Successful Tableting Supplement

Continuous Tableting | MODUL™ Q | A-Type Tooling

engineering for a better world

Operational excellence

For more than a hundred years, our innovation, driven by our passion for excellence, has pioneered tablet compression technology, allowing pharmaceutical and industrial companies to prosper, produce extraordinary products and change people's lives.

Our innovations include a unique technology that independently and simultaneously measures and controls both tablet weight and hardness, and a weight control system that provides increased sensitivity at lower forces. Our presses offer an extended dwell time — up to 300% — resulting in higher outputs and enhanced productivity. And that's just the tip of the iceberg.

To meet your production challenges, we have developed a higher level of understanding of ingredient and manufacturing variables. And by implementing the philosophy of Six Sigma to reduce critical process variation and lean manufacturing to eliminate waste, our technologies and expertise can help you to produce a better quality tablet, reduce the risk of product failure, improve your cash flow and improve your bottom line profit.

Our technology is world renowned for its reliability, flexibility and economy. We offer truly rapid changeover solutions, increased productivity, flexibility and safety. But it's much more than that; it's about how we work with you, the customer. We understand your needs; we use our expertise and know-how to develop solutions and optimize processes that bring your products to market quickly and provide the commercial advantage you need.

In this supplement to our Successful Tableting book, we present our solutions for continuous manufacturing, a brand new addition to the MODUL™ range of rotary tablet presses and the features and benefits of A-type tooling for our MODUL™ and PERFORMA™ machines.

GEA and Continuous Manufacturing

Continuous pharmaceutical manufacturing means that ingredients are continuously being fed in at one end of the production unit and end product is continuously being generated at the other. Continuous manufacturing is more cost-effective than traditional batch processing, as the amount of product generated effectively depends on how long the equipment is run for.

Drugs can therefore be manufactured according to demand. Critically, in continuous manufacturing, all process and quality parameters are constantly monitored and controlled at each stage of the process with integrated process analytical technology (PAT) systems. This continual analysis ensures the highest product quality and efficiency, whilst minimizing resource use, wastage and environmental impact.

Continuous pharmaceutical manufacturing is a key element of the US Food and Drug Administration's 2002 *Pharmaceutical Quality for the 21st Century: A Risk-Based Approach* initiative. One of the aims of the initiative is to modernize the pharmaceutical manufacturing industry. The use of PAT technologies to monitor and control quality as an integral part of processing and manufacturing is fundamental to the global drive to design analytical and quality control capabilities into the production process. This is an increasingly important concept known as quality by design or QbD.

As a leading innovator of manufacturing concepts, analytical technologies and processing equipment design and optimization, GEA will continue to play a major role in the global drive to develop oral solid dosage (OSD) manufacturing technologies that improve the quality, efficiency and cost-effectiveness of pharmaceutical production for the ultimate benefit of patient health.

Continuous Processing Technology

ConsiGma™: The Future of Tableting

Tablet presses have always operated continuously. Until now, however, because of regulatory restrictions and the fact that granules were delivered to the press in batches, they have mainly been used in batch mode. Both of these hurdles to continuous tableting have been removed in recent years.

GEA MODUL™ tablet presses are an essential component of the company's ConsiGma™ continuous processing line for solid dosage forms. ConsiGma™ is an innovative technology, unique to GEA, that meets both the demands of the regulatory authorities and pharmaceutical companies for continuous manufacturing to provide better quality and consistency, just-in-time production and get products to market faster in a more flexible and environmentally conscious way.

The ConsiGma™ family of continuous manufacturing technologies includes state-of-the-art continuous high-shear granulation and drying lines for continuous OSD processing plants (ConsiGma™ CTL), as well as the ConsiGma™ CDC platform for blending and direct compression.

These lines are complemented by ConsiGma™ 1, the R&D-scale version of the larger industrial platforms, which has been developed as a laboratory stage unit for small-scale research and development applications, and the ConsiGma™ coater to complete the continuous tablet production line.

The ConsiGma™ Continuous Tableting Line

A Game Changing Solution — ConsiGma™ CTL

Taking a blue sky powder-to-tablet approach to pharmaceutical manufacturing, ConsiGma™ offers continuous oral solid dosage granulation, drying and tablet compression in a single production line. The ConsiGma™ continuous tableting line (CTL) is a multipurpose platform that has been designed to transfer powder into coated tablets in development, pilot, clinical and production volumes in a single integrated unit.

The ConsiGma™ system is designed for plug flow, first-in first-out production (avoiding back mixing), providing consistent quality and allowing for the inline control of critical quality attributes. The system can be configured to perform dosing and mixing of raw materials, wet or melt granulation (using the same co-rotating twin screw granulation unit), drying (cooling for melt granulation), tableting, coating and quality control, all in one line.

The ConsiGma™ Principle

ConsiGma™ incorporates high shear granulation, drying and tablet production into a single, continuous process. It allows users to make exactly the number of tablets required to meet immediate demand with the batch size limited only by the running time of the machine or by how much inbound material is supplied; and, because of ConsiGma's innovative design, the amount of waste produced during startup and shutdown is significantly reduced compared with conventional methods.

The ConsiGma™ system is capable of undertaking particle design and mimic any traditional batch granulation process — with a much higher and consistent quality resulting from its continuous production set-up and "risk-based approach" to GMP. The granules have better intragranular porosity, with improved compressibility characteristics that help tablet presses to run more efficiently at maximum speed with hardly any weight adjustments being required. Parametric release is achieved through inline testing.

Quality is measured throughout the process and, as such, drastically reduces the cost per tablet. Critical quality attributes are measured second-by-second and any deviation from the norm is immediately reported to the operator. Optionally integrated advanced process control and PAT tools enable monitoring during production, so quality can be designed into products from the start.

From R&D to Production on One Machine

The ConsiGma™ concept enables small amounts of product to be processed and developed quickly and efficiently. And, once a formulation has been optimized, it can be reliably reproduced in pilot, clinical or production batches, simply by running the machine for longer, avoiding scale-up problems and the lengthy validation processes that hinder bringing new products to market faster.

Environmental Benefits

Combining processes into a single machine means reduced space requirements, smaller buildings, smaller cleanrooms, less waste and less consumption of power and raw materials.

ConsiGma™ provides maximum output in an energy efficient way, has been tested using more than 120 different formulations and is already being used by several large pharmaceutical companies, and both ethical and generic research and manufacturing centers worldwide.

To enhance its flexibility even further, the ConsiGma™ can also be configured for dry and melt granulation, and connected to a MODUL™ tablet press with an Exchangeable Compression Module (ECM) and a double drum ConsiGma™ coater to form a truly continuous tableting line.

Key Features

- Maximal end-product safety using online quality control
- 10 times faster testing in R&D
- 40% saving on labor
- Reduction of manufacturing space by 60% compared with the current standard
- 50% energy savings based on reduced installed power and heat recovery
- 0.5–5% yield improvement

The ConsiGma™ Continuous Tableting Line

Continuous High-Shear Granulation for More Efficient R&D — ConsiGma™ 1

CONSIGMA™ 1

maximum flexibility and simplicity during R&D and formulation development

The ConsiGma™ 1 is a mobile laboratory scale continuous granulator with an optional fluid bed dryer segment for early research and development work. Designed for maximum flexibility and simplicity during R&D and formulation development, the ConsiGma™ 1 is capable of processing batch sizes starting from 500 g with less than 10 g of product in process. The optional fluid bed dryer can accommodate batch sizes of 500–1500 g.

As direct transfer of the granulation parameters to the production-scale ConsiGma™ CTL (25) can be achieved, no scale–up is required. And, as the retention time of the product in the system is minimal, any change in parameters is almost immediately visible in the product. This enables the design space to be explored in a quick and easy manner.

Built for easy deployment, the ConsiGma™ 1 is compact and maneuverable. The plug and play system only requires electricity and standard utilities such as water and compressed air for installation. The user-friendly operator interface comprises touchscreen technology and logical user graphics.

In addition, to enhance R&D flexibility even further, the ConsiGma™ 1 can also be configured for hot melt granulation. An optional Lighthouse Probe™ for online moisture monitoring can be supplied, as well as an upgrade for contained and solvent-based processing.

Key Features

- Flexible batch size
- No scale-up
- Minimized losses
- Fast changeover
- Advanced, user-friendly process control
- Plug and play technology

The ConsiGma™ Continuous Tableting Line

Dispensing, Blending, Tableting and Quality Control Embedded in One Machine — ConsiGma™ CDC

The ConsiGma™ CDC for direct compression is the latest addition to the ConsiGma™ family, our continuous portfolio of cost effective, compact, high yield manufacturing systems with embedded quality control.

This compact, all-in-one, tablet production line for direct compression (DC) formulations (approx. 4 x 4 x 3 m) means that the dispensing area, blending area and intermediate storage requirements are a thing of the past. Up to six ingredients can be fed separately via specially developed LIW feeders and, thanks to the integration of the feeding, blending and compression operations, segregation issues are eliminated.

Proven blending technology results in minimized startup and shutdown losses and the unique GEA Air Compensator compression technology offers extended and controlled dwell times, accurate weight management and minimal variability in critical tablet quality attributes (an automatic tablet sampling and analysis system is also available).

The modular design allows for containment, Wash-off-Line (WOL) cleaning and fast product changeover. The system complies with the latest QbD guidelines (ICH Q8, Q9, Q10) and is fully compatible with the latest developments in co-processed materials and DC-specific excipients with enhanced compression characteristics.

Key Features

- Fast deployment for new and existing DC formulations
- Close integration to prevent segregation
- Embedded QMS, reduced quality costs and increased security of outcome
- Reduced work in process
- Reduced space requirements
- Fast changeover using Wash-off-Line principle
- Reduced cost per tablet

The ConsiGma™ Continuous Tableting Line

Revolutionary, High Performance Tablet Coating Technology — ConsiGma™ Coater

The ConsiGma™ coater from GEA is a revolutionary, new, high performance tablet coating technology that accurately deposits controlled amounts of coating materials on tablets — even if they are extremely hygroscopic or friable. Designed specifically to be an integral part of the ConsiGma™ continuous tableting lines, the ConsiGma™ coater is able to process small quantities of tablets at very high rates, offering improved heat and mass transfer.

Presenting a paradigm shift in tablet coating, this new type of coater entrains tablets in a cascading movement that enables greater fluid application rates (higher coating build-rates) than traditional coating pans. The functionality of enteric coatings, for example, is greatly dependent on weight gain and coating uniformity. In traditional coating pans, fast coating application rates often result in poor uniformity, requiring a higher weight gain to achieve enteric protection.

Inconsistent and imperfect, this “standard” practice of tablet coating often delivers a non-homogenous product. Because the tablets are loaded in large rotating pans and vented for hot air drying, tablet edges can get rounded off, intagliations can get filled in by coating material, and edges and corners may not be coated with the same thickness as the tablet faces.

The inaccuracy of coating material deposition limits the use of modified release coatings. In a laboratory setting, it is necessary to coat several kilograms of tablets at one time, making the research and development of a solid dosage form costly and difficult. In addition, extremely hygroscopic tablets cannot be coated using current technology, nor can flat or oddly shaped cores be consistently coated. The ConsiGma™ coater from GEA is your solution to these problems.

The MODUL™ Range of Tablet Presses

A Range of Opportunities and Solutions

THE MODUL™ RANGE

sets new standards in efficiency, productivity and reliability

The MODUL™ Q rotary tablet press sets new standards in efficiency, productivity and reliability. Like its predecessors, the MODUL™ Q features GEA's Exchangeable Compression Module (ECM). However, the next generation version of the ECM has fewer parts, is even more convenient to use and offers a higher level of containment performance. The feeder height and ejection finger height can be set outside the machine, with the ECM positioned on its trolley. Dust-free operation is also possible.

With easier access for cleaning and set-up operations and improved functionality, the MODUL™ Q also incorporates the Exchangeable Die Disc with conventional dies or die holes, which was only previously available on the PERFORMA™ P press.

Operationally, the MODUL™ Q has a bigger pitch diameter (300 mm) and, in terms of size, is positioned between the MODUL™ P and MODUL™ S. The use of A-type tooling is now possible, which allows a die table with 51 punch stations to be incorporated and an output of up to 367,200 tablets per hour.

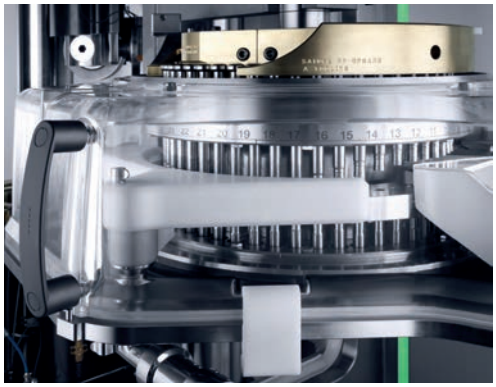
The MODUL™ Range of Tablet Presses

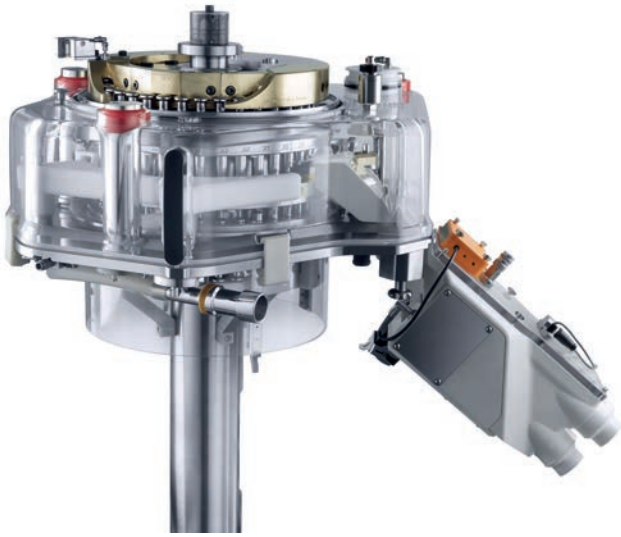
A Range of Opportunities and Solutions

Key Features

- MULTI-CONTROL 5 (MC5) control system, offering multiple compression modes
- Overall equipment effectiveness (OEE) monitoring
- Single and bilayer compression
- Freely adjustable dwell time at pre- and main compression
- Easy to assemble, operate and clean
- Compact footprint (1 m^2).

Designed for full-scale production, the MODUL™ Q represents the very best of GEA's compression technology in an equally attractive casing, bringing next-generation tableting technology to the pharmaceutical industry. Manufacturers are welcome to bring their most challenging formulations to the company's plant in Halle, Belgium, for trials and testing.





Data Sheet

Technical Data MODUL™ Q

Tooling (EU or TSM)	**D**	**B**	**BB**	**A**
Maximum tablet diameter [mm]	25.4	16 (L=19)	13 (L=14,3)	11
Punch body diameter [mm]	25.4	19	19	12
Outside die diameter [mm]	38.1	30.16	24	(no die)
Die height [mm]	23.81	22.22	22.22	(no die)
Number of stations	24	30	36	51
Maximum fill depth [mm]	20	19	19	19
Top punch penetration [mm]	1 to 4	1 to 4	1 to 4	1 to 4
Maximum pre-compression force [kN]	10	10	10	10
Maximum compression force [kN]	80	80	80	80
Maximum output capacity [tab/h]	157,000	220,000	264,000	367,200
Machine Specifications/Requirements				
Electrical requirements	3 phase + PE; 380V/400V/415V/460V/480V — 50Hz/60Hz (nominal consumption 6 kW; power installed 11.9 kVA)			
Compressed air requirements	clean & dry; 7–8 bar; 500 L/min			
Dust extraction requirements	150 m^3/h at 15 mbar			
Machine dimensions & weight	W = 1030 mm x D = 1555 mm x H = 2170 mm — 2500 kg			

A-Type Tooling

Higher Production Capacity at No Extra Cost

Now available for GEA's MODUL™ and PERFORMA™ tablet presses, A-type tooling offers a number of benefits and advantages. Enabling a higher number of stations to be accommodated on the same pitch, more tablets can be produced at the same linear speed and higher output rates — up to 140% — can be achieved. The use of an Exchangeable Die Disc (EDD) without dies ensures a perfectly even die table surface with no grooves, higher yields and reduced powder loss.

And, in addition, the single tablet reject feature optimizes quality assurance and minimizes powder loss.

Technical Specifications

- Contact surface area similar to 19 mm tooling
- Punch body = 12 mm
- Maximum tablet size = 11 mm

Technical Data A-Tooling

A-Tooling (EU or TSM)	MODUL™ Q	PERFORMA™ P
Maximum tablet diameter [mm]	11	11
Punch body diameter [mm]	12	12
Outside die diameter [mm]	(No die)	(No die)
Die height [mm]	(No die)	(No die)
Number of stations	51	51
Maximum fill depth [mm]	19	19
Maximum output capacity [tab/h]	367,200	367,200

The EDD (Exchangeable Die Disc) for A-type tooling (where no dies are used) is made of hardened stainless steel. The A-type EDD is reversible.

We live our values.

Excellence • Passion • Integrity • Responsibility • GEA-versity

GEA Group is a global engineering company with multi-billion euro sales and operations in more than 50 countries. Founded in 1881, the company is one of the largest providers of innovative equipment and process technology. GEA Group is listed in the STOXX® Europe 600 index.

GEA Group
186, B-1500 Halle, Belgium
Tel +32 2 363 8300
Email: pharma@gea.com

gea.com