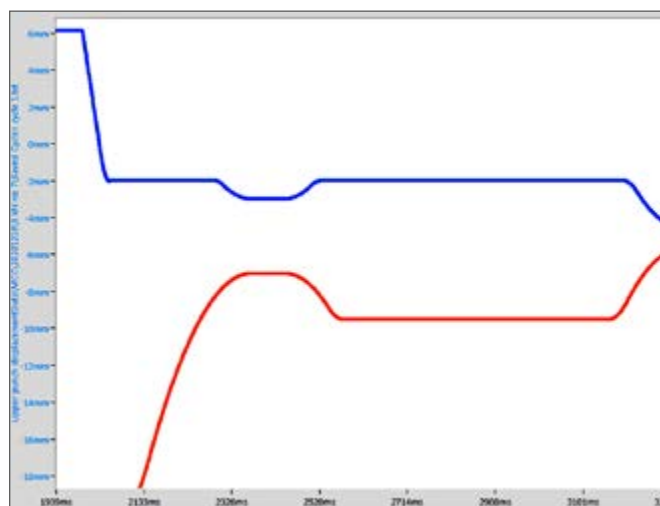
Profiles

Specific R&D Profiles

- Saw tooth = constant compression speed to characterize API & Excipient or evaluate formulation. Largely used to analyze and standardize strain rate sensitivity tests (speed sensitivity).
- Square compression = extended dwell time for viscoelasticity analysis (analyze particle rearrangement)

Pre-loaded rotary tablet press profiles

- Full library of rotary press profiles to perform development / troubleshooting under production conditions



Connection to Tablet Tester

Analisis can be connected to external tablet testing equipment (tablet weight, thickness, tablet breaking force, length, width) to automatically collect and process the corresponding data in correlation with the compression force data measured on the STYL'One Evo.

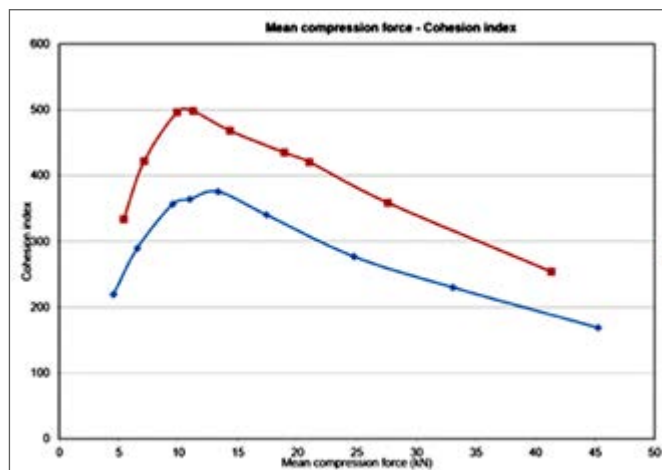
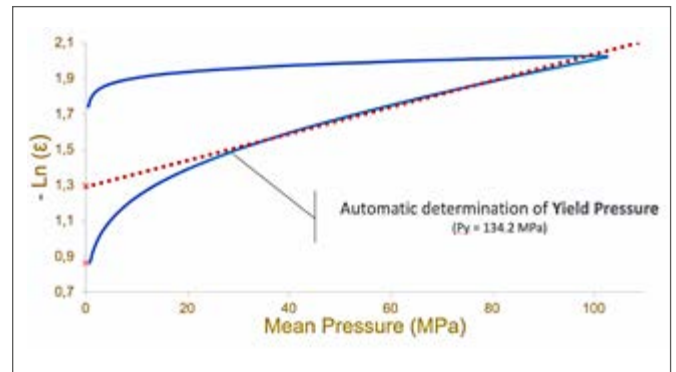


Analisis acquires all data in real time. USP <1062> plots for tablet characterization are integrated into STYL'One Evo software. Manufacturability profiles (tablet breaking force vs compression force) and tableability profiles (tensile strength

vs pressure) are readily available. Compressibility and compactibility profiles can be used when powder true density is known. The user can also build customized plots and reports. As a result, Analisis expedites research projects.

Single Tablet Capability

This part of the software permits analysis of tests conducted on a single tablet. It allows the full waveform data to be exported to an Excel or CSV file. A report showing Heckel plots and the calculated compression energies (compression energy, flow energy, elastic energy, plastic energy) can also be generated.



Multi-Criteria Analysis

The multi-criteria functionality permits the analysis on several tests containing multiple tablets. The multiple values can then be exported into a single Excel or CSV file. Multi-criteria plots show the evolution of one criteria depending on one another. The following plots are possible:

- $Y=F(X)$ with any parameter
- Porosity
- Force - Hardness
- Preloaded common graphs

Scale-up and Production Support

The GMP Production Module for clinical and commercial batch production permits the quantity of tablets to be produced with automatic weight regulation and tablet rejection, with a corresponding audit trail. The micro dispensing unit allows production using external lubrication. The integration of a tablet tester permits the correlation of tablet parameter for the batch.

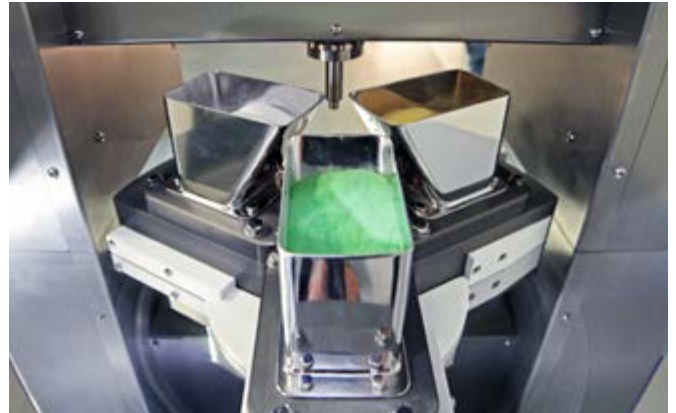


Unprecedented Flexibility

The STYL'One Evo is a flexible research tool that can accommodate virtually any tablet size, shape, and format, making it an ideal choice for OSD development applications.

Multi-Layer up to 5 Layers

STYL'One Evo can be fitted with one, two or three gravity or forced feeders to produce tablets up to five layers. The multi-layer software module permits the layer parameters to be established based on the tablet format. Critical process parameters including tamping force and filling height of each individual layer as well as precompression, main compression and ejection forces can be easily assessed. Multi-layer tablets can be designed using high-speed rotary tablet press profiles.



Tab-in-Tab

In addition to the multi-layer package, the system can be configured with a Tab-in-Tab device for the easy and fast production of dry coated tablets.

- Precise positioning of cores on three axes (X, Y, Z)
- Easy installation with magnetic fixing system
- Assessment of critical process parameters



Dry Granulation

By targeting solid fraction of "riblets" = "ribbon tablets", the system permits a feasibility assessment as to whether a dry granulation is a suitable process, and predefine the setup parameter of his roll compactor (gap, speed, pressure).

- Mimics sinusoidal kinetics of roller compactors
- Preset solid fraction
- Preset compaction pressure
- Preset gap



Containment Solutions

The STYL'One Evo is designed to work under negative pressure and as such, the standard execution does offer a clean working environment. For applications that require a higher level of powder containment, the system is offered in a medium and high containment execution. The medium containment execution with the Enhanced Operator Safety

module includes improved seals, negative pressure regulation and an inlet HEPA filter. The high containment version, suitable for OEB 4/5, offers a full wash-in-place capability, a containment isolator, and glove port access to the working area. The tablets are being produced and can be checked before exiting the isolator.

Enhanced Operator Safety (EOS)

EOS adds extra safety by reducing operator exposure to airborne particles during operation.

Vacuum and manual control of air flow ensure permanent negative pressure in the compaction area of the simulator.

Compaction area can also be flooded with Nitrogen allowing experiment with Oxygen-sensitive or explosive powders.



OEB 4/5 Solution with Isolator

Full high containment and wash-in-place execution:

- Automatic negative pressure control and monitoring
- Continuous liner or RTP port to bring material in and out
- Safe cleaning with integrated vacuum wand and spray guns

The STYL'One Evo can safely run while the operator performs other tasks inside the isolator like measuring tablet weight and hardness.

STYL'One Evo can also be safely operated with the isolator open when working with non-hazardous material.



Advanced Training

The STYL'One Evo is a sophisticated compression data acquisition tool, and to ensure that the full capability of the system can be realized, our team of experts can provide advanced training to convey best practices for experimental design, data acquisition, data analysis, and interpretation of the results.

- Understanding your APIs & Excipients
- Product characterization
- Formulation Development and Optimization
- Scale-up
- Troubleshooting

Join the Community

Enhance your tableting skills by joining MySTYL'One resource center and user community to share information and access a comprehensive library of STYL'One scientific content.



SCIENCE LABORATORY



MEDELPHARM LYON



INNOVATION CENTER



KORSCH BERLIN



INNOVATION CENTER



KORSCH BOSTON

Formulation Development Services

KORSCH and MEDELPHARM scientists have been collaborating with customers on tableting projects for decades. Our mission and passion are problem solving and helping accelerate your product development. Our international network of tableting experts and laboratories is equipped with the latest techno-

logy to provide formulation services from early API characterization all the way to high-speed process optimization. All we need from you is a few grams of powder to generate data and suggestions to help with your decision making.

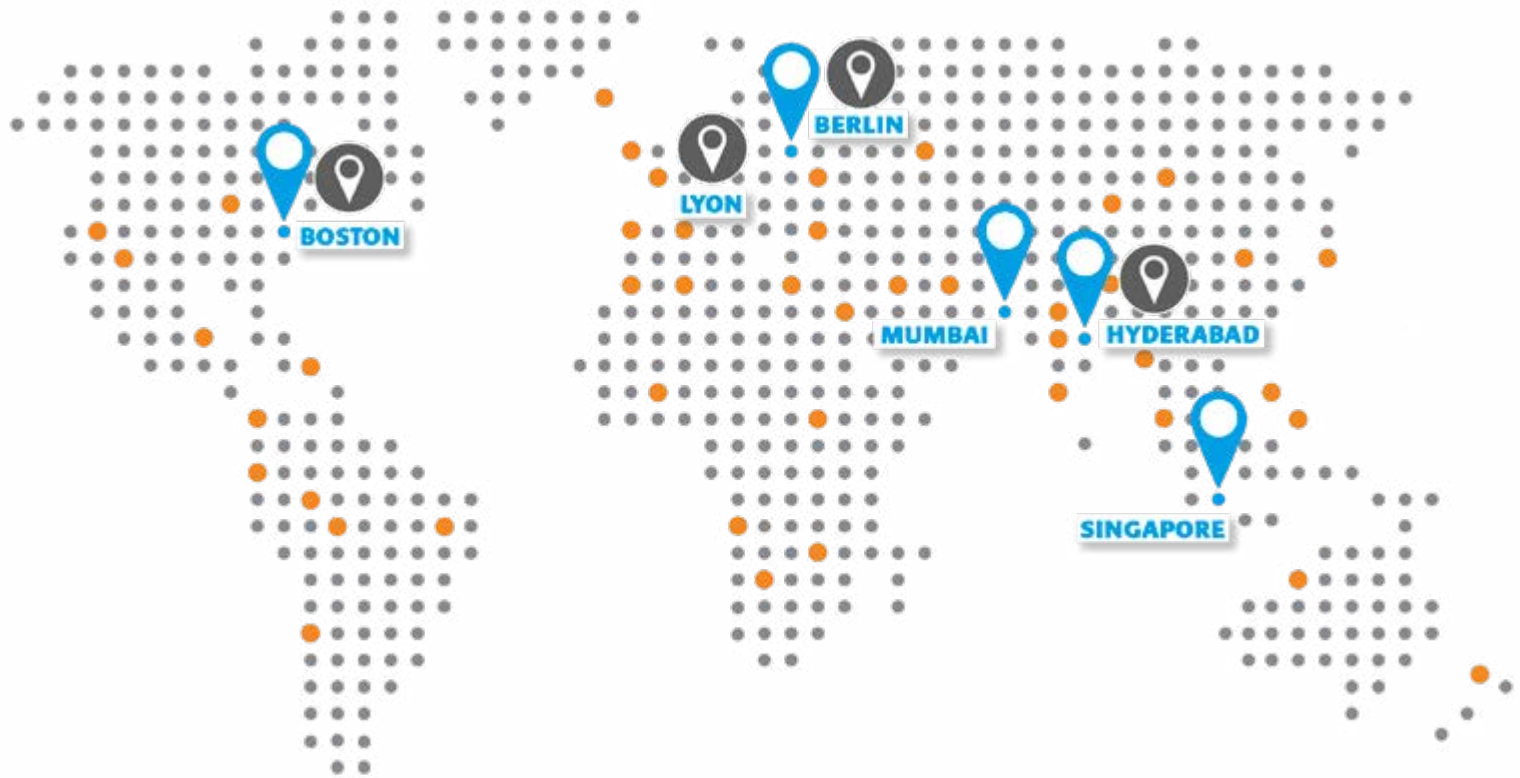
STYL'One Evo Machine Specifications

Description		
Punch Stations		1
Tool Type		EU / TSM B and D and non-standard
Die		BBS, BB, B, D and non-standard
Max. Production Output	tabs/h	1,750
Max. Tablet Diameter	mm	25 or 40 (non-standard)
Max. Die Filling Height	mm	21 (B), 23 (D), 34 (non-standard)
Compression Mode		Force or displacement driven
Upper Punch Penetration Depth	mm	2 – 12
Max. Precompression Force	kN	50 (80 optional)
Max. Main Compression Force	kN	50 (80 optional)
Load Application		Upper and/or lower punch
Punch Velocity (each)	mm/s	490
Powder Bed Reduction	m/s	~ 1.2
Punch Acceleration (each)	m/s ²	25,000
Dwell Time	millisecond	2 – 3,000
Power Supply Voltage		Europe: 400 V 3-Phase 50/60 Hz USA: 480 V 3-Phase 50/60 Hz
Power	kW	7 kW nominal 2 kW during operation
Electric Protection	A	32 (Type C)
Fault Current Protection	mA	Leakage current : 300 (Type Asi)
Compressed air (Tab-in-Tab option and/or external lubrication pack)	Bars L/min (nominal)	6 10
Flow required for aspiration	m ³ /h	10 – 30
Weight	kg	1,075
Load distribution	kg/m ²	2,500

Technical modifications reserved.

The technical specifications included in this document represent optimal parameters and are dependent on product quality and machine settings.

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