

GMP-compliant cleaning, rust prevention and storage of

Tableting Tools

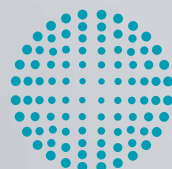
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GMP-compliant cleaning, rust prevention and storage of tableting tools in the pharmaceutical industry

The transport, cleaning, rust prevention and storage of tableting tools play a decisive role when it comes to tablet quality. Fette Compacting recommends the storage and cleaning steps outlined below to achieve optimal tool life:

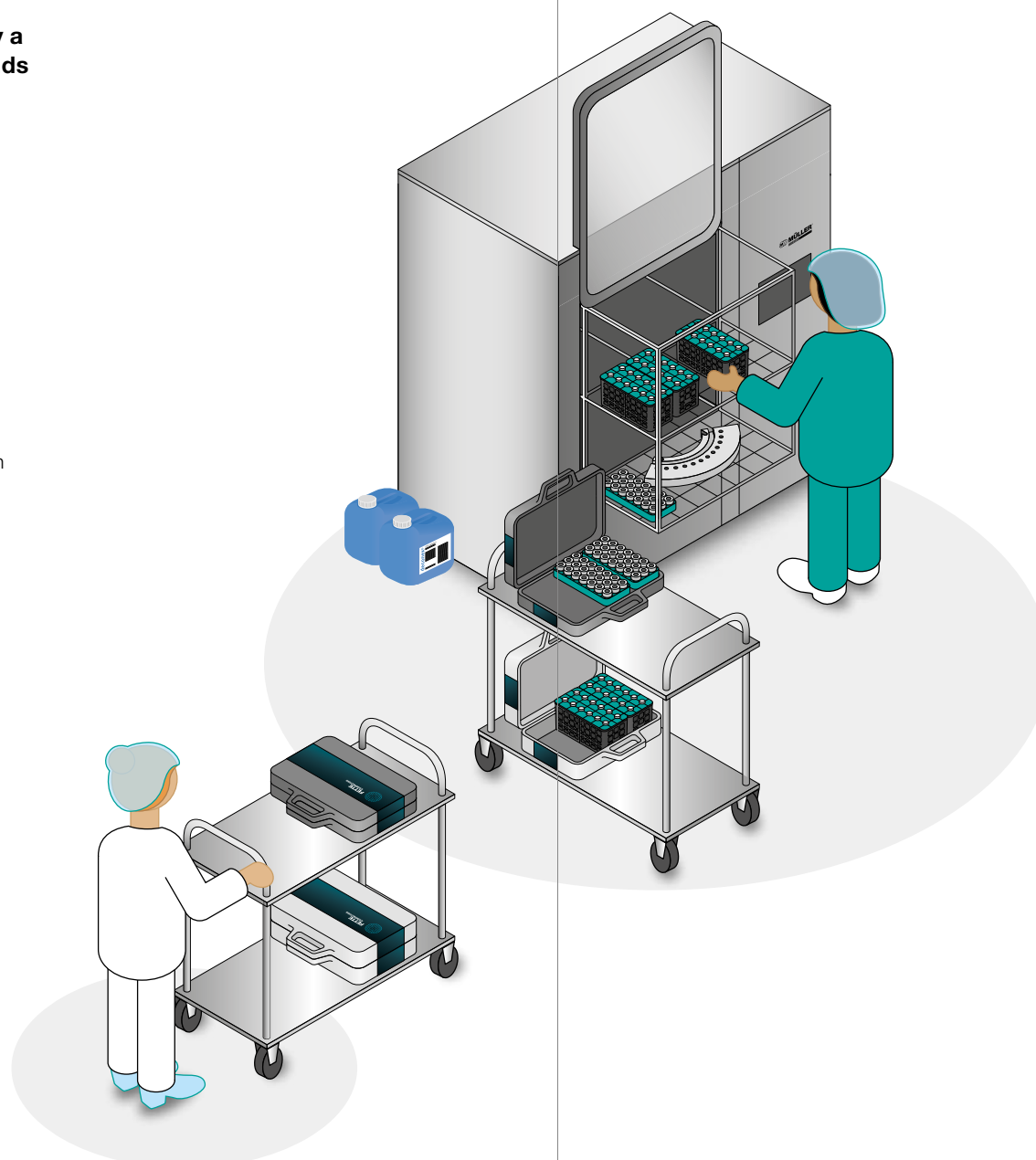
Inspecting tools prior to storage in the tool case

Fette Compacting recommends a visual inspection of all tableting tools after each use. This includes, in particular, the pressing area, the flat head and, if necessary the key. A suitable microscope can be used for this (e.g. Hexagon Tigo 05.06.05 SF). Other test equipment such as templates and test rings for keys are available from Fette Compacting.

Storage of tools

Tool cases from Fette Compacting are recommended for optimal storage:

- Specially developed cases for punches, dies and segments, providing protection from environmental influences
- Cases and trays can be stacked in the respective storage systems
- The long-term preservation deconex® HT 1191 is recommended for the preservation of tableting tools
- Tools can be stored without preservation at a humidity level of < 35%, at a temperature of 20 °C ± 2 °C



Cleaning of tools and accessories after use

The following components are recommended for GMP-compliant cleaning of simple or multi-tip tools, dies and segments:

- TRI.EASY trays with predefined positions for punches and dies from Fette Compacting
- Cleaning plant with GMP-compliant hygienic design from Müller Cleaning Solution AG including specially developed wash racks with predefined position for Fette Compacting TRI.EASY trays
- Cleaning and anticorrosive agent from Borer Chemie AG for residue-free and validated cleaning

Cleaning: deconex® CIP power-x, special alkaline cleaning agent for the pharmaceutical industry

Corrosion protection: deconex® HT 1191 specially suitable for preserving tableting tools. The remaining corrosion protection is approved as a food supplement in accordance with the US CFR 21 standard, sections 172, 175 and 181

Prerequisite

- Water quality: DI water, min. 60 °C
- Free programming of the cleaning plant (e.g. direct dosing)
- Cleaning process must be adaptable to the product
- deconex® HT 1191 must also be used in the final rinse

Note

The tableting tools must never come into contact with demineralised water alone. Tools in water (regardless of water quality) may start to rust. They must either be in a solution of deconex® CIP power-x or deconex® HT 1191.

Fette Compacting recommends the use of IXP steel for WiP tablet presses.

Queries concerning the cleaning process should be directed by e-mail to Borer Chemie AG: lifesciences@borer.ch or Fette Compacting GmbH: tablet@fette-compacting.com



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.

Gloves must be worn each time the tableting tools are handled (e.g. medical examining gloves made of Nitril, powder-free). Tools may only be handled by trained personnel. Fette Compacting offers training courses on handling tableting tools.

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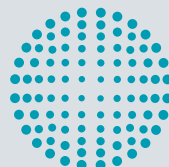
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