CONTAINMENT GUARD

FETTE COMPACTING
be efficient

protecting your efficiency

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EFFICIENCY GUIDE

TECHNOLOGY stands for everything we offer in production technology – from tablet presses and capsule filling machines through Process Equipment to tableting tools and format parts.

SERVICE covers all the services related to machines, Process Equipment and installations such as spare parts supply, plant modernization and technical field service department.

COMPETENCE is the overarching idea behind all our process-related services. This includes training, product trials, application and Performance Consulting as well as engineering.

Efficient development of safe containment solutions for tableting

Increasing demands for user and environmental protection, avoiding cross-contamination, growing technical complexity of systems: the expanding usage of highly-potent and toxic substances means greater responsibility for pharmaceutical manufacturers.

Whether researching pharmaceutical companies or manufacturers of generic products / contract manufacturers – those hoping to take advantage of the opportunities for growth associated with these new, highly-potent substances are in need of safe and efficient containment solutions. But that's not all. Increasingly protective measures are necessary for many drugs previously manufactured without any special precautions. Low-dust production systems are the new minimum standard.

Despite comprehensive guidelines and increased specifications by the regulatory authorities, exact standards for individual production steps are still lacking in practice, which is why Fette Compacting is taking an initial step in the area of tableting. The Containment Guard is the first quality certificate establishing and documenting the retention efficiency of containment tableting systems prior to the subsequent risk assessment carried out by the operator.

The Containment Guard is both a test process and the basis for technical development of containment solutions in tableting. Furthermore, extensive services, training and consulting are available which are specifically tailored to the requirements of production under containment conditions. Users benefit from safe, simple and swiftly available solutions along the entire life cycle of the plant.

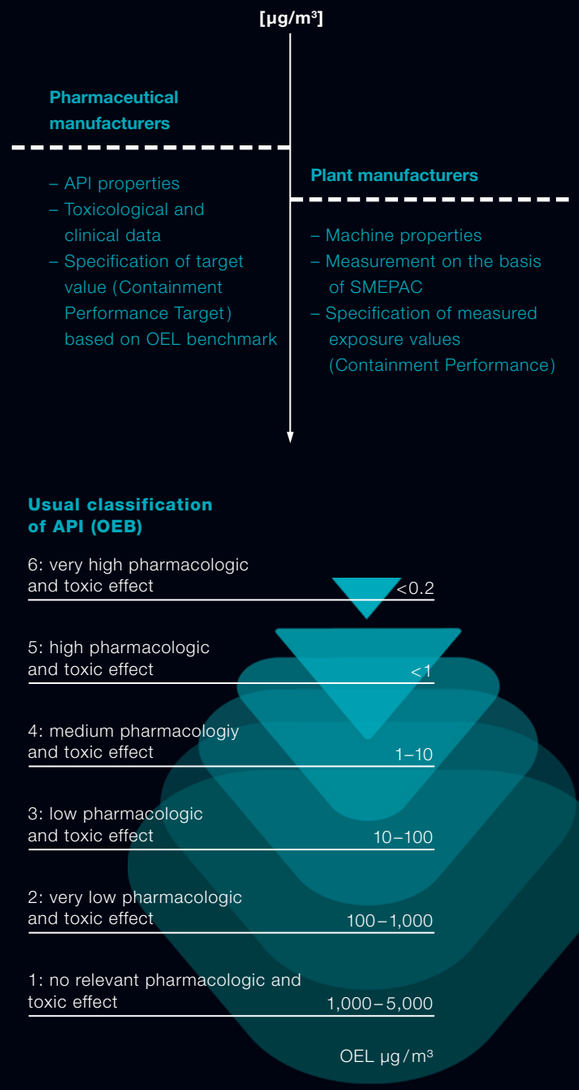
The Containment Guard is the comprehensive solution offered by Fette Compacting for efficient production of tablets under containment conditions. It is based on a modular system comprising services from the areas of Technology, Service and Competence in accordance with the Efficiency Guide.

A new standard for measuring the containment performance of tableting systems

Standard process: limit values as a basis for system design

A containment system design is always based on the toxicological assessment of the substances to be processed by the pharmaceutical manufacturer. This assessment is used to derive maximum permissible limit values. For this, the manufacturers use models such as Occupational Exposure Limit (OEL) or Permitted Daily Exposure (PDE). The specified limit values subsequently provide the reference point for the risk assessment when commissioning the complete system using the Standardized Measurement of Equipment Particulate Airborne Concentration Directive (SMEPAC). It offers a suitable framework for assessing the containment qualities of systems in general. The Containment Guard complements the SMEPAC Directive with additional practical aspects in order to make a reproducible evaluation possible for containment tableting systems:

– Position of measuring probes
– Location of operators
– Number of samples
– Machine operating conditions
– System reactions to errors or faults
– Calculation of the overall system output including process equipment



Containment Guard: more accurate measurement, less expense

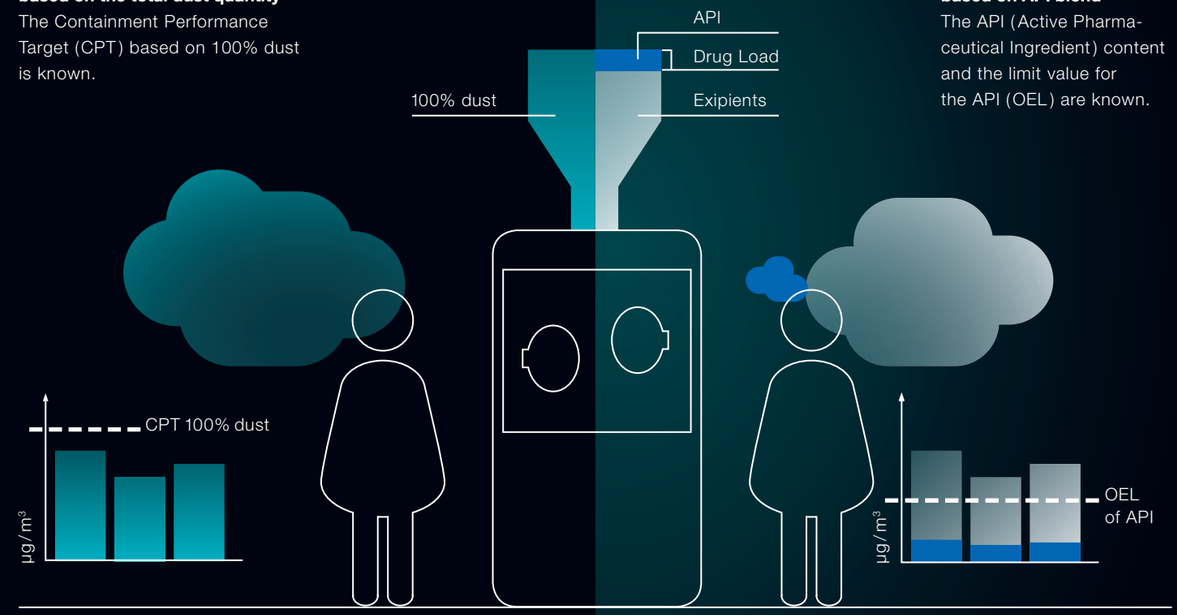
The Containment Guard from Fette Compacting adds additional cycles to the existing process. The measuring criteria correspond to the SMEPAC guidelines. The Containment Guard, however, always involves the total installation, including the process and safety equipment. The structure and flow of the test procedure is standardized. Fette Compacting performs the test in a test room at the Competence Centre in Schwarzenbek.

After testing, the equipment receives a Containment Guard certificate. The Containment Guard stages are based on the OEB levels of the containment pyramid. The total dust volume (100% dust) is used as the basis for calculating the Containment Guard level. In cases where the granulation contains less than 100% of the active ingredient, the Containment Guard classification changes accordingly.

Possible methods for determining the containment requirement

Exposure measurements based on the total dust quantity
The Containment Performance Target (CPT) based on 100% dust is known.

Exposure measurements based on API blend
The API (Active Pharmaceutical Ingredient) content and the limit value for the API (OEL) are known.



Comprehensive solutions for safe and efficient tableting

The Containment Guard marks the efficiency of the comprehensive solutions offered by containment tableting systems. The technical basis is formed by a modular system based on the FE and i series offered by Fette Compacting. Apart from tablet presses, this also includes the process and safety equipment as well as services and consulting specially tailored to containment requirements.

Competence
This offer covers consulting during design of the plant prior to project planning, the user training as well as the consulting and training during ongoing operation.

Technology
The containment systems from Fette Compacting offer efficient solutions for conventional and Wash-In-Place (WiP) cleaning, along with modular standard platforms for every requirement: from low-dust production up to high containment plant with integrated safety process equipment.

Service
Apart from the standardized Containment Guard test method, commissioning of the plant and maintenance therefore are also included in the service offering.

COMPETENCE

Consulting

Engineering

Training

TECHNOLOGY

Tablet press

Conventional cleaning

Wash in Place

Safety Equipment

Filtration

Air-Management

WiP Center

Process Equipment

Deduster + Metal check

IPC Unit

Isolator

SERVICE

SMEPAC

Commissioning

Maintenance

Example Containment Guard: FE Series – Standard for low-dust tableting

The FE55 and FE75 tablet presses represent the standard platforms offered by Fette Compacting for low-dust production. Fitted with an optional containment package and the associated process equipment, they form the basis up to Containment Guard 4.
The tableting process is fully automated in the FE series – smooth containment from filling the machine through tablet ejection.
The machines are accessible from all sides thanks to gloveports, enabling operators to carry out work inside the tablet press both swiftly and safely without interrupting the containment process.
The containment package for the FE55 and FE75 also includes:

– Flat valve for a safe product feed
– Hermetically-sealed and automatically-locking window flaps
– Rapid Transfer Port (RTP) access points for removing or introducing components
– Low-dust tablet discharge chute
– Hepa-filter H13
– Hand-held suction hose for preliminary manual cleaning
– Interface for containment deduster, metal check device and IPC unit (In-Process Control)
– A special safety concept and safety-oriented pressure monitoring

FE75 in 2-layer production with containment package and corresponding process equipment

Liner system as the connecting element between the individual system components

Single-use containment valves for connection to the tablet containers

Example Containment Guard: solutions with optimized cleaning technology

When processing highly-potent and toxic pharmaceutical substances, the use of Wash-in-Place (WiP) system significantly reduces the strain on machine operators in cleaning. Product changes are faster which means considerably reduced machine downtimes.

To ensure that product residue in the press room can be easily removed, the i series containment presses are, in addition to a fully automated WiP system, fitted with a manual wash gun and vacuum wand. A Rapid Transfer Port (RTP) can also be added, through which tools can be introduced and removed.

↑ Previous cleaning of process room without breaching containment.

Example Containment Guard: tableting systems for maximum safety requirements

The isolator technology from Fette Compacting is the basis for Containment Guard systems up to level 6. Encapsulated tableting solutions offer maximum safety in production and optimal protection for operating personnel.

The isolators can be fitted with various options such as:
– vertical deduster
– metal check device
– IPC-Checkmaster (In-Process-Control)

Using the integrated gloveports and RTP access points, operators can easily carry out all work inside the machine and isolator. The individual steps associated with tablet compression and in-process control can be monitored at the HMI. The same applies for air purification which operators can monitor via a software-controlled Air Management System that includes a negative pressure emergency system. In combination with a WiP Center from Fette Compacting, presses can be automatically cleaned in no time.

↑ Installation example of a 2090i Containment-WiP with isolator technology for the process equipment and the patented Air Management System by Fette Compacting

← Removing a punch

Example Containment Guard test method: a new standard for assessing the containment performance by tableting systems

The Containment Guard certification takes place in Fette Compacting's Competence Centre in Schwarzenbek. When the tests have been completed, Fette Compacting hands over the press and the test results to the customer. These form the basis for the operators' risk assessment, as well as reduce the ongoing expense once the press is brought into operation.

This approach allows us to consider all the system components as a whole, particularly the process and safety equipment by suppliers, as well as the patented Air Management System by Fette Compacting. The users receive a solution that is technically and economically customized to their needs. They invest in optimal cost effectiveness and a sustainable and long-lasting solution.

Fette Compacting makes containment efficient.

→ Double rotary press FE75 with containment package, process equipment and the patented Pmax® segment technology for up to 1.6 million tablets per hour

Exposure measurements: seven steps to the Containment Guard level

Exposure measurements developed on the basis of the APCPPE good practice guide from the ISPE are a central element of the Containment Guard. This standardized method measures the concentration of particles that escape from the equipment. The APCPPE guide applies to different types of equipment, and cannot therefore fully capture the specific requirements of a containment tableting system. The Containment Guard therefore goes one step further: On top of the measurement specifications used so far, such as the defined probe-taking process, or the selection of the test substance, it adds further methods, in order to realistically simulate all the production conditions encountered in tablet production.

For example, where the measuring probe or the operator is located during the measurement procedure, how many tablets samples are withdrawn for quality control in the Checkmaster, or which operating states and malfunctions of the tablet press are possible, are important for exposure measurements in tablet production. The Containment Guard tests all of these in seven measurement scenarios (cycles). The measurement results are reflected in the Containment Guard level.

Cycle 1: Zero measurement
The background level of the test substance in the measurement room is determined at the beginning of the measurement procedure. The subsequent test cycles can be more effectively classified with this information for reference.

Cycle 2: Production
The operator sets up the tablet press and begins operation. The machine runs normally for half an hour in order to measure the retention performance during ongoing production. Typical processes, such as the withdrawal of sample tablets for quality control, are also tested in this cycle.

Cycle 3: Introduction and removal of components
The operator transfers the punches and tools into the machine through the Rapid Transfer Port (RTP). He then uses the gloveports to change the punches. The tools are taken out of the press again at the end of the cycle.

Cycle 5: Cleaning the interior
The operator reaches into the interior of the machine through the gloveports, and cleans the interior of the press room as well as the isolator, in relevant cases. Depending on the press, a manual washing gun is also passed through the port, and the components are cleaned again manually. The washing program then starts. The machine's window flaps remain closed the whole time.

Cycle 6: Removing process equipment
The upward deduster and the Checkmaster are disengaged. There are two measurement scenarios for this step: tablet presses with isolator and tablet presses with washable process equipment. This step is omitted if a machine with an isolator is measured, and the process proceeds from cycle 5 straight to cycle 7.

Cycle 4: Fault test
The fault test simulates a power failure. The tablet press and the filter unit are first run in regular operation for five minutes, and are then switched off. The emergency system takes over the air management system from this point on. The measurement then takes another 25 minutes.

Cycle 7: Removing the Fill-O-Matic
The operator opens the window flaps and dismantles the Fill-O-Matic and the punches. The press is wiped out wet.

To achieve measurement results with the maximum accuracy, the cycle runs are repeated three times for every press to be measured.

Top: Surface samples (SWAB test) are also taken from defined areas at the beginning and end of a of a run

Right: Illustration of a measuring probe

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