

WHAT'S NEXT?



**FETTE
COMPACTING**

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FETTE COMPACTING MAGAZINE 2021/2

片剂连续生产流程
Continuous production line of tablet

制粒混合
Granulation & Mixing

压片
Pressing

包衣
Coating

FOCUS ON CHINA

Looking into the future together

CONTINUOUS MANUFACTURING

Continuity pays off

NEW i SERIES

A worthy successor

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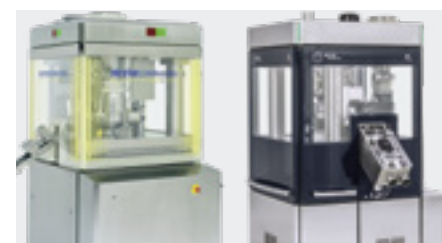
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DEAR READERS,

The way to the future is a continuous one: apart from the batch process, an increasing focus is now being attributed to continuous manufacturing. One example of how continuous lines are already producing large volumes today is presented by our cooperation with the pharmaceutical manufacturer BY-HEALTH in China. In this edition of What's Next?, we also explain when and how continuity is a feasible option.

The points are also set for the future in terms of tableting presses and tools: the new i Series has been commissioned and, in the case of the F10i, replaces the previous model. EasyCare is a new overall solution for safe and efficient handling of tableting tools. We also report on the digital troubleshooting tool, LiveGuide, which has proved to be very effective for an Irish customer.

You can also read about why the nutrition sector is growing so fast and the special role played by tablets and capsules. And we would like to celebrate an anniversary with you: ten years of the FE Series – that's ten years of top performance in tablet production.

We hope you enjoy reading!
Your team at Fette Compacting



TECHNOLOGY stands for all offers in production technology – from tablet presses and capsule filling machines through process equipment to tableting tools and format parts.

SERVICE comprises all services relating to machines, plants and process equipment, e.g. provision of spare parts, plant modernization, and the technical field service.

COMPETENCE is the umbrella term for all process-related services. These include training offers, product tests, performance consulting, and engineering.

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LOOKING INTO THE FUTURE TOGETHER

The growth figures recorded by the Chinese health industry are impressive. But production volumes are only one aspect of this success story. The significantly higher quality requirements by manufacturers of nutrition supplements and medication are at least just as remarkable. One example of this is presented by the long-term collaboration between BY-HEALTH and Fette Compacting China.

The business relationships between the Chinese pharmaceutical manufacturer BY-HEALTH and Fette Compacting China began in 2009 with the purchase of an initial tablet press. Meanwhile, twelve machines are up and running at the production site in Zhuhai. In spring 2021, the two companies agreed to further intensify their cooperation.

This includes developing a new continuous production line with three 3030 tablet presses as well as regular exchanges concerning technical development and optimization of the systems. Another element of this strategic cooperation is the fact that Fette Compacting China can use the BY-HEALTH transparent factory for customer seminars. This gives participants in seminars access to state-of-the-art production technology and the experience offered by both companies. The concept is convincing: more than 200 trade visitors representing the Chinese pharmaceutical and health sectors attended the first joint seminar in spring 2021 in Zhuhai.

For Liangping Cai, Chief Operating Officer (COO) at BY-HEALTH, events such as this one are an important contribution for the industry as a whole. "With our transparent factory, we want to communicate the relevant knowledge about production processes. Together with our partner Fette Compacting, we are making a valuable contribution for the Chinese pharmaceutical industry."

BY-HEALTH – a pioneer of continuous production in China

The production line already up and running and featuring a granulation plant, mixer, coater and filler is set up around two P3030 tablet presses. Serial production as of 2019 was precluded by a research and development process which lasted six years and during which BY-HEALTH examined the requirements and technical prerequisites for a continuous process taking consideration of both the technical equipment and the processes and personnel.

Orientation was offered by the Made in China 2025 strategy by the Chinese government and the German Industry 4.0 initiative. Experts from Fette Compacting were intensively involved in the project since 2015. Together with BY-HEALTH, they sorted out numerous technical details and were able to commission the first pilot plant in 2017. This was the first continuous production plant in the Chinese pharmaceutical and health industry. "Fette Compacting combines technical excellence with many years of experience in the Chinese market and intensive on-site support. This is decisive for success," is how Liangping Cai praises the companies' collaboration.



»FETTE COMPACTING COMBINES TECHNICAL EXCELLENCE WITH MANY YEARS OF EXPERIENCE IN THE CHINESE MARKET AND ON-SITE SUPPORT.«

Liangping Cai, Chief Operating Officer (COO) at BY-HEALTH

The process of digital production

With its new plant, BY-HEALTH aims to continue to comply with its pioneering role in China. As the third line in its smart factory, the new plant is to be largely automated and digitalized. The goal is to achieve practically automatic production enabling the continuous process to optimally display its strengths. Andreas Risch, Managing Director Fette Compacting China, emphasizes how important collaboration based on partnership is: "We are collaborating with BY-HEALTH on a manufacturing line of world-class level. The challenges we face can only be resolved together."

Essential challenges include the digital connection of individual components, particularly the feedback loops between the three central steps of granulation, tableting and coating. Continuous synchronization of parameters of quality relevance, such as particle size and distribution in the granulate, as well as temperature control and spray settings during coating, are of decisive significance.

Another step entails establishing flexible processing of smaller batch sizes for various products which is then to be extended to existing lines. These are still dreams of the future but the project partners are optimistic that they will continue the success story they have already embarked on together.



The P3030 tablet press forms the heart piece of continuous production at BY-HEALTH.

CONTINUITY PAYS OFF

The advantages of continuous manufacturing compared to batch production are well-known: increased process reliability and efficiency through integrated processes, leaner process development, and more flexible production. Yet many pharmaceutical manufacturers are still hesitant. Dr. Marten Klukkert, Manager Technology Center and Pharmacist at Fette Compacting, explains these reservations and how to counteract them.

Dr. Klukkert, what is the current situation regarding continuous tablet production?

As a general rule, continuous manufacturing is working its way into pharmaceutical and nutrition production. At some manufacturers, however, reservations remain as they associate high investment and conversion costs with continuous manufacturing.

Why is that?

Apart from validation, which is associated with increased costs and effort regardless of the type of product conversion, some particular reservations can be observed: base areas which are still often rather extensive and the height of continuous systems, the long lead times for construction and manufacture, as well as the device prices which tend to be high as these plants are very customer-specific. Such calculations can swiftly give rise to a negative business case which is why the next step is often not even tackled.

Sample overall design of a continuous direct compression line with material feed and dosing (upper level), mixing system and tablet press (lower level)

How do you deal with this?

We basically ask ourselves what plant design is necessary in order to produce a positive business case. Continuous manufacturing will only assert itself wide scale if these typical reservations are countered with offers which are easier to adapt and therefore economically attractive. That means leaner plant designs and a simplified process chain, insofar as formulations make this possible. We can offer an attractive overall solution here that combines maximum production efficiency with minimum complexity.

What plant design would you favor?

We specialize in direct compression. The powder is fed directly from the dosing mixer module into the tablet press without any additional granulation. This dispenses with several cost-intensive production steps, such as roll compacting and grinding, which are required for dry granulation. As a result, this reduces the spatial requirements and steering complexity of the process. The low hold-up mass in the plant is a key factor for improved process steering and faster achievement of stable production conditions. A lean plant design also permits faster product changes and shorter cleaning times.



»USERS CAN COUNT ON NEW TECHNOLOGICAL ADVANCES IN CONTINUOUS MANUFACTURING. AGAINST THIS BACKDROP, OUR RECOMMENDATION FOR COMPANIES EXPRESSING INTEREST IS TO ASSESS THEIR RESPECTIVE POTENTIALS WITHOUT DELAY.«

Dr. Marten Klukkert, Manager Technology Center and Pharmacist at Fette Compacting

What role does the tablet press play in the process as a whole?

It is and will remain the heart piece of processing. We deploy a versatile FE55 rotary press for direct compression as it can be used to manufacture a wide range of different tablet types and formats in various configurations. The machine also features three instead of two compression rollers which permits longer dwell times at lower pressure. This gives rise to more gentle processing of raw materials and improves the versatility of the tableting process.

To what extent has direct compression asserted itself among users?

Initial pharmaceutical and nutrition producers have long been giving preference to direct compression over more complex production methods, accompanied by a corresponding focus on the raw materials. This has already resulted in several positive business cases which also take consideration of factors such as the personnel deployed and the number of cleaning cycles.

What do you recommend companies expressing interest?

The technological maturity of continuous production will improve fast. Innovative plant concepts are about to be launched which promise to offer a high potential for reducing complexity. Accordingly, users can count on new technological advances in continuous manufacturing. That is why our recommendation for companies expressing interest is to assess their respective potentials without delay.

Detailed view of the direct compression line: material feed and dosing station at the upper level



A WORTHY SUCCESSOR



The 1200i single rotary press is one of the most successful tablet presses in the history of Fette Compacting. The F10i represents a worthy successor to this successful machine.

The 1200i was one of the most successful tablet presses in the history of Fette Compacting. The last model is now being commissioned in Malaysia. But Fette Compacting already has a machine on the market which is every bit a match for its successor: the F10i.

This is the last chapter of an illustrious career. In summer 2021, the last 1200i left the plant in Schwarzenbek and embarked on its journey to a customer in Malaysia. For Fette Compacting, this marks much more than the end of an item of corporate history. After all, the 1200i is not just any old tablet press among many others. It is one of the most successful machines the company has produced.

With its compact format, flexible application and short conversion times, this high-performance single rotary press was a popular choice for contract manufacturers and smaller customers in particular. "We hit the mark with the 1200i," claims Jörg Gierds, Senior Product Manager at Fette Compacting. "It can be used in production, galenics or laboratories. It is small, versatile, ready for use in a short space of time, and exceedingly mobile thanks to its integrated switching cabinet. All features which made it very popular up until the end."

Just how well Fette Compacting hit the nail on the head in the form of the 1200i became obvious shortly after sales commenced in 1994. The sales figures rose swiftly after only a short time. Many machines were used by customers. "The 1200i was an international best-seller," claims

Gierds. "Many of the machines were deployed in France and Germany. But they were and are also very popular in South America and Eastern Europe."

Developed for the future

Jörg Gierds thinks it is appropriate that the last 1200i will be operating in Malaysia: "In recent years, Asia has become one of the most important production locations for the pharmaceutical industry. The fact that a successful machine such as our 1200i is to make its last appearance there is a wonderful reflection of the developments in the market."

But Jörg Gierds does not feel too much melancholy regarding the end of the 1200i. He knows, after all, that Fette Compacting already has a more than worthy successor on the market. The F10i, the single rotary press in the new i Series, is an innovative development of the classic i Series. Apart from the discontinued 1200i, this range also includes the 2200i, 3200i, 2090i and 3090i models which are all still available.

Numerous new features - from dust-tight standard designs to digital connectivity - make the F10i and indeed the entire new i Series the gold standard for pharmaceutical production of the future. Designed as an equally efficient and versatile machine for smaller batches, the F10i offers numerous innovative features. One of these is its cross-generation system compatibility, which is a mark of all tablet presses in the new i generation.

»THE 1200I HAS SUCCESSFULLY PASSED THE BATON TO THE MACHINES IN THE NEW I SERIES.«

Jörg Gierds, Senior Product Manager at Fette Compacting



Fit for the future: the tablet presses in the new i Series are connectible, system-compatible and dust-tight as standard.

Despite its modern machine design, all parts of the F10i with product contact are identical to those of the old i Series. Dies and segments turrets can therefore be adopted from the tablet presses of previous generations, as can entire turrets. This compatibility measurably minimizes the effort involved in validation and qualification. Thanks to their horizontal integrability, the new tablet presses are perfect fits in existing production environments: old and new machines, such as the 1200i and the F10i, work efficiently side by side.

Connectible and dust-tight

Furthermore, the F10i also features technical connectivity for state-of-the-art production environments, even up to so-called Pharmaceutical production 4.0. This includes process equipment integrated via plug-and-play as well as open interfaces for connections to the internet of things (IoT) and for a Manufacturing Execution System (MES).

Software solutions facilitate operation of the tablet press. A human machine interface permits intuitive control and monitoring of the machine and process equipment, while a workflow wizard guides users through standard procedures. Via a mobile app, the production process can be monitored in real time independent of its location.

As operator protection is steadily gaining in importance, the F10i, as well as the larger F30i, are already consistently dust-tight even in their standard versions, starting with the press room through to the connections between the machine and its process equipment. This not only protects operators from active substances but from any type of exposure.

"In the form of the F10i, we have built a machine which fully complies with the requirements on modern pharmaceutical production," is how Gierds summarizes the new product. "The 1200i has successfully passed the baton to the machines in the new i Series."



Jörg Gierds, Senior Product Manager at Fette Compacting

SPECIALISTS INSTEAD OF GENERALISTS

The global nutrition sector is growing rapidly. In 2020 alone, the market grew by 14 percent. But this only the beginning as nutrition supplements, organic products and confectionery are enjoying ever-increasing popularity. The opportunities and challenges offered by this new market segment are explained by Johan Van Evelghem, Business Development Manager and Nutrition Lead at Fette Compacting.

Mr. Van Evelghem, what requirements do nutrition manufacturers have on the production of their goods?

The sector as a whole is very dependent on trends and is obliged to react swiftly to new market demands. As a machine manufacturer, therefore, we want to help to keep the timeframe between product development and market positioning as short as possible. For us, that means we need to deliver and install fast and have the requisite spare parts available if necessary.

What does this mean for modern tablet presses and capsule filling machines?

The greatest challenge for our machines is productivity, whereby this not only concerns conversion from one batch to another but also how the plants handle the various products. Our extensive product portfolio and international network of experienced specialists clearly distinguishes us from the competition.

What sector trends are particularly relevant for Fette Compacting?

There is a variety of dosage forms. While Boomers prefer tablets and capsules, Millennials often lean towards liquids and nutrition bars. This shows how fragmented the formulation is and how important it is to observe new trends. The two biggest markets are North America and Asia-Pacific, each accounting for about a third of global sales volume. Europe is traditionally a strong market for us and has also gained volume.

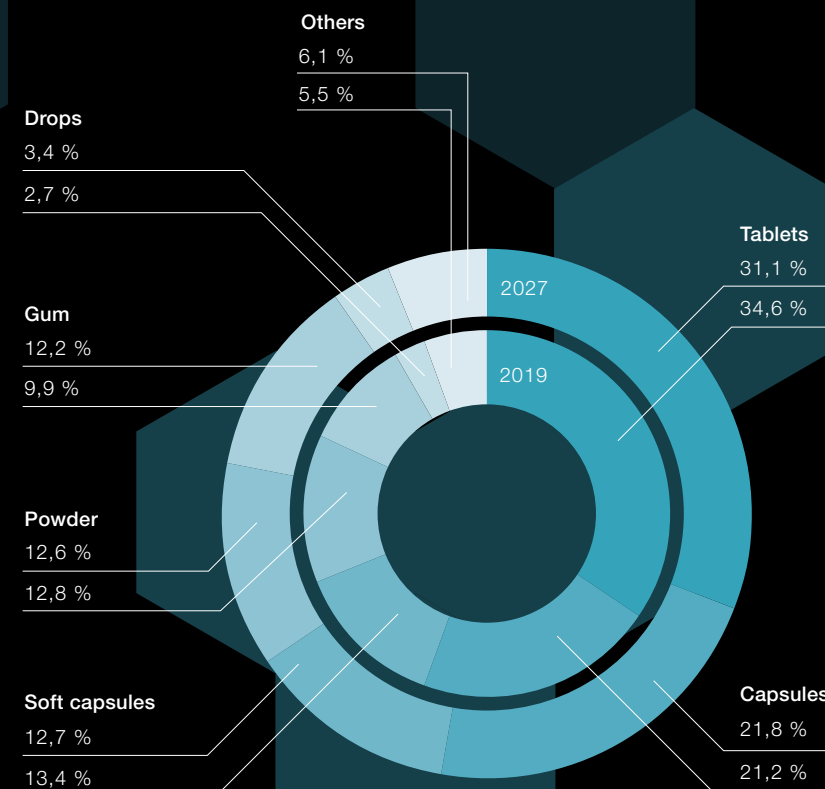
How will Fette Compacting develop in the future on the nutrition market?

Our product portfolio and our Lifetime Efficiency approach are unique in terms of quality and specialization. This affords Fette Compacting a good position, even among the major players. On the other hand, some companies perceive us to be expensive on account of the high quality we offer. We need to counter this impression as our customers are always offered the most economically attractive solution.



Smart Food Performance
by Fette Compacting

NEXT LEVEL NUTRITION



* Market share by form of administration
Source: Grand View Research, figures are rounded off.

»OUR PRODUCT PORTFOLIO AND OUR LIFETIME EFFICIENCY APPROACH ARE UNIQUE IN TERMS OF QUALITY AND SPECIALIZATION.«

Johan Van Evelghem, Business Development Manager and Global Nutrition Lead at Fette Compacting



REMOTE SOLUTIONS



LiveGuide

Short cut to expert support

A software error suddenly caused a galenic tablet press to fail at the Irish pharmaceutical manufacturer Chanelle Pharma. As the machine is not connected to the internet, a technician would have needed to travel there. But the new LiveGuide troubleshooting tool from Fette Compacting quickly and elegantly can solve the problem remotely.

Sometimes it is the supposedly minor problems in pharmaceutical production which bring everything to a standstill without any advance warning. Problems which could actually be easily resolved if a technical expert were on site at short notice. The generic drug manufacturer Chanelle Pharma recently found itself in exactly this situation.

The company has been deploying the 102i tablet press from Fette Compacting at one of its Irish production facilities since 2006. This machines usually used for process-oriented galenics and the production of smaller pharmaceutical batches. Then all of a sudden: nothing.

No machine connection

"There were problems with a software configuration of the machine processor," remembers Declan Treacy, Director of Engineering and Facilities at the Chanelle Pharma. "The 102i was no longer capable of communicating with the Checkmaster which examines the tablets during in-process control of weight, thickness, diameter and hardness. This meant that we were initially unable to continue production with this machine."

This is a situation in which service engineer Michael Furche from Fette Compacting has already acquired experience: "The problem experienced by Chanelle Pharma is basically pretty easy and fast to remedy. That's why it is of course so annoying if something like that causes longer downtimes."

The experts at Fette Compacting can often access the respective tablet press on their own computer and correct this type of problem via remote access. But that was not possible in this case, claimed Furche, as the machine was not connected to the internet. A different approach was selected instead.

LiveGuide, the problem-solver

"In order to solve such a problem remotely, we need to ask the customers lots of questions about the current software settings. Then the customer sends us lots of photos where everything is documented in detail," explains Furche. "Sending this information by e-mail simply takes too long which is why we decided to use the new LiveGuide tool."

LiveGuide is an innovative troubleshooting app developed by Fette Compacting's digital spin-off OSDi. The real-time tool enables users to contact a technical expert at Fette Compacting via live chat, to exchange documents or hold video conferences. The app is available on all mobile devices such as smartphones, tablets and smart glasses and enables personnel on site to implement the tips and instructions issued by the experts directly on the machine.

» THANKS TO OSDI LIVEGUIDE, FETTE COMPACTING WAS ABLE TO SOLVE OUR PROBLEM FAST AND EFFICIENTLY WITHOUT HAVING TO SEND A TECHNICIAN. «

Declan Treacy, Director of Engineering and Facilities at the Chanelle Pharma

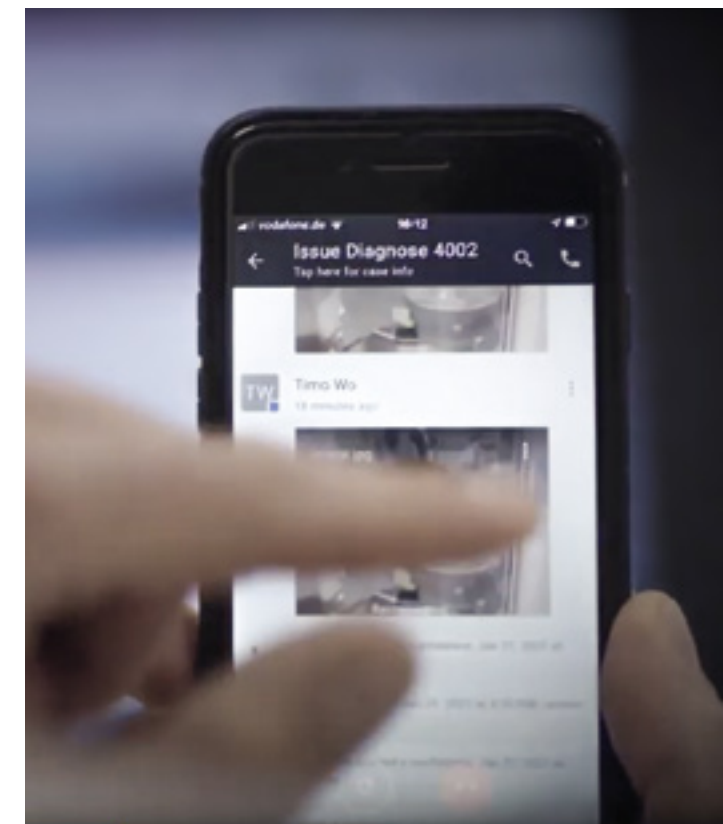


"Under current conditions, it could possibly have taken two or three days until an employee from Fette Compacting arrived on site to handle the problem. With the LiveGuide, everything happened much faster," claims Declan Treacy. "We only had to install the app on one of our mobile devices and then we could get started. As a result, the problem was resolved in no time at all."

110% satisfied

Thanks to numerous live images on site, he was quickly able to obtain an overview of the respective software status of the 102i, Furche remembers. Then, in a series of clearly defined steps, he instructed those responsible to find and eliminate the cause of the problem. "LiveGuide was the ideal solution for such a scenario in which urgent action was required but the machine was not directly connected to the internet."

Declan Treacy is also enthusiastic about the smart tool: "We are 110 percent satisfied with the service. Thanks to OSDi LiveGuide, Fette Compacting was able to solve our problem fast and efficiently without having to send a technician. The dedication shown by those involved was fantastic and we look forward to our ongoing collaboration."



chanelle
PHARMA

For Human and Animal Health: Chanelle Pharma

Chanelle Pharma is Ireland's largest manufacturer of generic drugs for human and veterinary medicines. The company supplies customers in 96 countries and holds more than 5,000 licenses for human and veterinary pharmaceuticals in Europe, Canada, South Africa, Australia, New Zealand, Japan and the USA. In the EU, Chanelle Pharma holds the highest number of veterinary pharmaceutical licenses in the market.



TEN YEARS IN TOP FORM

Ten years ago, we asked the following question: How do you define top performance in tablet production? One answer has emerged since then: the FE Series.

It all started with the FE55 in 2011. This single rotary press was the first model of a new generation of high-performance tablet presses. Even then, trends indicated that pharmaceutical companies would only be able to prevail among international competitors if they improved in terms of efficiency. Accordingly, development of the new series pursued the guiding principle of offering users a maximum gain in efficiency.

The technology of the FE Series is today regarded as the standard at numerous production facilities. It includes the turret with a unique relationship between the number of punches and the base area, the innovative compression stations for single- and bi-layer tablets, the Fill-O-Matic for optimal feed of complex mixtures, and much more.

Machine meets humans

Right from the start, a particular focus was attributed to user requirements. The goal is to achieve smooth and safe operations independent of the level of qualification. How to get there: simplicity in terms of operation, conversion and maintenance. The result was the TRI.EASY design by Fette Compacting which has led to 360° access to the machine and an intuitively operable HMI (Human Machine Interface).

One, two, three

One year after the FE55, the FE35 followed for extremely fast product changes. And then the FE75 came out two years later for maximum output. This trio has been responsible for changing the process of product changes. Enthusiastic users include pharmaceutical customers of all sizes but also manufacturers of nutrition supplements. All of them are counting on decades of efficiency.



THE EFFICIENCY QUADRO

A use case in the USA shows that when the product volume increases but the space available remains unchanged, efficiency becomes the sole lever for success.

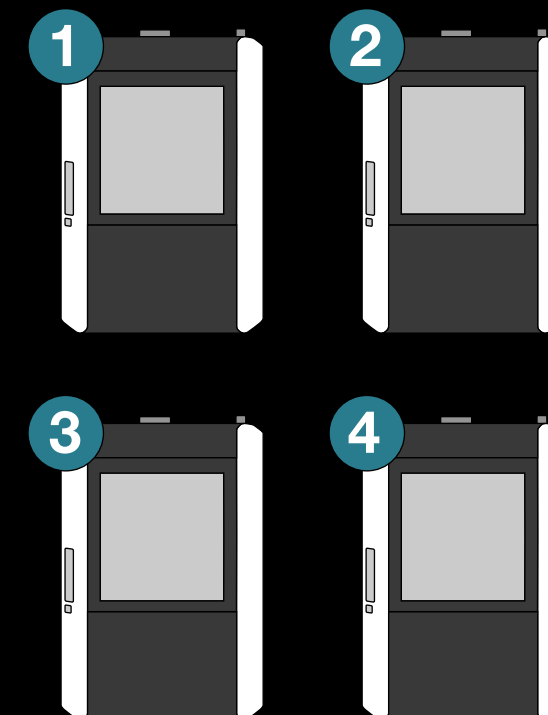
A manufacturer of over-the-counter medication wanted to increase its production of painkiller tablets. In the process, he encountered a problem: his sites in the USA lacked enough space. Consequently, the company had to find a way to achieve more output within the same spatial confinements.

"We have been collaborating with the manufacturer for more than 20 years," reports Ulrik Frodermann, President Fette Compacting America. "So, we put our heads together here to find a solution for this tricky task. The solution comes in the form of the FE75."

A job for the big guy

The FE75 is the largest model in the FE Series. However, "big" is relative as it presses more than 1.65 million tablets per hour on the roughly two square meters of space it takes up. This is possible because, as a double rotary tablet press, it can be fitted with up to 115 punch stations – as is the case with four new machines at the manufacturer in the USA. All of this has paid off: the four FE75 machines produce significantly faster than older presses with a similar footprint. All in all, this results in a whopping 15 billion tablets per year.

Corona has meant that in some cases approval procedures, installations and training have been taking place virtually. Despite these difficult circumstances, Frodermann has an optimistic outlook for the future: "The use of the FE75 will change tableting in many ways at the customer. Our goal is to replace all older machines in the future."



»THE USE OF THE FE75 WILL CHANGE TABLETING IN MANY WAYS AT THE CUSTOMER. OUR GOAL IS TO REPLACE ALL OLDER MACHINES IN THE FUTURE.«

Ulrik Frodermann, President at Fette Compacting America

CLEAN ALL ROUND AND FRESHLY POLISHED

There are three different methods for cleaning tableting tools. But GMP requirements are best complied with fully-automated cleaning.

High-quality tablets require tableting tools which are always in impeccable condition. Accordingly, manufacturers of pharmaceuticals and nutrition supplements, quality auditors and supervisory authorities are demanding permanent adherence to GMP standards (Good Manufacturing Practice) for handling tools.

With a GMP-conformant quality management system, manufacturers can guarantee the product quality and compliance with official health requirements. In an effort to meet these requirements, Fette Compacting and specialized suppliers are relying on

high-quality system solutions for tool management, cleaning and polishing.

Automated hygiene system

“We want to offer our customers in all areas GMP-compliant solutions for handling their tableting tools and which are reliably reproducible,” explains Carmen Ackermann, Product Manager Tableting Tools at Fette Compacting. “We can achieve this by maximizing the degree of automation while keeping the number of manual interventions as low as possible.” In the form of EasyCare, Fette Compacting offers a highly-efficient hygiene system for tableting tools which primarily relies on fully-automatic and standardized methods. Fette Compacting optimizes technologies and processes in all areas, as well as in how it handles tableting tools. The TRI.EASY Tool Box makes it

possible to transport, store and clean tableting tools in a single container, which reduces to a minimum the logistical effort associated with these individual work steps. Along with the washable trays, which feature predefined positions for punches, segments, dies, bellows and dust caps, the case forms a compact unit.

Cleaning coordinated to all tableting tools

Best cleaning results for tableting tools require an interplay by chemicals and mechanics. The washing trays offered by Fette Compacting are therefore also optimally suited for the fully automated ARUNA SDC 800 cleaning plant with an integrated drying unit and GMP-conformant hygiene design. This guarantees the removal of dirt without any residue. The cleaning process is coordinated to the maintenance of tableting

»WE WANT TO OFFER OUR CUSTOMERS IN ALL AREAS GMP-CONFORMANT SOLUTIONS FOR HANDLING THEIR TABLETING TOOLS AND WHICH ARE RELIABLY REPRODUCIBLE.«

Carmen Ackermann, Product Manager Tableting Tools at Fette Compacting



tools and includes preservation as well as the cleaning cycle. Once the care program with deconex CIP power-x has been completed, the tools come out of the plant fully preserved with deconex HT 1191 from Borer Chemie AG. The cleaner and the conservation product are matched to each other and achieve the best result when used in combination. The remaining corrosion protection is approved as a food supplement.

This so-called automatic flush-cleaning prevents cross-contamination and ensures maximum hygiene. Unlike the other two conventional cleaning processes – manual and ultrasound cleaning – it is distinguished by maximum operating safety and reproducibility. This is compounded by the fact that all process steps are documented in detail and can be verified in a report.

Process monitoring, cleaning agent dosing, parameter adjustments as well as drying and preservation are all entirely independent in automatic flush-cleaning. Thanks to this maximization of efficiency, the ARUNA SDC 800 cleans more than twice the number of punches per hour than a comparable ultrasound cleaner. And as all parts are washed in trays, operators do not come into any direct contact with the tools or chemicals when unloading the cleaning plant. This particular GMP requirement cannot be satisfied by other, more manual cleaning methods, which are also more time-consuming.

Efficiency in a closed cycle

Although manual polishing of punches is possible, it is not reproducible in the same quality across the entire set of up to 120

punches. The automatic PA500 pharma polishing machine from Nortec is therefore one of the superior machines used at Fette Compacting. It specializes in polishing tableting tools and features special holders for punches and dies. The smooth polished surfaces reduce the tendency of products to stick of products, which in many cases improves the performance of the tablet press and increases the service life of the tableting tools. After being used for the production of tablets, the punches are restored to an optimal condition and prevent sticking. This makes it a closed cycle. Comprehensive solutions produce not only better results - they also work to counteract problems where they arise.

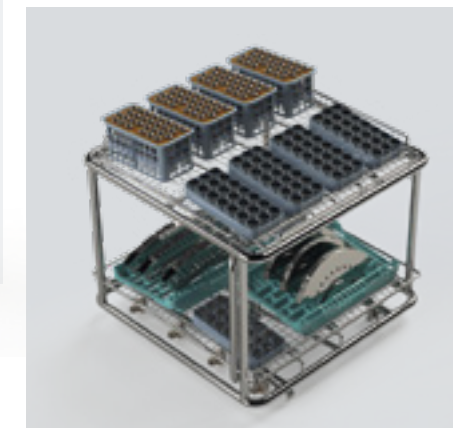
Cleaning process in the GMP environment

Criteria	Manual cleaning	Ultrasound cleaning	Automatic flush-cleaning
Execution of Cleaning process	Detailed instruction, planning and monitoring of the process	Combination of SOP instructions and automation	Standardizable and reproducible
Reproducibility	Dependent on employees	Only ensured by draining th cleaning liquid or complex process monitoring	Yes
Process monitoring	Manual	Manual / semi automatic	Fully-automatic process monitoring
Documentation	Manual	Manual	Automatic batch report
Audit trail	Changes need to be recorded manually	Changes need to be recorded manually	All changes of relevant parameters are recorded automatically
Operational safety	Direct contact with cleaning agent, special PPE required	Direct contact with cleaning agent, special PPE required	No direct contact with cleaning agent as dosing system is automatic
Drying	Manual	Dripping (manual, time-intensive)	Fully-automated drying unit integrated
Preservation	Manual	Preservation is possible in an additional bath	Fully-automated preservation integrated

Thanks to an automated process, flush-cleaning is essentially more reliable and safer than other cleaning methods.



The SDC800 cleaning system offered by ARUNA AG features greatly-reduced water and energy consumption.



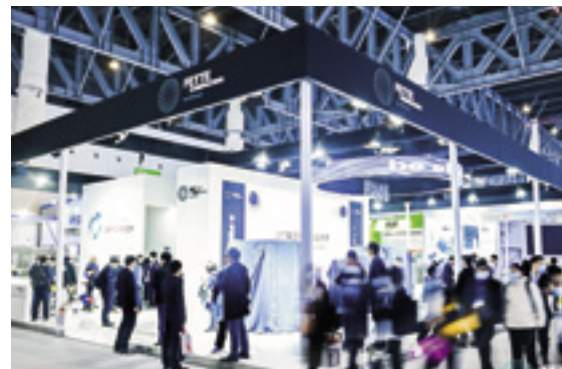
The TRI.EASY Tool Box System from Fette Compacting now also includes washing trays for segments, bellows and dust caps.

FROM THE WORLD OF FETTE COMPACTING

Premiere in Chengdu

The world of pharmaceutical engineering convened in the southern Chinese mega-city of Chengdu where the China International Pharmaceutical Machinery Exposition (CIPM) Autumn opened its doors for the 61st time from November 2-4, 2021. The Fette Compacting booth featured a premiere as the F30i tablet press was presented in China for the first time. This new double rotary press designed for large batches is dust-tight, system-compatible and conformant with Pharma 4.0. But visitors to the trade fair also were able to assess the smaller F10i model with containment package. Furthermore, Fette Compacting once again presented a wide range of machines, tableting tools and services on site.

CIPM



Impressions from the CIPM Autumn in Chengdu in November 2021.

At CIPM 2021, the double rotary press F30i celebrated its premiere in Asia.



Anke Fischer is new CFO

Anke Fischer has been Chief Financial Officer (CFO) at Fette Compacting since September 1, 2021. Together with CEO Joachim Dittrich, she is responsible for further development of the company in her capacity as a member of executive management. In anticipation of her new tasks, she says: "I very much look forward to this new personal challenge and good collaboration".

The 52-year-old economist has many years of management experience in the area of finance. She has worked for both American corporations and in medium-sized structures. Her profile is supplemented by many years of expertise in the areas of IT and HR. Her most recent position was as CFO of an international technology leader in the extrusion sector.

100th WiP machine approved

In August 2021, the Technology Center in Schwarzenbek celebrated a special anniversary when the 100th Wash-in-Place machine (WiP) achieved customer approval. For decades, WiP tablet presses have stood for efficient cleaning and – in combination with containment – fully-protected processing of highly-active substances. The use of containment and WiP systems, therefore, safeguards the health of those who operate them while reducing the effort associated with product changes.

The circumstances surrounding approval were also unusual: instead of joining the user on site to inspect the machine design, the process was carried out digitally.



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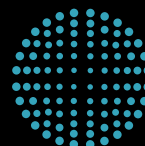
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