KORSCH
PRODUCT RANGE

XP 1

The Single Punch Tablet Press

Proven and Reliable

KORSCH
The Specialist.

Innovations Made in Berlin Since 1919

Focus Drives Perfection

Specialization is the key. Since 1919, KORSCH has focused on its core competency of tablet compression technology.

This focus and resulting experience base is the foundation for the broadest and most innovative product line for tablet compression technology.

KORSCH offers an optimal solution for virtually every tablet compression application – through initial feasibility, research, scale-up, clinical production, and full scale 24/7 production.

KORSCH presses are used successfully all over the world and are supported by a global network of sales and technical service specialists.

www.korsch.com

MADE IN GERMANY

KORSCH Quality

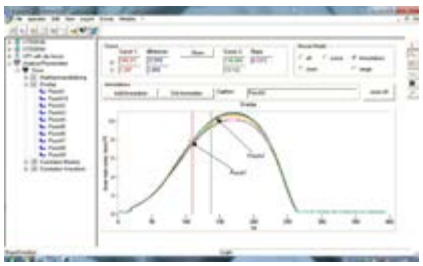
The XP 1 design permits the highest level of GMP, and the ability to conduct product development with minimum material quantities, using standard EURO and TSM press tooling. All press adjustments can be made during machine operation. The XP 1 offers robust and ergonomic design with optimal accessibility. The complete separation of the product area from the mechanical area guarantees a GMP compliant work environment. A full instrumentation package allows precision measurement of press force and punch displacement. In combination with the KORSCH PharmaResearch®, the XP 1 offers a comprehensive data acquisition and analysis capability.

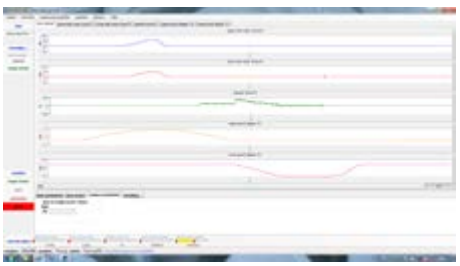
- Easy Set Up During Operation
- Uses Standard EURO and TSM Press Tools
- 50 kN Compression Force Capability

Fully Portable Version with Caster Base

- Extremely Fast Changeover
- Fully GMP Compliant
- Fully Automatic Operation

Table-Top Version





Data Acquisition and Analysis

Ultimate Flexibility

The KORSCH XP 1 offers high flexibility for product development and material characterization. Innovative tool adaptors permit the use of EURO and TSM B/D tooling. The XP 1 can work with a wide range of tablet formats, including micro-tablets to a maximum tablet diameter of 25 mm. The precise adjustments for dosing height and upper punch insertion depth permit tablet specifications to be established quickly and maintained during automatic operation. A simple touch screen control permits the adjustment of press speed and the real-time display of compression and ejection forces. The design of the XP 1 also offers a high-containment execution. Equipped with the most modern data analysis and acquisition system, the XP 1 is the ultimate tool for small-scale product development.

Flexible Operation

The XP 1 is available as a table-top version or fully portable version with a locking caster base. Feeder and material hopper configurations permit the ability to produce large quantities up to 5 liters or small quantities up to 8 ml. An innovative tool adaptor permits the fast change of press tooling.

- Table-Top Version
- Adaptor for TSM B/D or EU B/D Tools
- Adaptor for KORSCH EK-0 Tools
- Feeder for Small Material Quantities (8 ml)

User friendly Operation and Changeover

Tablet parameters are established initially under manual operation, and the machine can be placed quickly into automatic operation. The tablet weight, thickness, and hardness can be adjusted while the machine is running. The open design and the smooth surface as well as the separation of the product area from the technical area enable easy and fast cleaning.

Ergonomical and Robust Design

The unique and robust design of the XP 1 allows 50 kN compression force. The drive is frequency controlled and infinitely variable across the full speed range. The operation is done via a simple touch-screen which is integrated to the machine.

The benefits at a glance:

- Ultimate Flexibility
- Containment Solutions
- Comprehensive Data Acquisition and Analysis

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Containment Solutions

The KORSCH XP 1 WipCon® addresses all aspects of operator safety in a contained R&D press and permits extreme flexibility for feasibility, development and material characterization. The WipCon® design eliminates the need for personnel protection apparatus (PPA). The use of a standard RTP permits granulation and finished tablets to be passed in and out of the machine in a fully contained manner. A fully integrated air handling system insures a negative pressure which is precisely controlled. The engineered placement of glove ports insures an ergonomic design which is fully functional and safe.

Negative Pressure Control

The XP 1 WipCon® ensures a safe operator environment with isolator and negative pressure control for the handling of high dosage active and potent products. Insertion and extraction of material, tools and machine parts like material hopper and feeder, via RTP (Rapid Transport Port).

- Fully Integrated
- Glove Port Access
- Pressure Control

Sterile Product Development

For product safety the XP 1 can also be operated with a positive pressure/sterile environment. Thereby a decontamination of the compression area (e.g. with H_2O_2) is possible. The easy change of the operation mode from negative to positive pressure ensures that both full product safety and/or full operator safety from the isolator is guaranteed.

Conventional Operation

The use of gloves for the handling and cleaning of the machine is not necessary when harmless materials are produced. As a solution, a cover with safety interlock has been designed for the movable parts (feeder). The XP 1 WipCon® can then be operated with an open isolator door as a conventional press for R&D.

Full GMP Compliance According to GAMP 5

21 CFR Part 11 Conformity with password login, electronic audit trails and secure data storage format.

- GMP-Risk analysis
- Computer system validation
- Quality mangement
- Certification

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Comprehensive Data Acquisition and Analysis

PharmaResearch® was developed specifically to permit data collection and analysis for press force and punch displacement data. The system can collect data locally, or write data to a SQL server on a central network, to permit centralized data storage and analysis.

All compression forces for each punch station are collected and the average value from one revolution as well as the resulting relative standard deviation are calculated and displayed in real time.

The XP 1 Functionality

The basic module of the XP 1 includes safe login, error display, service and calibration menu. The optional module for the production of clinical batches includes also:

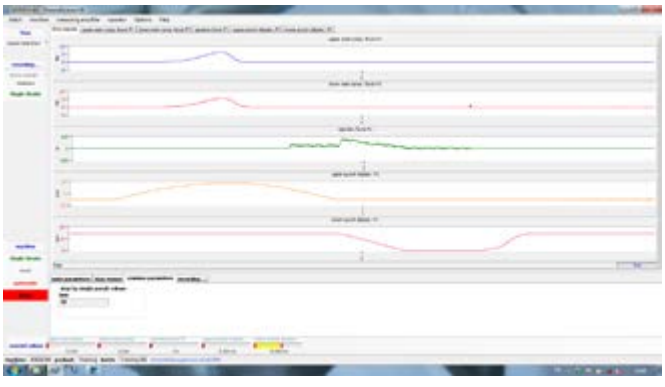
- Data acquisition
- Data analysis

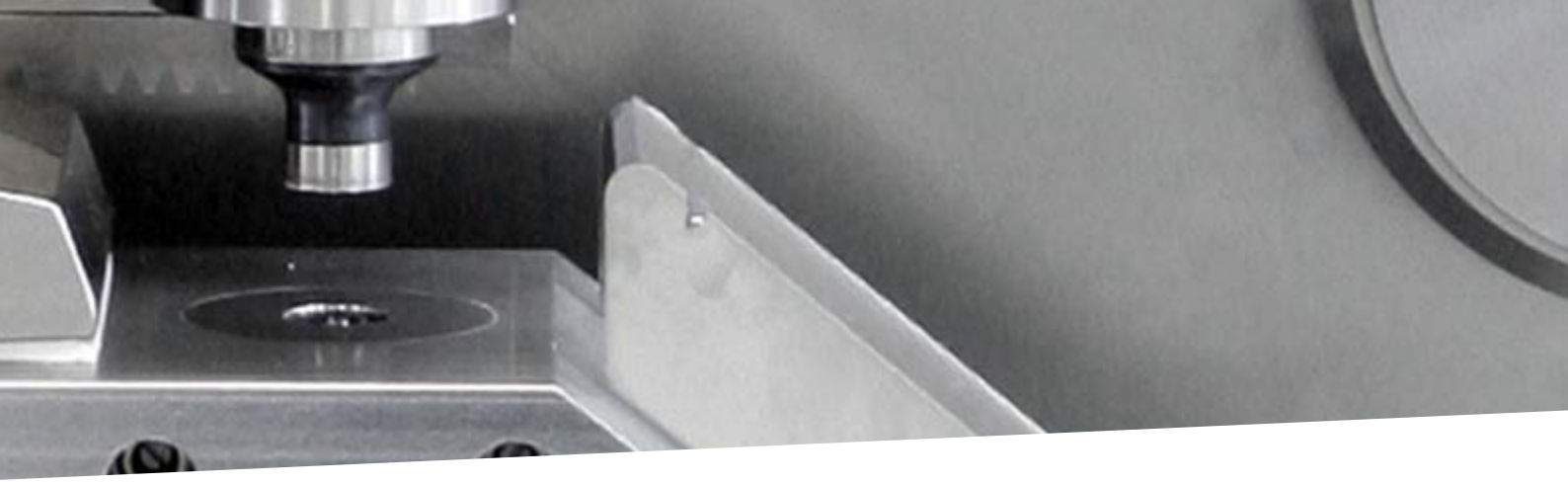
Process Optimization: Instrumentation and Automated Data Acquisition

PharmaResearch® is a comprehensive analysis software which calculates the tablet properties according to the press information collected. It conforms with the FDA approach for process oriented consideration of the press procedures (Process Analytical Technology – PAT)

Instrumentation:

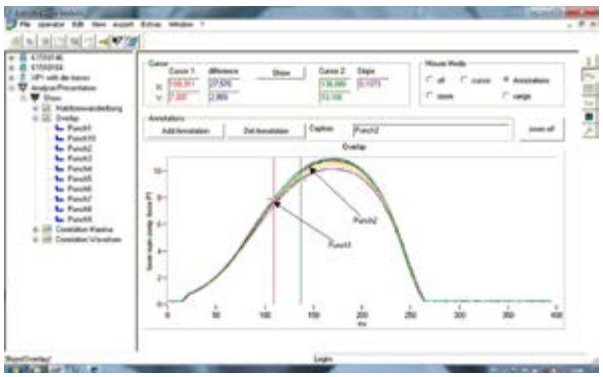
- Upper/Lower Compression Force
- Ejection Force
- Scrape-off Force
- Upper/Lower Punch Displacement

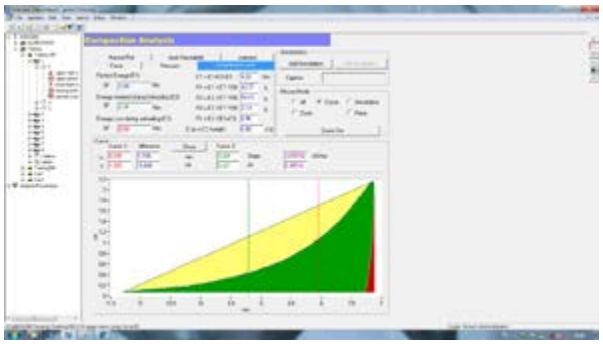


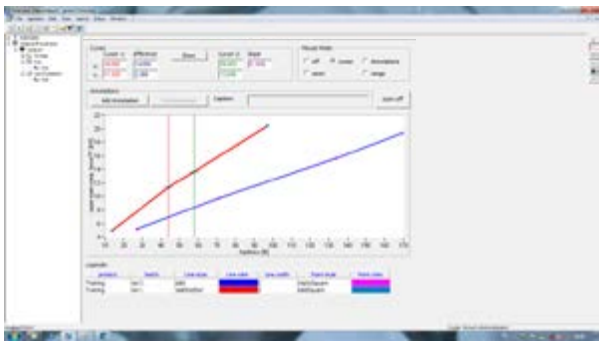


Data Analysis

- Free format graphic and statistical analysis to allow the export of many data formats
- Reports can be automatically generated in a variety of data formats with and without an electronic signature
- Charts can be dimensioned, comments added, formated and exported before being processed in the MS Office world
- Fingerprint recording during production. Overlay Technology allows safe and quick recognition of subsequent waveforms
- Correlation Analysis to establish a “Knowledge Database” that serves to easily compare the properties of known and unknown ingredients
- The database enables the user to correlate measuring values from the tableting process and derived and externally recorded quantities (e.g. tablet hardness, density, etc.)
- Compaction Analysis allows evaluations e.g. Heckel plot, energy, work of compression, contact time, compressibility
- “Built-in” PAT function, i.e. the database is automatically filled with process data, thereby helping to define and complete PAT requirement for Knowledge Space and Design Space
- Network capability







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

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Technical Data

KORSCH XP 1 / XP 1 WipCon®

		XP 1	XP 1 WipCon®
Pressing Tools/Adapters for		TSM/EU: B-/D-Tool + EK-0	TSM/EU: B-/D-Tool
Die Plate for		TSM/EU: B-/D-Tool + EK-0	TSM/EU: B-/D-Tool
Compression Force	kN	50	50
Tablet Diameter max.	mm	25	25
Filling Depth max.	mm	20 (22 for TSM/EU-D)	20 (22 for TSM/EU-D)
Press Speed	strokes/ min	10–60 (infintely variable)	10–60 (infintely variable)
Tablet Output max.	tabs/h	3,600 (for single tool)	3,600 (for single tool)
Upper Punch Insertion Depth	mm	1–12	1–12
Machine Dimensions	mm/ L x W x H	600 x 780 x 1,024 (Bench Top Model) 600 x 600 x ca. 1,680 (with Pedestal)	1,980 x 970 x 1,485
Net Weight of the Machine	kg	Approx. 400	Approx. 980
Pedestal	kg	Approx. 80	–
Electrical Load	kVA	3	3
Motor Ouput	kW	1.1	1.1
Noise Level	dBA	< 80	< 80
Power Supply		230 V / 50 Hz / 60 Hz	230 V / 50 Hz / 60 Hz

Technical modifications reserved.

KORSCH tablet presses comply with the EC machinery directive, the current GMP and FDA regulations, as well as with the EMC guidelines. KORSCH tablet presses are delivered with CE certificate and meet the requirements of 21 CFR Part 11.

Peripherals delivered with KORSCH tablet presses also comply with these regulations.

The technical specifications included in this document represent optimal parameters and are dependent on product quality and machine settings. The maximum compression force varies in relation to tablet/punch size and output.

The maximum output varies in relation to material, tablet/punch size and compression force

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