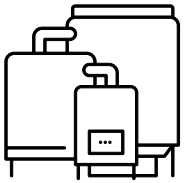
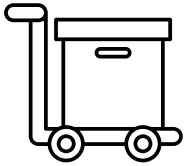
SOLID DOSAGE MANUFACTURING



1. PURIFIED WATER PRODUCTION PLANT

The solid dosage forms factory has its own plant for the production of purified water. On account of the critical importance of the quality of purified water, GMP requirements are implemented across all stages of sourcing, development, and validation of the system.

Purified water is made from drinking water by reverse osmosis and electrode ionization.



2. WAREHOUSE

Only raw materials and packaging materials previously approved by Quality Control are delivered to and stored at the SDFF warehouse from the starting and packaging materials warehouse. The warehouse is an automated high-bay warehouse that enables fast and safe handling of raw materials and packaging materials.

The raw materials are transported by a mobile crane to the platform on the first floor, where the vacuum lifter transfers them to aluminum pallets for indoor use, after which they are brought into the area for the preparation and weighing of raw materials through the de-dusting cabin and the raw material bandpass.

3. TECHNICAL FLOOR: WEIGHING, SIEVING, AND PREMIXING

The automated weighing process, which follows the computer monitoring of the status of each production container, eliminates the risk of any mix-up or error at all stages. The control of the clean/dirty container status is especially important and integrated into the automated container washing line.

All raw material measurements are carried out in a controlled environment, in the raw material preparation and weighing area on the first floor:

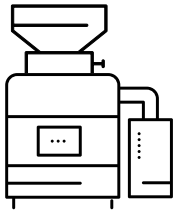
a) in weighing cabins, or

b) in a separate room called the safety cabin, which is intended for measuring small quantities of specific raw materials, such as paints, highly active raw materials, and the like.

The weighing procedure is fully managed by the IT system for batch weighing control.

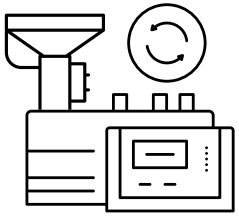
Before batch weighing, certain raw materials are sieved. A vibrating sieve is used for this technical operation. The sieved material goes into the receiving container, which has a sealed-type connection to the sieve outlet.

In line with the existing production procedures, the production of a number of products involves the making of premixes. The premix is made using a drum blender. The premix prepared with previously weighed raw materials, after the prescribed mixing, gets a new raw material code, after which it is used in the production of either a single batch or a number of batches within one production campaign.



4. GRANULATION

There are three granulation departments at the SDFF. In line with existing and planned technological procedures, two granulation departments are equipped with integrated granulation lines — high shear mixer, wet granulate calibrator, fluid bed dryer and dried granulate calibrator, while the third department is equipped with a vacuum processor and dried granulate calibrator.



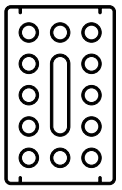
5. MIXING

The final (homogeneous) mass for tableting and encapsulation is prepared either by mixing powders (direct compression, encapsulation) or by mixing granules and other powdered raw materials (lubricants, etc.). The mixing itself is done in a separate room, right before tableting or encapsulation, which is why there is no dedicated buffer storage for these intermediates.

6. ENCAPSULATION

Products in the form of hard gelatin capsules are made by filling either a powder mixture or pellets into hard gelatin capsules on the capsule filling machine.

Empty capsules are brought to the capsule filling room and loaded using an elevator for empty capsules, where empty capsules are also selected. The dosing system transfers a predetermined quantity of product from the dosing chamber to each capsule. After filling, the capsules pass through a system that removes the empty ones, and then through the vertical de-duster and metal detector. The full capsules are placed into the appropriate container and transported to the intermediate quarantine storage. After a positive certificate from Quality Control, the containers with full capsules are transported from the intermediate quarantine storage to their specific primary packaging room.



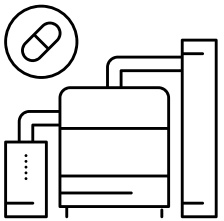
7. TABLETING

Top quality tablets are made on four tableting machines, using a controlled process involving continuous checking of the tablet mass, possible presence of metal particles in the material, and de-dusting. The product in the form of tablet is mainly made using the following processes:

1. compression of previously prepared granules
2. direct compression of the powder mixture

Some products are in the form of bilayer tablets.
After tableting, the tablets pass through the vertical tablet de-duster and metal detector and go into a suitable container.

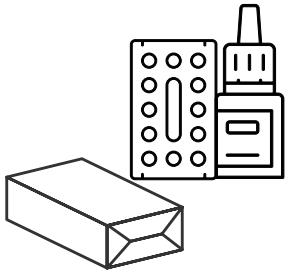
Products in the form of uncoated tablets are transported to the intermediate quarantine warehouse, and after a positive certificate from Quality Control, they are transported to their specific primary packaging room.



8. COATING

Around half of the products from the range are coated tablets, with the coating procedures including film coating (film coated tablets) or coating with a sugar suspension (dragees).

There are two lines for water- and organic solvent-based film coating, and two lines for sugar coating.



9. PRIMARNO I SEKUNDARNO PAKOVANJE I OTPREMA

The primary packaging of tablets and capsules takes place across four lines for blister packaging and one for bottle packaging.

The lines continue to automated lines for secondary packaging and forming transport packages.

Transport packages are placed on a pallet that is wrapped with foil on the pallet wrapping machine and transported to quarantine at the finished products warehouse.

A high degree of safety in the packaging stage is ensured by cameras that check the blisters, built-in scales that check packaging, and pharma code readers of printed packaging. Safety and a high quality with a reduced risk of human or machine error provides the entire production at the new factory with a high degree of automation.

All systems are connected to the central control system, which enables their management, control, response to warnings, quality reporting, and data archiving.

PLANT TOUR

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