



KORSCH
PRODUCT RANGE

X 3

Maximizing Mid-Range Production



Pharmaceutical Single
and Bi-Layer Rotary
Tablet Press

KORSCH
The Specialist.

Innovation Made in Berlin Since 1919

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.

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MADE IN
GERMANY

X 3 Maximizing Mid-Range Production

The X 3 is a breakthrough in the small-scale and mid-range tablet press segment, designed from the ground up to incorporate the latest KORSCH advancements. The X 3 is a single-sided rotary tablet press that redefines flexible technology with a new approach to architectural and ergonomic design elements, which were previously available only on larger machines.

The X 3 is smarter and Pharma 4.0 ready, which permits a deeper understanding of what is happening in the compression suite. This is the basis to optimize both the process, and the manner in which the process is executed by the operations team, to obtain the maximum product quality.

Flexibility of Use:

- Product development / Scale-up
- Clinical batch production
- Mid-range production
- Continuous production

Containment:

- DryCon version (OEB 3/4)
- WipCon® version (OEB 4/5)



Multi-Layer:

- X 3 SFP: dedicated single-layer capability
- X 3 MFP: flexible single and bi-layer capability

Operational Efficiency:

- Extreme accessibility in a flexible platform of this size (no corner columns)
- Cleanability (closed design)
- Serviceability (dual-column design)
- Integrated electrical cabinet

Smart: Pharma 4.0 ready:

- Smart-Touch HMI with comprehensive on-board help
- Industry 4.0 ready
- PharmaView® (Augmented Reality platform)
- Remote service



Flexibility of Use

The X 3 is a robust, portable, single and bi-layer rotary press which is ideal for scale-up, clinical manufacturing and mid-range production. The integrated control cabinet ensures a minimized footprint without cables in the room.

The single and bi-layer capability, and exchangeable turret technology offer unprecedented flexibility that permits the press to be adapted to future production requirements.

Product Development

The X 3 can be fully instrumented for the measurement of precompression force, main compression force, and ejection force. An optional integrated data acquisition system will permit the full characterization and documentation of scale-up parameters.

- Optional integrated data acquisition and analysis (PharmaResearch)
- Documentation of scale-up parameters
- Mixed turret
- Operation with reduced press tools and low volume feeders

Clinical Manufacturing and Mid-Range Production

The X3 offers a robust production capability with a high-speed and fast-change design. The X3 offers a long filling length, and large 2-chamber feeder for precision die filling at high speeds. The superior access to the compression zone permits the fastest change times for maximum efficiency and uptime. Due to its size the X 3 is the ideal tablet press for continuous production.

- Exchangeable turret
- Lowest noise level
- Press force control
- Comprehensive batch reporting

Installation Flexibility

The innovative, self-contained design of the X 3 offers a range of installation options.

- Portable platform
- Conventional installation in compression suite
- Through-the-wall installation



One Common Platform – Two Machine Models



The X 3 design offers a single-layer only, and a flexible single and bi-layer capability in two machine models that share a common platform, and fully interchangeable components. For any single and bi-layer product portfolio, the X 3 platform

ensures the highest efficiency, common best practices for setup and changeover, and interchangeable turrets and product contact parts.

X 3 SFP:

Dedicated Single-Layer Mid-Range Production

- Up to 266,400 single-layer tablets per hour
- 40 kN precompression capability
- 80 kN main compression capability
- 120 RPM maximum press speed

X 3 MFP:

Flexible Single and Bi-Layer Mid-Range Production

- Up to 266,400 single-layer tablets per hour
- Up to 133,200 bi-layer tablets per hour
- 5 or 20 kN first layer tamping force capability
- 40 kN precompression capability
- 80 kN main compression capability
- 120 RPM maximum press speed (single-layer)

Operational Efficiency

The X 3 features large windows for excellent visibility and unlimited access to the compression zone to streamline product changeover and turret exchange. At the rear of the machine, the multi-function column houses in two separate compartments, the electrical components and the main dust extraction connection. The water-cooled chiller serves both

the torque drive as well as the heat exchanger in the integrated electrical cabinet. The result is a fully sealed machine exterior with no heat transfer to the compression zone of the press, or to the compression room. The closed design ensures no contamination in the machine base or electrical cabinet to support the streamlined cleaning and changeover.

Superior Accessibility by Design

- Compression zone without corner columns
- Machine base with open framework and ergonomic arrangement of components for extreme serviceability
- Easily accessible central connection panel for peripherals for fully integrated control

Cleanability

- Quick disconnect on all product contact parts for streamlined changeover
- Isolated dust collection housing with optimal access for cleaning
- Sealed exterior design ensures contamination free machine base and multi-function column
- Large smooth surfaces simplify cleaning

Minimal Noise and Vibration

The carrier plate that supports the dual column for pre and main compression is mounted on dampers.

This unique and patented design fully isolates vibration from the head piece and machine base. The result is an extreme reduction in operating noise level.

- Very low noise emission < 80 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



Streamlined Turret Removal

The X 3 turret may be exchanged – quickly, easily, and safely – including the cams, and press tools. A lifting arm is installed in the carrier plate to facilitate turret removal and installation. The control system has a turret recognition capability to permit the turret parameters to be recognized automatically.

- Turret removal in less than 15 minutes
- Transport cart for turret preparation and off-line cleaning



Robust Dual-Column Design

The X 3 features a combined compression roller column for pre and main compression. It is a fixed column which is secured on the main carrier plate. The lower and upper compression rollers swivel to the outside for cleaning and maintenance purposes. The upper rollers feature a high vertical stroke to permit turret exchange.

- Swiveling lower and upper compression rollers
- Motorized insertion depth adjustment for pre and main compression
- Motorized edge thickness adjustment for pre and main compression
- Drives below carrier plate provide full accessibility for maintenance



Smart and Pharma 4.0 Ready

The X 3 is fully prepared to fit into the smart factory concept. The KORSCH control system features an open architecture and the ability to easily integrate the machine to a central network, with domain authentication, central recipe management, and central batch report archiving. In addition, a standard OPC UA Server permits press parameters to be passed to a SCADA or Historian system in real time. Advanced capabilities further leverage the data through secure cloud

solutions for OEE assessment and predictive maintenance. In addition, machine data may be made available for sharing with external systems through Cloud or VPN connection. This digitalization strategy for the machine design will provide a higher product quality, lower total cost of ownership, and significant advantages and convenience in the day-to-day machine operations, from electronic production monitoring to operator assistance through virtual reality.

Programming Suitable for Industry 4.0

To reach the goal of industry 4.0 which is a fully digital supply chain, the key point is that all components can communicate inside the machine and to external systems. Programming carried out according to international standards in the sector guarantees the communication with other machines and systems.

- Programming of all machine components on one single platform (SIMOTION)
- Programming according to Norm PackML (Packaging Machine Language) from OMAC
- Tableting control algorithms based on our Specialists' knowledge are constantly optimized

Intelligent Components Industry 4.0 Ready

In order to support required advances in operational efficiency, the X 3 is smarter. This means that the machine features intelligent sensors which play a key role in making Industry 4.0 a reality. They are the interface between the real and digital worlds. Sensors which function on a fully digital basis enable data to be interpreted accurately for the process.

- Smart sensors, featuring IO link, to pre-process data
- Memorizing sensor technology enables machine features to be stored directly in the sensor
- Electronic type plates record identity, configuration and calibration of components

Cloud Solutions

Digitalization of the machine permits data to be transmitted to a secure cloud solution from KORSCH (PharmaInsights) or via the customer directly. Cloud computing can analyze and process these data via different apps and software. Data can also be made available for external service providers, if required.

- Calculate and visualize key performance indicators to detect optimization potential
- Calculate and assess OEE and efficiency optimization strategies
- Track and optimize energy consumption of your machine



Augmented Reality Support with PharmaView®

KORSCH PharmaView® is an interactive operational assistant based on Microsoft HoloLens augmented reality technology. The smart glasses beam holograms and additional information into the user's actual visual axis, enabling guided, hands-free setup, operation, and maintenance. The remote service via video call function permits a secure, streamlined, remote troubleshooting capability that will save time, reduce costs, and improve overall efficiency and uptime.

- Holographic support for production, trouble shooting and maintenance
- Access to multi-media support files
- Augmented training (without machine or on the machine to see inside the assemblies)

Intuitive Controls with Smart-Touch HMI

The advanced control system interface provides an intuitive operating environment and Smart-Touch HMI, which permits move, zoom, and scroll gestures. The HMI environment offers a comprehensive On-Board help capability, which includes a vast array of multi-media help files to present

procedures and to support the operation and maintenance. At the heart of the control system is a Siemens SIMOTION controller, which merges PLC and motion controls in a single, integrated system. This permits extensive remote diagnostic support.

On-Board Help Capability

The Smart-Touch HMI sets a new standard for help content which is integrated in the HMI environment to permit direct access during the machine operation and maintenance.

- Direct link to support documents, including manuals, drawings, and schematics
- Multi-media support files (videos, pictures) to support equipment procedures (turret change, machine changeover, calibration, etc.)
- Access to an electronic spare parts catalog
- Troubleshooting and diagnostic support



PharmaControl® Press Force System

The X 3 uses the proven PharmaControl® press force control system to monitor individual compression forces and to provide closed loop feedback to the dosing cam for precise tablet weight control. The Smart-Touch HMI displays average force and the single force on each punch station in real time. The optional single-tablet rejection system will reliably reject an individual tablet from a known punch station across the full speed range, and build a reject log which may be viewed in real time, and included in the electronic batch report.

- Press force monitoring and regulation for precise tablet weight control
- Single-tablet rejection across the full speed range
- Real-time reject log and reject log report at batch end



Containment Solutions

KORSCH offers a wide range of containment options on most machine models, including DryCon (OEB 3/4) and WipCon® (OEB 4/5) versions. Featuring a fully engineered and turnkey execution, KORSCH containment projects incorporate the tablet press, deduster, metal check, tablet tester, air handling

system with negative pressure control, containment valves, and WIP skid. KORSCH engineers are expert in developing the concept, execution, integration, and final SMEPAC testing to fully validate the containment capability.

DryCon Execution

- OEB 3/4 containment capability
- Ergonomic placement of glove ports and RTP permit contained access to the compression zone
- Negative pressure control and integrated vacuum wand for dry cleaning
- Eliminates requirements for PPE
- Formal SMEPAC Testing for containment level certification

WipCon® Execution

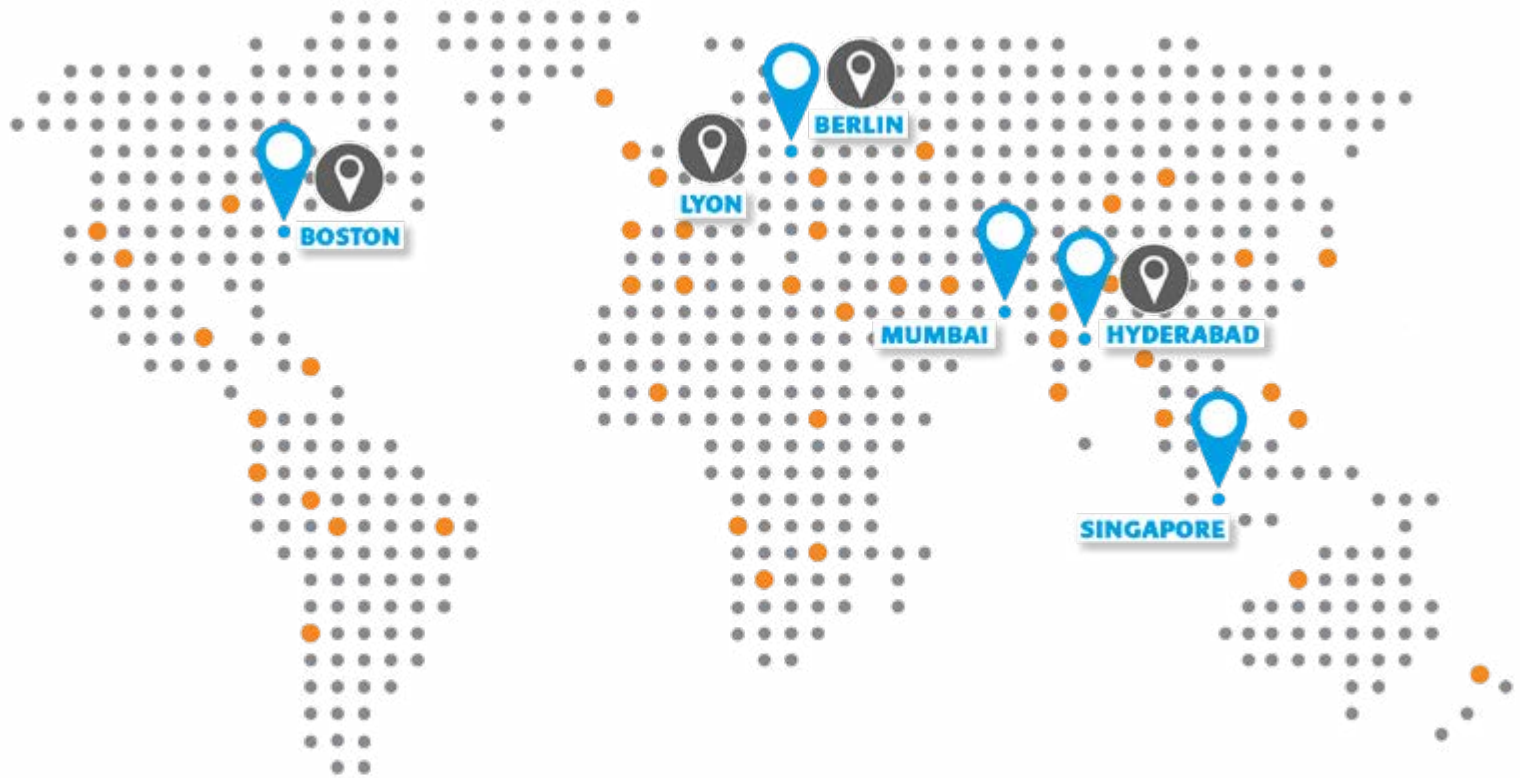
- OEB 4/5 containment capability
- Containment isolator with recipe driven wash-in-place capability
- Turnkey system with fully integrated peripherals and containment valves
- R&D, scale-up, and full scale production models
- Formal SMEPAC Testing for containment level certification



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

KORSCH
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Technical Data

KORSCH X 3 1-2-Layer

| | | | | | |
|--|-----------------|---|---------|---------------------|--------------------|
| Number of Punch Stations | | 37 | 34 | 16/28 | 16/23 |
| Press Tools | EU/TSM | BBS | BB | B | D |
| Main Compression Force | kN | 80 | 80 | 80 | 80 |
| Precompression Force | kN | 40 | 40 | 40 | 40 |
| Tamping Force Standard (Optional) | kN | 5 (20) | 5 (20) | 5 (20) | 5 (20) |
| Max. Tablet Diameter | mm | 11 | 13 | 16 | 25 |
| Max. Filling Depth | mm | 18 | 18 | 18 | 22 |
| Turret Speed Single-Layer | RPM | 5 – 120 | 5 – 120 | 5 – 120 | 5 – 100 |
| Turret Speed Bi-Layer | RPM | 5 – 60 | 5 – 60 | 5 – 60 | 5 – 50 |
| Max. Tablet Output (Single-Layer) | Tabs/h. | 266,400 | 244,800 | 115,200/ 201,600 | 96,000/ 138,000 |
| Tablet Output (Bi-Layer) | Tabs/h. | 133,200 | 122,400 | 57,600/ 100,800 | 48,000/ 69,000 |
| Pitch Circle Diameter | mm | 325 | 325 | 325 | 325 |
| Max. Tablet Thickness | mm | 8.5 | 8.5 | 8.5 | 8.5 |
| Machine Dimensions | mm L x W x H | 1,728 x 900 x 1,920 – Dimensions are identical for all versions | | | |
| Net Weight of the Machine | kg | 2,800 | 2,800 | 2,800 | 2,800 |
| Total Connected Electrical Load | kVA | 27 | 27 | 27 | 27 |
| Power Consumption | kW | 10 – 12 | 10 – 12 | 10 – 12 | 10 – 12 |

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.