



KORSCH
PRODUCT RANGE

XL 100

Pharmaceutical Rotary Tablet Press



Tablet Press for Product
Development and
Clinical Production

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

The logo consists of three vertical bars in black, red, and gold, followed by the text "MADE IN GERMANY" in a bold, sans-serif font.

MADE IN
GERMANY

A Versatile Design Concept

The patented design of the XL 100 offers extreme versatility in a small scale machine. The exchangeable turret permits the production of any size tablet. A mixed turret option permits the use of both B and D punches on the same turret. The fully integrated design insures a fully portable platform that can be easily transported in a product development setting.

The XL 100 Pro adds another dimension, including a 15 inch touch screen, and the ability to add integrated data acquisition, as well as a press force control system to permit the production of clinical batches using automatic weight control and single-tablet rejection.



XL 100
with mixed Turret



Research & Development



XL 100 Pro
with PharmaResearch



Development and Scale-Up



XL 100
with Compression Force control and single tablet rejection



Clinical Batch Production

Maximum Flexibility

The KORSCH XL 100 Tablet Press offers a very powerful tool for product development, scale-up, and clinical batch production. The XL 100 offers specialized components which are specifically intended to permit development with minimal material quantities.

The exchangeable turret permits the use of any size press tools, including B, D, and BB. A mixed turret option permits

the use of B and D tooling on the same turret. The control system offers a simple touch screen and the capability to add an integrated press force control module, single tablet rejection module, and an integrated data acquisition module.

The XL 100 is fully self-contained and portable with a very simple and robust mechanical design – the ideal tool for the production development setting.

Product Development

The XL 100 permits the execution of full compaction studies with limited material quantities. A reduced volume product hopper and reduced volume feeder paddles insure efficient operation, and the control system is fully functional with reduced press tools. The mixed turret design permits the development and B and D size tablets on the same turret. The 120 RPM press speed permits meaningful data on compression dwell time and feeder dwell time to be developed and analyzed.

- Comprehensive Data Analysis
- Documented Product Development Process
- Special Configuration for Small Quantities
- Mixed Turret, B/D Tooling

Optimization and Scale-Up

The XL 100 may be fully instrumented for the measurement of precompression force, main compression force, ejection force (segmented cam), and scrape off force, to permit product development parameters to be evaluated and stored. KORSCH offers PharmaResearch, a Windows-based data acquisition system that permits storage, analysis, and export of compression and ejection force data.

- Integrated Data Analysis and Press Force Control
- Graphical and Statistical Display
- Validatable Data Export and Processing

Clinical Batch Production

The XL 100 features a large feeder for optimal and constant material flow. The XL 100 offers a maximum press speed of 120 RPM, a precompression capability of 10 kN, and main compression capability of 60 kN. An automatic lubrication enhances the production and the strong and robust design ensures reliable results.

- 10 kN Precompression Force / 60 kN Main Compression Force
- Press Force Control and Single Rejection
- Permits Full Compliance with 21 CFR Part 11

The benefits at a glance:



- **Maximum Flexibility**
- **PharmaResearch**
- **Optimal Control and Full Compliance**

PharmaResearch

PharmaResearch is a Windows-based system that offers data acquisition and analysis for press force and punch displacement data. The PharmaResearch system is available in a stand-alone execution for the XL 100 and in an integrated execution for the XL 100 Pro and WipCon models. The system

displays press force waveforms in real time and permits on demand data collection. The system can collect data locally or write the data to a networked SQL server for centralized data storage and analysis. The PharmaResearch permits the execution of full compaction studies with limited material quantities.

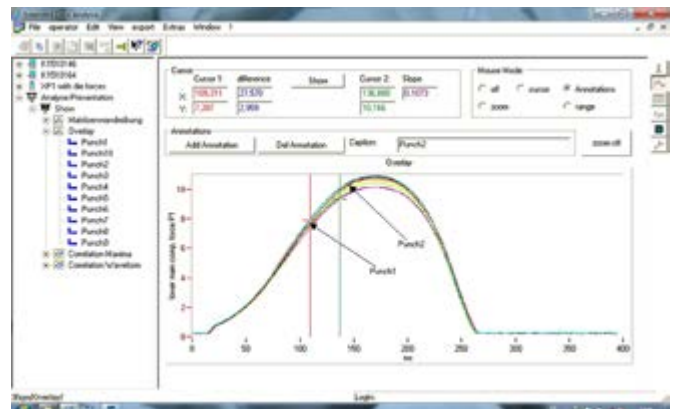


Data Acquisition

- Real-time acquisition of press force data and automated analysis of force peaks, area under the compression curve, rate of force application, rate of force decay, and contact time
- 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, formatted and exported before being processed in the MS Office world

Advanced Compaction Analysis

- Advanced compaction analysis allows evaluations of Heckel plot, energy, work of compression, compressibility, and theoretical punch displacement.
- 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 granulations. The database enables the user to correlate press force values and physical tablet properties (e.g. tablet hardness, friability, dissolution, etc.)



Network Solution

- Network connectivity to SQL Server for central data storage
- Workstation module for off-line data analysis



Comprehensive Instrumentation and Data Analysis

Full Instrumentation

- Upper and Lower Main Compression Force
- Upper and Lower Precompression Force
- Ejection Force
- Scrape-off Force

Statistical Assessment

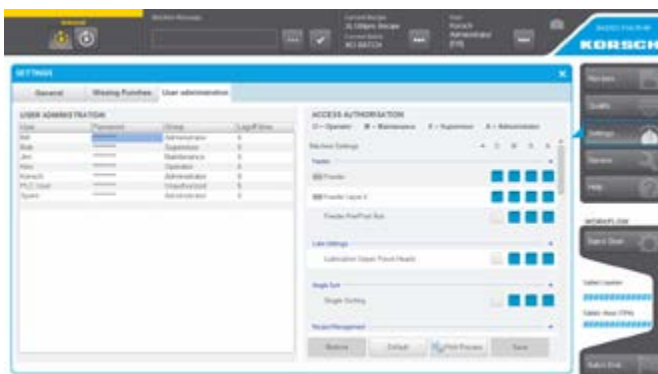
- Peak Force
- Area under the Force-Time Curve
- Contact Time
- Rate of Force Application
- Rate of Force Decay



Optimal Control and Full Compliance

The XL 100 Pro offers an enhanced control system to permit the integration of a tablet weight control system, single tablet rejection system, and integrated data acquisition

system. The Pro controls are ideal for clinical batch production and include operator login, product recipe, electronic audit trail, and batch data reporting.



User Friendly Touch Screen Control

The XL 100 Pro control screens offer a graphical and userfriendly environment. All critical press parameters are displayed and may be adjusted in real-time.

- Press Force Control
- Single Tablet Rejection
- Product Recipe
- Batch Reporting

21 CFR Part 11 Compliant

KORSCH controls permit full compliance with 21 CFR Part 11.

- Password Login with Four Access Levels
- Electronic Audit Trails (event log, alarm log, reject log)
- Product Recipe Version Control
- Secure Batch Report File Format for Data Integrity



Screens apply exclusively to the XL 100 Pro version.



XL 100 WipCon® Execution

The KORSCH XL 100 WipCon® is an innovative tablet press which offers a comprehensive wash-in-place (OEB 3) and high containment (OEB 4/5) capability for product development, scale-up, and clinical batch production of highly hazardous products. The XL 100 WipCon® can be fully instrumented for the measurement of precompression force, main compression force, ejection force (segmented cam), and scrape-off force to permit product development parameters to be evaluated and stored.

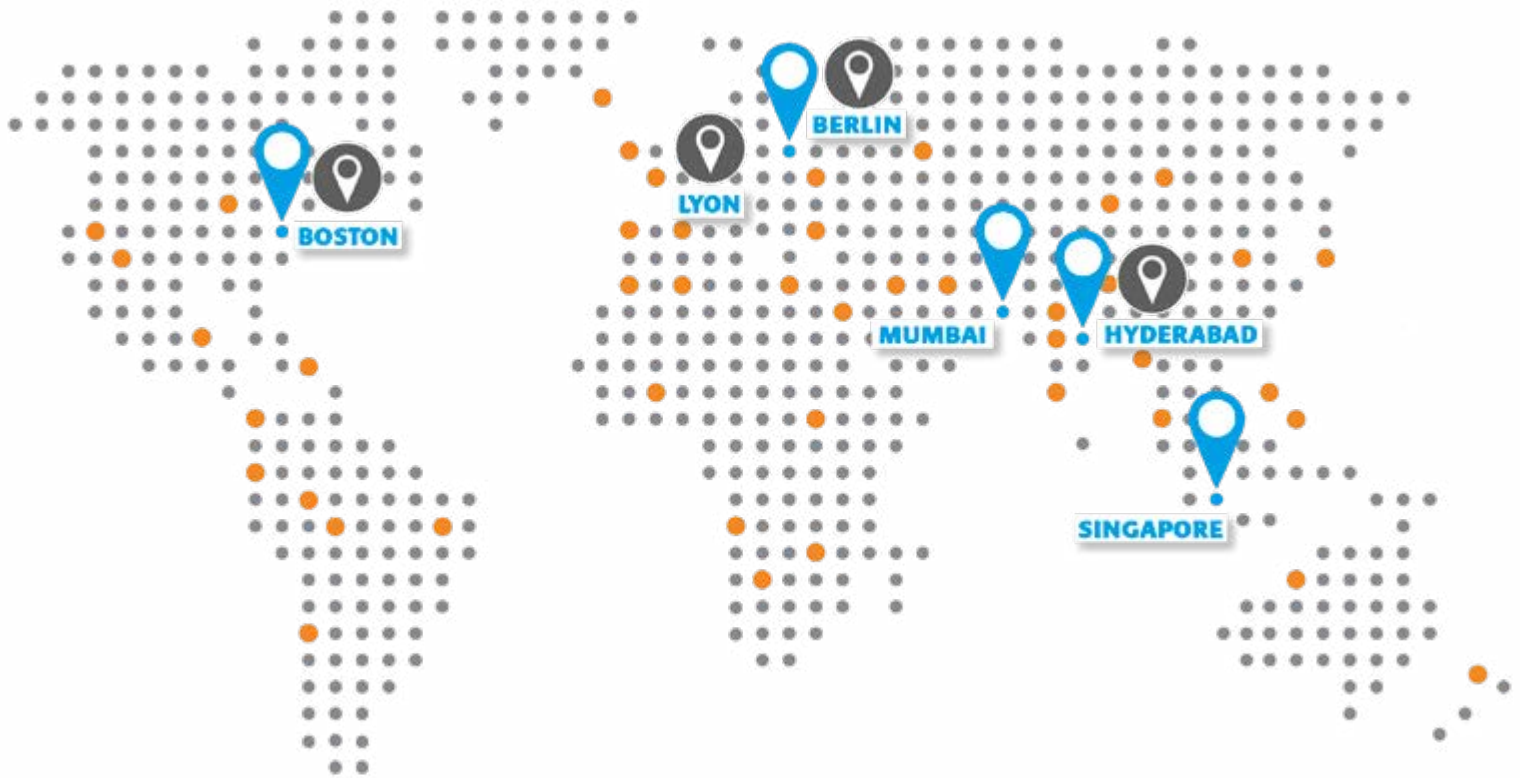
- Minimum space requirements, portable design
- Best cleaning / decontamination results for product specific demands
- Optimized glove port ergonomics
- High containment range for lab scale and medium size batches OEB 5 ($1 \mu\text{g}/\text{m}^3 > \text{OEL} > 0.1 \mu\text{g}/\text{m}^3$) with RTP transfer system
- Medium containment range for small production batches OEB 4 ($10 \mu\text{g}/\text{m}^3 > \text{OEL} > 1 \mu\text{g}/\text{m}^3$) with split valve connections
- Connection to wash-in-place tablet deduster on same containment level OEB 4 ($10 \mu\text{g}/\text{m}^3 > \text{OEL} > 1 \mu\text{g}/\text{m}^3$)
- Negative pressure control and safe-change filter to permit a turnkey and integrated solution




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


KORSCH
The Specialist.

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Technical Data

KORSCH XL 100 Pro / XL 100 WipCon®

Number of Punch Stations		12	10	8
Number of Press Stations		1	1	1
Press Tools	EU/TSM	BB	B	D
Main Compression Force	kN	60	60	60
Precompression Force/ Tamping Force	kN	10	10	10
Tablet Diameter max.	mm	13	16	25
Filling Depth max.	mm	6-10-14-16-18	6-10-14-16-18	6-10-14-16-18
Turret Speed	RPM	20–120	20–120	20–60
Tablet Output	tabs/h	86,400	72,000	29,000
Pitch Circle Diameter	mm	118	118	118
Tablet Thickness max.	mm	8	8	8
Machine Dimensions ■ XL 100 Pro	mm/ L x W x H	1,355 x 690 x 1,959	1,355 x 690 x 1,959	1,355 x 690 x 1,959
Weight of the Machine	kg	860	860	860
Electrical Load	kVA	4.5	4.5	4.5

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.