KORSCH
PRODUCT RANGE

XL 200

Pharmaceutical Rotary Press

For Mid-Range
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.

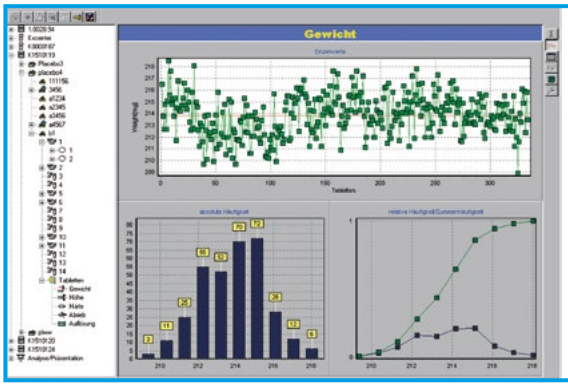
www.korsch.com

MADE IN GERMANY

Full Production Capability

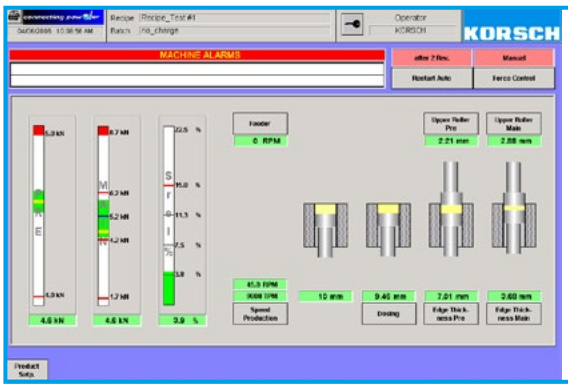
The XL 200 is a robust, high-speed rotary tablet press which is ideal for scale-up, clinical manufacturing, and high-speed production. Offering a smaller footprint, the XL 200 maximizes output in a small space, especially if the machine is mounted in a through-the-wall configuration.

The XL 200 offers an identical feeder, cam, and compression roller design – to insure direct scalability to larger KORSCH machines. The XL 200 is equipped with the complete production control system, and offers full compliance with 21 CFR Part 11.



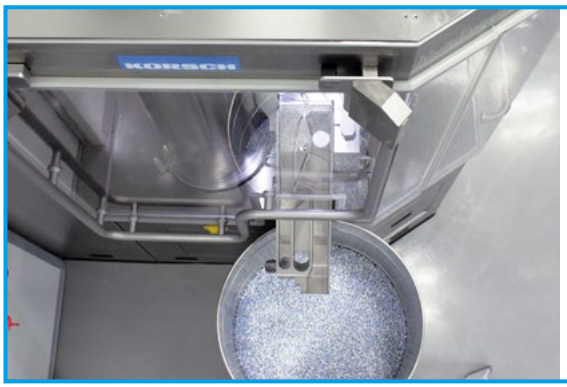
XL 200 with PharmaResearch®

Scale-Up and Clinical Manufacturing



XL 200 with PharmaControl®

Mid-Range Production



XL 200 Through-the-Wall

Minimized Footprint and Maximized Efficiency

Optimized Design

The XL 200 offers all of the design advantages of the proven XL-series, in a mid-range machine that offers superior efficiency and a reduced overall footprint. The XL 200 offers an extremely wide range of capability – with full instrumentation and data acquisition for scale-up, through fully automated, high-speed production of clinical and mid-range production batches. The control system permits full compliance with 21 CFR Part 11, and offers full product recipe, electronic audit trails (alarm log, event log, reject log), press force control, and single-tablet rejection.

Scale-Up and Clinical Manufacturing

The XL 200 can be fully instrumented for the measurement of precompression force, main compression force, and ejection force. An integrated data acquisition system will permit the full characterization and documentation of scale-up parameters. The XL 200 is also ideal for clinical manufacturing with recipe control and full batch data management.

- Integrated data acquisition
- Documentation of scale-up parameters
- Clinical batch data management

Mid-Range Production

The XL 200 offers a robust production capability with a high-speed and fast-change capability. The XL 200 offers a long filling length, and large 3-chamber feeder for precision die filling at high speeds. The unique carrier plate design, common to all XL-series machines, insures the lowest noise levels at all production speeds. The exchangeable turret and superior access to the compression zone permits the fastest change times for maximum efficiency and uptime.

- High-speed, Fast-change capability
- Exchangeable turret
- Maximum efficiency and uptime

Minimized Footprint

The XL 200 is ideal for smaller compression suites, and the footprint can be further minimized when the machine is mounted Through-the-Wall. The TTW (Through-the-Wall) configuration permits access to the major machine components from the technical area and minimizes the total space requirement in the GMP space.

- For smaller compression suites
- Through-the-Wall installation option
- Full separation of technical zone and GMP space

The Benefits at a Glance:

- High Capacity Operation on a Small Footprint
- Fast Changeover for Maximum Efficiency
- Optimal Control, User Friendly HMI, Fully 21 CFR Part 11 Compliant

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High Efficiency, Utilization and Uptime

The design concept of the XL 200, including the rear multi-function cabinet with all major press components, and open compression zone, offers superior access for operation, cleaning, changeover, and maintenance.

The compression zone of the XL 200 features minimal components and smooth surfaces to streamline the changeover process. The XL 200 is built to operate at high-speeds, with maximum efficiency and reliability.

High Efficiency

The XL 200 offers a maximum press speed of 120 RPM, and a robust and rugged design that is geared for the most demanding production environments. The recipe-driven product set-up, and streamlined changeover process, insures maximum uptime and operational efficiency. The control system permits full compliance with 21 CFR Part 11, and offers full product recipe, electronic audit trails (alarm log, event log, reject log), press force control, and single-tablet rejection.

- 120 RPM press speed capability
- Recipe driven product set-up
- Streamlined product changeover

Exchangeable Turret

The XL 200 features an exchangeable turret capability which permits the production of all tablet sizes on a single machine. An internal lift arm simplifies the turret removal process, and each turret is mounted on a dedicated transport and service cart. The turret can be cleaned and serviced off-line while the machine continues in production.

- Simple turret removal – 10 Minutes
- Wide range of turret sizes (20, 25, 30, 32-stations)
- Internal lift arm

Superior Accessibility to Compression Zone

The innovative carrier plate design of the XL 200 eliminates the traditional corner columns and offers extreme access to the compression zone for cleaning and maintenance. All components in the compression zone utilize quick disconnects to streamline the cleaning process. The carrier plate design isolates vibration and insures the lowest noise level at all operating speeds. All major components are accessed through the rear multi-function cabinet.

- Superior access to compression zone (no corner columns)
- Smooth surfaces for easy cleaning
- Superior access to major components in the multi-function column

Minimal Noise and Vibration

The unique and patented design of the carrier plate, with mechanical dampers, fully isolates vibration from the head piece and machine base.

The result is an extreme reduction in operating noise level, even with high compression forces and high press speeds.

- Very low noise emission < 75 dB(A)
- No vibration transmission to the floor of the compression room
- No segregation of powder in the feeding system which can occur with machine vibration

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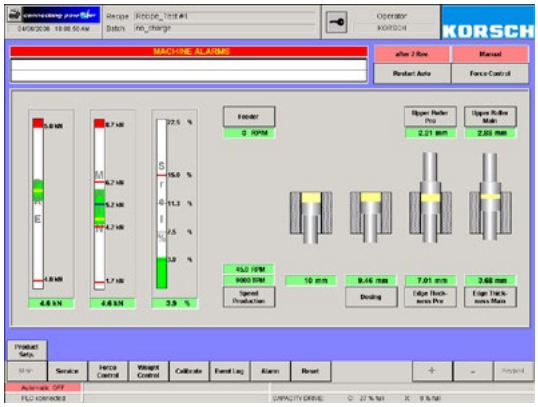
Optimal Control, User Friendly HMI, Fully 21 CFR Part 11 Compliant

KORSCH controls are based on a standard Siemens or Allen-Bradley PLC. The touch screen HMI also uses industry standards, including WinCC and WonderWare, which are operating on an industrial PC platform.



User Friendly Touch Screen Control

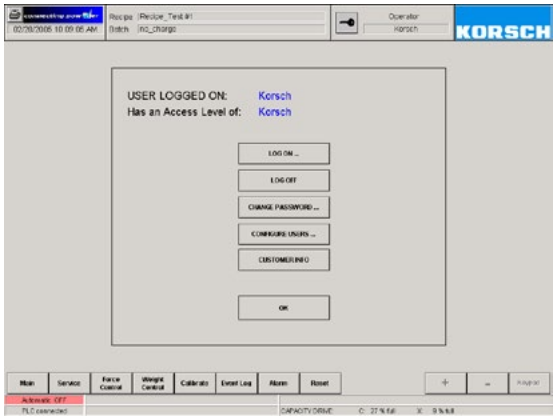
The main screen presents all important press parameters in a graphical format. The language may be changed at the push of a button.

- 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



Special Features for Product Containment

The XL 200 offers a range of containment options including:

- High containment and wash-in-place execution (WipCon®) including peripheral equipment for OEB 5 containment applications (< 0.1 µg/m³).
- Medium containment execution (OEB 3) for hormone applications.

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

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