SYNTEGON
PROCESSING & PACKAGING

FlexiTab XL.

IN COOPERATION WITH RÖLTGEN, GERMANY VERSION 2020

SINGLE STATION TABLET PRESS WITH ENHANCED DAQ SOFTWARE FOR R&D & GALENICS.

The FlexiTab XL is designed (HW and SW) to serve your needs in R&D and galenics.

As a single punch machine the FlexiTab XL is designed for early stage tablet development, the production of clinical trial batches, the screening of powders and granules for subsequent product development, as well as the assessment of multi-layer drug dosing and characterization of powder properties.

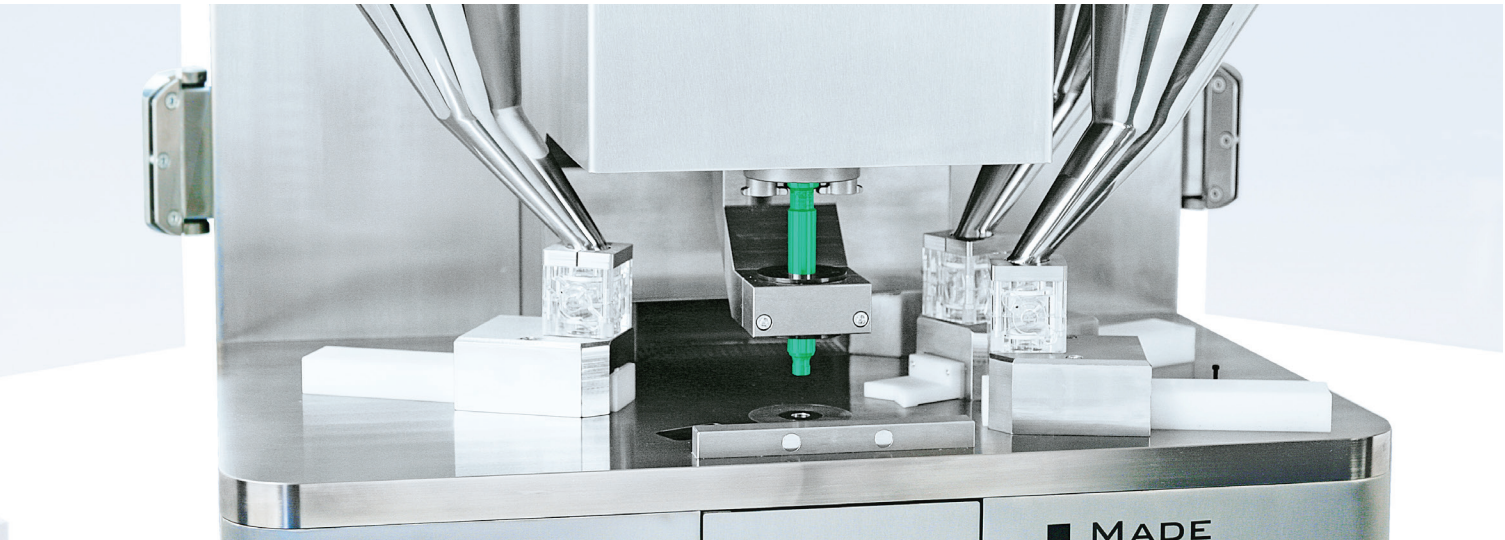
A large range of tablet and oblong shapes can be produced creating many layers, using up to three APIs. Separation layers are possible as well.

The Flexitab XL does allow the formulator to manually or automatically sequence tablet production. It is not bound to a fixed compression parameter setting, instead all parameters can be determined individually. In addition software macros do allow the programming of the compression process from “simple” to “complex”. Scale up parameters can be derived.

Its control is IPC based using Windows 10. The HMI is a modern 21“ color touch screen, serving a batch report including all USP 1062 and cGMP relevant data as well as a recipe memory. Along with the enhanced FlexiTab XL software, this equipment offers an ideal platform for developing new drugs. The software is CFR21 part 11 and USP 1062 compliant.

Your benefits

- Movable execution
- External magnesium stearate lubrication of punches and dies
- Air blast die cleaning and vacuum dust extraction
- Laser type die fill monitoring
- Reporting features (USP 1062 and cGMP)
- DAQ 4 data acquisition software
- Press parameters displayed in real time
- CFR21 part 11 and USP 1062 compliant simple adjustments for tablet weight, compression force, dwell time and thickness (tablet weight/thickness indirectly via fill depth)
- No relevant residues in product hoppers



FLEXITAB XL PROCESS CONTROL (MACRO LANGUAGE)

- Including all hardware implemented process steps
- Each step individually configurable
- Production mode (= „series mode“) or easy, intuitive step-by step-mode allow wide range of tablet shapes and diameters

USE CASES / EXAMPLES

- Pre- and main compression
- Multiple stroke compaction
- Increasing force sequence
- Manual feeding with open doors
- Press zone shift
- Tamping
- Unlimited layers with max. three API‘s
- Separation layer possible
- Force controled or displacement controled compaction possible

GENERAL PROCESS CONTROL OPTIONS

- Repeated and agitational feeding
- Overfill
- Feed level check (laser)
- Pneumatic compression (4 kN max.)
- Hydraulic compression (60 kN max.)
- Hydraulic compaction speed adjustable
- Triangle, rectangle or asymptotic sinusoidal profile
- Extended dwell time
- Damped ejection with resting upper punch

Technical Specifications

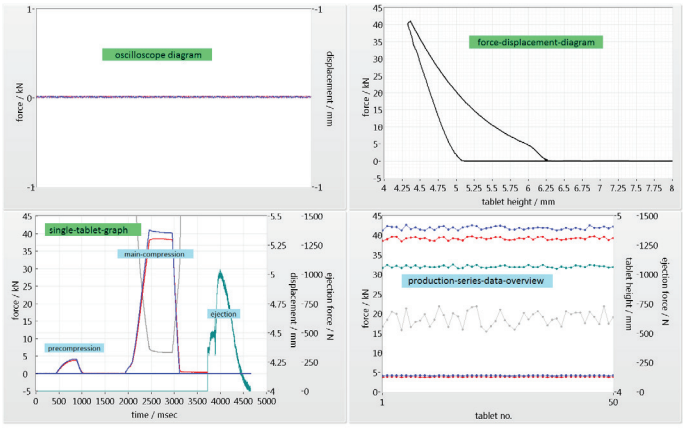
	1 Layer	2 Layer	3 Layer
Output per hour	900*	600*	300*
Max. tablet diameter	25.4 mm** (29 mm)		
Max. fill depth	21 mm		
Max. operating pressure	60 kN (150 kN)		
Punch/die type	TSM / Euro B/D		

* Output depends on characteristics of material

** When using EU 1 or TSM 1 tooling

DATA ACQUISITION SOFTWARE

Next generation of process understanding and documentation



Data evaluation of single tablets

ONLINE CHARACTERIZATION

- Oscilloscope diagram – real time process control
- Single-tablet raw data diagram
- Maximum value diagram
- Force-displacement diagram (FDD) = precursor to a Heckel analysis!
- Digital data display

REPORTING

- Series report completely automated PDF file, configurable
- All USP <1062> relevant data included in report (if measured), configurable
- All GMP relevant data (audit trail, user list, punch list, error log) printable to PDF file

ADVANCED ANALYSIS

- USP <1062> Tablet Compression Characterization
- Automatic energy and powder analysis always performed (USP <1062>), manual analysis also possible offline
- Automatic online Heckel analysis, based either on set value or measured value of tablet weight
- Offline software package: Heckel analysis, Kawakita analysis, Cooper-Eaton analysis (Heckel evaluation software available for free download on Roeltgen website)

CHARACTERISTIC VALUES PER TABLET

Examples (in total 37 paramters):

- CR - Compression Ratio
- MXSF - Max. Solid Fraction
- RCV - Recovery
- RLX - Relaxation
- TS - Tensile Strength
- YIP - Yield Pressure

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